ASEAN DEFINITION OF COSMETICS AND ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

APPENDIX I*

ILLUSTRATIVE LIST OF COSMETIC PRODUCTS BY CATEGORIES

A. BACKGROUND

The definition of a cosmetic product which has been adopted by the ACCSQ Product Working Group on Cosmetics is that of the European Directive. In order to understand the thought processes behind the words it does help to look at the way that the original 1976 definition was modified in 1993.

Original : Any substance or preparation intended for placing in contact with the external parts of the human body ... or with the teeth and mucous membranes of the oral cavity with a view exclusively or principally to cleaning them[1], perfuming them[2] or protect them[3] in order to keep them in good condition[4] change their appearance[5] or correct body odour[6]

Current : Any substance or preparation intended to be placed in contact with the external parts of the human body... or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for cleaning them[7], perfuming them[8], changing their appearance[9], and/or correcting body odours[10] and/or protecting[11] or keeping them in good condition[12]

By removing the words "in order to" and replacing the three functions (1-3) and three objectives (4-6) by six individual purposes (7-12) the 1993 definition removes several legal anomalies including the one that effectively excluded all decorative products from being cosmetics.

It should be noted that while the phrase "exclusively or principally" has been changed to "exclusively or mainly" reinforces the fact that the regulators recognise that cosmetic products may have functions other than six individually listed.

B. ASEAN ILLUSTRATIVE LIST BY CATERGORY OF COSMETIC PRODUCTS APPEARS IN ATTACHMENT I

This list is not exhaustive and that currently unimagined product forms and types should be considered against the definition of a cosmetic and not the list (such as ASEAN uniqueness.)

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* Number of Appendix and Annex is given for easy referred as stated in the ASEAN agreement on cosmetics

ANNEX I

ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of chemical peeling products).
- Tinted bases (liquids. pastes, powders).
- Make-up powders, after-bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils. gels, etc.).
- Depilatories.
- Deodorants and anti-perspirants.
- Hair care products.
  - hair tints and bleaches.
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc.).
- Products for making-up and removing make-up from the face and the eyes.
- Products intended for application to the lips.
- Products for care of the teeth and the mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.
- Anti-wrinkle products.

ASEAN COSMETICS LABELING

REQUIREMENTS

APPENDIX II

ASEAN COSMETIC LABELING REQUIREMENTS

A. OBJECTIVE

1. This document provides guidance for labeling requirements requirements of cosmetic products to which Article 5 of the ASEAN Cosmetic Directive 05/01/ACCSQPWG apply.

B. SCOPE AND DEFINITIONS

1. For the purpose of this document

   Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trade mark or the name of the manufacturer;

   Immediate packaging means the container or other or other form of packaging immediately in contact with the cosmetic product

   Outer packaging means the packaging into which is placed the immediate packaging;

   Labelling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets

   Registration holder means the holder of the authorization for the cosmetic products

B. LABELLING COSMETIC PRODUCTS

1. The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products.

   a) The name of the cosmetic products and its function, unless it is clear from the presentation of the product;

   b) Instructions on the use of the cosmetic products, unless it is clear from the product name or presentation;

   c) Full ingredient listing. The ingredients shall be specified by using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated;

      The following shall not, however, be regarded as ingredients;
      - Impurities in the raw materials used;
      - Subsidiary technical materials used in the preparation but not present in the final product;
      - Materials used in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions.

d) Country of manufacture

e) The name and address of the company or person responsible for placing the product on the local market;

f) The contents given by weight or volume, in either metric or both in metric and imperials system;

g) The manufacturer's batch number;

h) The manufacturing date or expiry date of the product in clear terms (e.g. month/year);

i) Special precautions to be observed in use, especially those listed in the column "Conditions or use and warnings which must be printed on the label in Annexes _____", which must appear on the label as well as any special precautionary information on the cosmetic products.

Member countries may require specific warnings based on local needs e.g. declaration of ingredients from animal origin. In this case:

(i) There must be statement (of any format) on the product label that presence of ingredients from animal origin

(ii) For ingtedients from bovine and porcine origin, the exact animal must be declared.

(iii) Ingredients from human placenta must be declared specifically on the product label.

j) Registration number from the country of origin (manufacture) of the country of registration.

2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in para 1 (a) – (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap etc. shall be allowed. However, the following particulars at least shall appear on small immediate packaging:

(a) the name of the cosmetic products;

(b) the manufacturer's batch number

3. The particulars referred in para 1 and para 2 shall be easily legible, clearly comprehensible and indelible.

4. The particulars listed in para 1 shall appear in English and/or National Language and/or language understood by the consumer where the product is marketed.

Appendix A

Listed of Standard References to be use for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary
2. British Pharmacopeia
3. United States Pharmacopeia
4. Chemical Abstract Services
5. Japanese Standard Cosmetic Ingredient
6. Japanese Cosmetic Ingredients Codex

ASEAN COSMETIC CLAIM GUIDELINES

APPENDIX III

ASEAN COSMETIC CLAIM GUIDELINES

This document provides guidance in relation to cosmetic/drug interface in respect of product claims.

Products are determined to be either “cosmetic” or “drug” based on two factors:

- Composition of the product, and
- The proposed use (++) of the product

Compositon – The compostion of a product does not necessarily determine its classification. However it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification of a cosmetic.

Proposed use – According to the definition of the term “drug” and “cosmetic” in respective legislation, the key consideration for the classification of a drug is its proposed use. The claims made in package inserts, in advertisements, and especially in product labels, indicate to the consumers the intended use of the product.

As a general rule, cosmetic products must only make cosmetic claimed benefits; and not medicinal or therapeutic claimed benefits. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself. Manufacturers / product owners will be allowed to use their own scientifically accepted protocols / design in generating the technical data provided there is justification why such protocol / design is used.

ASEAN COSMETIC PRODUCT REGISTRATION REQUIREMENTS

APPENDIX IV

ASEAN COSMETIC PRODUCT REGISTRATION REQUIREMENTS

Technical Documents

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 Directve 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 regisration 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 LEAD TIME

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 Requirements : 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 / Manufacturer[1]; 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 competent authority of the country where the product is marketed starting 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.

[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 reference guideline for manufacturing standards in ASEAN within the agreed implementation timing of the Member States.

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 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 description/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:

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, hai 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.

COMMON REQUIREMENTS FOR IMPORT / EXPORT OF COSMETIC PRODUCTS

APPENDIX V

COMMON REQUIREMENTS FOR IMPORT / EXPORT

OF COSMETIC PRODUCTS

A. SCOPE

Only regulatory requirements imposed by health authorities are considered in this document. The requirements are applicable to Phase 1 of the harmonized scheme only.

B. IMPORT REQUIREMENTS

1. Registration of registrants or companies/persons responsible for placing the product in the market

This will facilitate investigation and follow up by regulatory authorities in the event of product problems. Registration of registrant or company/person responsible for placing the product in the market should be based on the requirements of individual countries.

2. Product Registration

Only countries which wish to register cosmetic products will be involved. The requirements in the approved Technical Document on Product Registration procedures should be followed.

3. Product Labelling

To ensure informed choice by consumers, to facilitate the work of healthcare professionals and to allow effective control by the regulatory authorities, cosmetic products in the market should conform with designated labeling requirements. The requirements in the approved Technical Document on Product Labelling requirements should be followed.

4. Compliance With Allowed, Prohibited and Restricted Ingredient Lists

To ensure that only safe ingredients are used in cosmetic products sold in ASEAN countries, lists of cosmetic ingredients and prohibited substances must be laid down for the cosmetic industries in ASEAN. The requirements in the approved Technical Document on Common Ingredient Listings should be followed.

5. Record Keeping By Registrant or Company/person Responsible for Placing the Product in the Markets

The registrant or company/person responsible for placing the product in the market must keep records of the primary distribution of their products, for the purpose of product recall according to the respective country's procedures.

C. IMPORTATION FOR DIRECT RE-EXPORTATION OUT OF ASEAN

Importation for direct re-export of cosmetic products can be exempted from cosmetic product import requirements as they will not impact the safety of local consumers, but the registrant or company / person responsible for placing the product in the market should maintain proper records and documents. These records should be open to inspection by the authorities at any time when required.

"Import for direct re-export" refers to importation by an ASEAN trader of cosmetic products which are subsequently exported out of ASEAN by the same ASEAN trader. The cosmetic products involved do not enter into the ASEAN market.

D. EXPORT REQUIREMENTS

Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any. If the products meant for the export market are also sold locally and hence comply with the relevant regulatory requirements, free sale certificates may be issued by the health authorities upon request. The list of health authorities in ASEAN member countries issuing Certificate of Free Sale can be complied later by ACCSQ CPWG and distributed to all ASEAN member countries.

E. SUMMARY

In summary, cosmetic products will be allowed for importation provided they comply with local registration and licensing requirements, labeling requirements and requirements on restriction of ingredients. The registrant or company / person responsible for placing the product in the market will be required to maintain records of primary distribution for the purpose of product recall. Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any.

ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE

APPENDIX VI

ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE

PREAMBLE

The GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN cosmetic Directive. As this document is particularly intended for cosmetic products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

The Good Manufacturing Practices presented here is only a general guideline for the manufacturers to develop its own internal quality management system and procedures. The important objective must be met in any case, i.e. the final products must meet the quality standards appropriate to their intended use to assure consumer's health and benefit.

1. INTRODUCTION

The objective of the Cosmetic Good Manufacturing Practice (GMP) Guidelines is to ensure that products are consistently manufactured and controlled to the specified quality. It is concerned with all aspects of production and quality control.

1.1 General Consideration

1.1.1 In the manufacture of cosmetic products, overall control and monitoring is essential to ensure that the consumer receives products of high quality.

1.1.2 The quality of a product depends on the starting materials, production and quality control processes, building, equipment and personnel involved.

1.2 Quality Management System

1.2.1 A quality system should be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organisational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.

1.2.2 The quality system should be structured and adapted to the company's activities and to the nature of its products and should take into consideration appropriate elements stated in this Guidelines.

1.2.3 The quality system operation should ensure that if necessary, samples of starting materials, intermediate, and finished products are taken, tested to determine their release or rejection on the basis of test results and other available evidence related to quality.

2. PERSONNEL

There should be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

2.1 Organisation, Qualification and Responsibilities

2.1.1 The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.

2.1.2 The head of production should be adequately trained and experienced in cosmetic manufacturing.

He should have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records.

2.1.3 The head of quality control should be adequately trained and experienced in the field of quality control. He should be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of al quality control procedures. He should have the authority to designate/assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions.

2.1.4 The responsibilities and authority of key personnel should be clearly defined.

2.1.5 An adequate number of trained personnel should be appointed to execute direct supervision in each section of the production and the quality control unit.

2.2 Training

2.2.1 All personnel directly involved in the manufacturing activities should be appropriately trained in manufacturing operations in accordance to GMP principles. Special attention should be given to training of personnel working with any hazardous materials.

2.2.2 Training in GMP should be conducted on a continuous basis.

2.2.3 Records of training should be maintained and its effectiveness assessed periodically

3. PREMISES

The premises for manufacturing should be suitably located, designed, constructed and maintained.

3.1 Effective measures should be taken to avoid any contamination from the surrounding environment and from pests.

3.2 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises and equipment provided that due care should be exercised to prevent cross contamination and risk of mix-up.

3.3 Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.

3.4 Appropriate changing rooms and facilities should be provided. Toilets should be separated from the production areas to prevent product contamination/cross contamination.

2.5 Defined areas should be provided for, wherever possible and applicable:

3.5.1 Materials receiving.

1.5.2 Materials Sampling

1.5.3 Incoming goods and quarantine.

3.5.4 Starting materials storage.

3.5.5 Weighing and dispensing.

3.5.6 Processing.

3.5.7 Storage of bulk products.

3.5.8 Packaging.

3.5.9 Quarantine storage before final release of products.

3.5.10 Storage of finished products.

3.5.11 Loading and unloading.

3.5.12 Laboratories.

3.5.13 Equipment washing.

3.6 Wall and ceiling, where applicable, should be smooth and easy to maintain. The floor in processing areas should have surface that is easy to clean and sanitise.

3.7 Drains should be of adequate size and should have trapped gullies and proper flow. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection..

3.8 Air intakes and exhausts and associated pipework and ducting, when applicable, should be installed in such a way as to avoid product contamination.

3.9 Buildings should be adequately lit and properly ventilated appropriate to the operations.

3.10 Pipework, light fittings, ventilation points and other services in manufacturing areas should preferably be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.

3.11 Laboratories should preferably be physically separated from the production areas.

3.12 Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.

3.12.1 Such areas should be suitable for effective separation of quarantined materials and products. Special and segregated areas should be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.

3.12.2 Where special storage conditions e.g. temperature, humidity and security are required, these should be provided.

3.12.3 Storage arrangements should permit separation of different labels and other printed materials to avoid mix-up.

4. EQUIPMENT

Equipment should be designed and located to suit the production of the product.

4.1 Design and Construction

4.1.1 The equipment surfaces coming into contact with any in-process material should not react with or adsorb the materials being processed.

4.1.2 Equipment should not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.

4.1.3 Equipment should be easily cleaned.

4.1.4 Equipment used for flammable substances should be explosion proof.

4.2 Installation and Location

4.2.1 Equipment should be located to avoid congestion and should be properly identified to assure that products do not become admixed or confused with one another.

4.2.2 Water, steam, and pressure or vacuum lines, where applicable, should be installed so as to be easily accessible during all phases of operation. They should be clearly identified.

4.2.3 Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled), steam, compressed air and gases (example nitrogen) should function as designed and identifiable.

4.3 Maintenance

Weighing, measuring, testing and recording equipment should be serviced and calibrated regularly. All records should be maintained.

5. SANITATION AND HYGIENE

Sanitation and hygiene should be practiced to avoid contamination of the manufacturing of products. It should cover personnel, premises, equipment/apparatus and production materials and containers.

5.1 Personnel

5.1.1 Personnel should be healthy to perform their assigned duties. Regular medical examination must be conducted for all production personnel involved with manufacturing processes.

5.1.2 Personnel must pratise good personal hygiene.

5.1.3 Any personnel shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle raw materials, packaging materials, in-process materials, and finished products.

5.1.4 Personnel should be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the products.

5.1.5 Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire appropriate to the duties they perform.

5.1.6 Smoking, eating, drinking and chewing, food, drinks and smoking materials and other materials that might contaminate are not permitted in production, laboratory, storage or other areas where they might adversely affect product quality.

5.1.7 All authorized personnel entering the production areas should practice personal hygiene including proper attire.

5.2 Premises

5.2.1 Adequate employee's washing and well ventilated toilet facilities should be provided and separated from the production area.

5.2.2 Suitable locker facilities should be provided at appropriate location for the storage of employees' clothing and personal belongings.

5.2.3 Waste material should be regularly collected in suitable receptacles for removal to collection points outside the production area.

5.2.4 Rodenticides, insecticides, fumigating agents and sanitizing materials must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products.

5.3 Equipment and Apparatus

5.3.1 Equipment and utensils should be kept clean.

5.3.2 Vacuum or wet cleaning methods are preferred. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.

5.3.3 Standard operating procedures must be followed for cleaning and sanitizing of major machines.

6. PRODUCTION

6.1 Starting Materials

6.1.1 Water

Special Attention should be paid to water, since it is an important raw material. Water production equipment and water systems should supply

quality water. Water systems should be sanitized according to well-established procedures.

The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

6.1.2 **Verification of materials**

All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labeled. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

6.1.3 **Rejected materials**

Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

6.2 Batch Numbering System

6.2.1 Every finished product should bear a production identification number which enables the history of the product to be traced.

6.2.2 A batch numbering system should be specific for the product and a particular batch number shall not be repeated for the same product in order to avoid confusion.

6.2.3 Whenever possible, the batch number should be printed on the immediate and outer container of the product.

6.2.4 Records of batch number should be maintained.

6.3 Weighing and Measurement

6.3.1 Weighing should be carried out in the defined areas using calibrated equipment.

6.3.2 All weighing and measurement carried out should be recorded and, where applicable, counterchecked.

6.4 Procedure and Processing

6.4.1 All starting materials used should be approved according to specifications.

6.4.2 All manufacturing procedures should be carried out according to written procedures.

6.4.3 All required in-process controls should be carried out and recorded.

6.4.4 Bulk products should be properly labeled until approved by Quality control, where applicable.

6.4.5 Particular attention should be paid to problem of cross-contamination in all stages of processing.

6.5 Dry Products

Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

6.6 Wet Products

6.6.1 Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.

6.6.2 The used of closed systems of production and transfer is recommended.

6.6.3 Where pipe-lines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

6.7 Labelling and Packaging

6.7.1 Packaging line should be inspected for clearance prior to operation. Equipment should be clean and functional. All materials and products from previous packaging operation should have been removed.

6.7.2 Samples should be taken and checked at random during labelling and packaging operations.

6.7.3 Each labelling and packaging line should be clearly identified to avoid mix-up.

6.7.4 Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly.

6.8 Finished Product: Quarantine and Delivery to Finished Stock

6.8.1 All finished products should be approved by Quality Control prior to release.

7. QUALITY CONTROL

7.1 Introduction

Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

7.1.1 A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

7.1.2 Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

7.2 Reprocessing

7.2.1 The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.

7.2.2 Additional testing of any finished product which has been reprocessed should be performed.

7.3 Returned Products

7.3.1 Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.

7.3.2 All returned products shall be tested if necessary, in addition to physical evaluation before being released for distribution.

7.3.3 Returned products which do not comply with the original specification should be rejected.

7.3.4 Rejected products should be disposed according to appropriate procedures.

7.3.5 Records of returned products must be maintained.

8. DOCUMENTATION

8.1 Introduction

The documentation system should include the complete history of each batch, from starting materials to finished products. The system should record executed activities for maintenance, storage, quality control, primary distribution and other specific matters related to GMP.

8.1.1 There should be a system for preventing the use of any superseded document.

8.1.2 If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and correction is made close to the original entry, initialled and dated.

8.1.3 Where documents bear instructions they should be clearly written step by step.

8.1.4 Documents should be dated and authorised.

8.1.5 Documents should be readily available to relevant parties.

8.2 Specifications

All specifications should be approved by authorised personnel.

8.2.1 Raw and packaging material specifications should include :

(a) Name of material

(b) Description of the material

(c) Testing parameters and acceptance limits

(d) Technical drawings, where applicable

(e) Special precautions e.g. storage and safety conditions, if necessary.

8.2.2 Bulk and finished product specifications should include :

(a) Name of product

(b) Description

(c) Physical properties

(d) Chemical assay and/or microbiological assays and their acceptance limits; if necessary

(e) Storage conditions and safety precautions, if necessary

8.3 Documents for Production

8.3.1 Master Formula

The Master formula should be available upon request. This document should contain the following information:

(a) Product name and product code/number.

(b) Intended packaging materials, and storage conditions

(c) List of raw materials used, whether they remain unchanged or become altered.

(d) List of raw materials used

(e) List of equipment used.

(f) In-process controls with their limits in processing and packaging, where applicable.

8.3.2 Batch Manufacturing Record (BMR)

(a) Batch Manufacturing Records should be prepared for each batch of product.

(b) Each BMR should include the following :

i. Name of product
ii. Batch formula
iii. Brief manufacturing process
iv. Batch or code number
v. Date of the start and finish of processing and packaging
vi. Identity of individual major equipment and lines or location used
vii. Records of cleaning of equipment used for processing as appropriate
ix. Packaging line clearance inspection records
x. Any sampling performed during various steps of processing
xi. Any investigation of specific failure or discrepancies
xii. Results of examinations on packed and labeled products

8.3.3 **Records for Quality Control**

(a) Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained.

(b) These records may include:

i. Date of test
ii. Identification of the material
iii. Supplier name
iv. Date of receipt
v. Original batch number if any
vi. Batch number
vii. Quality control number
viii. Quantity received
ix. Date of sampling
x. Quality control results

9. INTERNAL AUDITS

A internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purpose. Such audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each quality audit.

10. STORAGE

10.1 **Storage Areas**

10.1.1 Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.

10.1.2 Storage areas should be designed or adapted to ensure good storage conditions. They should be clean, dry and well-maintained. Where special storage conditions are required (temperature and humidity) these should be provided, checked and monitored.

10.1.3 Receiving and dispatch bays should protect materials and products from weather. Reception areas should be designed and equipped to allow incoming materials to be cleaned if necessary before storage.

10.1.4 Storage areas for quarantine products should be clearly demarcated.

10.1.5 Wherever possible sampling area for starting materials should be provided to prevent contamination.

10.1.6 Hazardous materials should be safely and securely stored.

10.2 **Stock Handling and Control**

10.2.1 **Receiving Products**

10.2.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity.

10.2.1.2 The consignment should be carefully inspected for defects and damage. Records should be retained for each delivery.

10.2.2 **Control**

10.2.2.1 Records should be maintained showing all receipts and issues of products.

10.2.2.2 Issues should observe the principle of stock rotation (first in - first out).

10.2.2.3 All labels and containers of products should not altered, tampered or changed.

11. CONTRACT MANUFACTURING AND ANALYSIS

The conditions of contract manufacturing and analysis should be clearly defined, agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards.

There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

12. COMPLAINTS

12.1 A person responsible for handling complaints and deciding the measures to be taken should be designated. If this person is different from the authorized person, the latter should be made aware of any complaint, investigation or recall.

12.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.

12.3 Complaints involving product defects should be recorded with all the original details and investigated.

12.4 If a product defect is discovered or suspected in a batch, consideration should be given to wether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.

12.5 Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.

12.5 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

12.6 Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.

12.7 The competent authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety isssues.

13. PRODUCT RECALLS

There should be a system of recall from the market of products known or suspected to be defective.

13.1 A person responsible for the execution and co-ordination of recalls should be designated, as well as sufficient personnel, to handle all aspects of recalls with the appropriate degree of urgency.

13.2 Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly .

13.3 The primary distribution records should be readily available to the person(s) responsible for recalls, and they should contain sufficient information of distributors.

13.4 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.

13.5 The effectiveness of the arrangements for recalls should be evaluated from time to time.

13.6 A written instruction should be established to ensure recalled products are stored securely in a segregated area while awaiting decision.

14 GLOSSARY

14.1 Batch

A quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality.

14.2 Batch Number

A designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution.

14.3 Bulk Product

Any processed product which will have to undergo the packaging operation in order to become a finished product.

14.4 Calibration

Combination of checking an instrument and adjusting it to bring it within its limits for accuracy according to recognized standards.

14.5 Date of Manufacture

Date of manufacturing of a batch of product.

14.6 Documentation

All written procedures, instructions and records involved in the manufacture and quality control of products.

14.7 Product

Any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, in or for cleansing, improving, altering or beautifying the complexion, skin, hair or teeth.

14.8 Finished Product

A product which has undergone all stages of manufacturing operations.

14.9 In-Process Control

Checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on environment and equipment in order to ensure that the end product will comply with its specification.

14.10 **Intermediate Product**

Any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product.

14.11 **Manufacture or Manufacturing**

The complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.

14.12 **Packaging**

The part of production cycle applied to a bulk product to obtain the finished product.

14.13 **Packaging Material**

Any material used in the packaging of a bulk product to obtain the finished product.

14.14 **Processing**

The part of production cycle starting from weighing of raw materials to obtaining a bulk product.

14.15 **Production**

All operations starting from processing to packaging to obtain a finished product.

14.16 **Quality Control**

All measures taken during manufacturing which are designed to ensure the uniform output of product that will conform to established specifications.

14.17 **Quarantine**

The status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution.

14.18 **Raw Materials**

Any ingredient to be used in the formulation of a cosmetic product.

14.19 **Rejected**

The status of materials or products which are not permitted to be used for processing, packaging or distribution.

14.20 **Released**

The status of materials or products which are allowed to be used for processing, packaging or distribution.

14.21 **Returned Product**

Finished products sent back to the manufacturer.

14.22 **Sanitation**

Hygienic control on manufacturing premises, personnel, equipment and material handling.

14.23 **Specification of Materials**

A description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations.

14.24 **Starting Materials**

Raw materials and packaging materials used in the production of products.

15. REFERENCES

15.1 Good Manufacturing Practices for Pharmaceutical Products, World Health Organisation (WHO) Technical Report Series No : 823, 1992

15.2 Good Storage Practice, 1st Edition, January 1995, ISBN 983-9870-14-9, National Pharmaceutical Control Bureau, Malaysia

15.3 Cosmetic Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association, July 1994

15.4 Australian Code of Good Manufacturing Practice for Therapeutic Goods – Sunscreen Products, Therapeutic Goods Administration (TGA), Australia, February 1994

15.5 Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines, National Pharmaceutical Control Bureau, Malaysia, 1st Edition, 1999