



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila



6 October 2005

ADMINISTRATIVE ORDER
NO. 2005 - 0025

**SUBJECT: Implementation of the ASEAN
Harmonized Cosmetic Regulatory
Scheme and ASEAN Common
Technical Documents**

I. RATIONALE

The State has a duty to protect and promote the right to health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution). Pursuant thereto, Republic Act No. 3720, as amended by Executive Order No. 175, series of 1987, otherwise known as the "Food, Drugs and Devices and Cosmetics Act", was enacted, among other things, to establish an effective system in the registration, monitoring and regulation of cosmetics products.

Meanwhile, Section 2, Article II of the 1987 Constitution provides that the Philippines adopts the generally accepted principles of international law as part of the law of the land and adheres to the policy of peace, equality, justice, freedom, cooperation, and amity with all nations.

On September 2, 2003, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme was signed by ASEAN Ministers, including then Secretary of Health Hon. Manuel M. Dayrit, during the 35th ASEAN Economic Ministers Meeting. This Agreement covers: (i) the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetic; and (ii) the ASEAN Cosmetic Directive.

However, the advent of a harmonized cosmetics regulation among ASEAN member countries raises some concerns on the conformity of the harmonized rules against current legislation, rules and regulations.

Hence, on April 21, 2005, the Department issued Administrative Order No. 2005-0015 (*Subject: Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents*) in order to formally align national standards with, and adopt, the ASEAN Harmonized Cosmetic Regulatory Scheme.

In furtherance thereof, this Order is being issued for the effective implementation of the ASEAN Cosmetic Product Registration Requirements and to assist the Cosmetic Industry in its compliance with the ASEAN Harmonized Cosmetic Regulatory Scheme.

II. PURPOSE AND OBJECTIVE

The purpose of this Order is to: (a) provide the implementing details for the incorporation and alignment of the ASEAN Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents into the national requirements; (b) allow BFAD and the Cosmetic Industry a transitory period for the shift from the previous cosmetic regulation and registration policies to the ASEAN Harmonized Cosmetic Regulatory Scheme, including the ASEAN Labeling Requirements; and (c) assist BFAD in strengthening the conduct of its post-market surveillance system.

III. DEFINITION OF TERMS

The definition of terms, words and phrase shall follow the definitions provided for by the ASEAN Cosmetic Directive and ASEAN Common Technical Documents insofar as they are not in conflict with national laws of the Philippines in which case the latter shall prevail.

1. ASEAN – means the Association of Southeast Asian Nations
2. DOH – means the Department of Health
3. BFAD – means the Bureau of Food and Drugs
4. PSD – means the Product Services Division of BFAD
5. INCI – means the International Nomenclature of Cosmetic Ingredient
6. Cosmetic Product – means any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. Provided that, in accordance with Republic Act No. 7394, this definition does not include soap.
7. Immediate packaging – means the container or other form of packaging immediately in contact with the cosmetic product.
8. Labeling – means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.

9. Name of the cosmetic product – means the name given to a cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer.

10. Outer packaging – means the packaging into which is placed the immediate packaging.

11. Registration holder – means the holder of the authorization for the cosmetic products.

12. Certificate of Free Sale – means the document issued by the Board of Health or any competent authority of the country where the product is marketed stating the country of manufacture.

13. License to Operate/Manufacture – means the license issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture.

14. Certificate of Good Manufacturing Practice – means the certificate issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture to show that the manufacturer has complied with the requirements of Good Manufacturing Practice.

15. Certificate of Origin – means the certificate 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).

IV. REGISTRATION REQUIREMENTS

A. Locally Manufactured Cosmetic Products

1. The following documents shall be required in the registration of locally manufactured cosmetic products:

1.1 Administrative Documents

1.1.1 Notarized Letter Application for Cosmetic Product Registration

1.1.2 Valid License to Operate of the applicant

1.1.2.1 For Manufacturers – List of Product Lines must be reflected

1.1.2.2 For Traders – List of Toll Manufacturer and List of Products Lines must be reflected

1.1.2.3 For Importer/Distributor – List of Product Source for imported cosmetic products as well as the Actual Manufacturer of the Product must be reflected

1.1.2.4 For Wholesaler/Distributor – List of Product Source must be reflected

1.2 Technical Documents

1.2.1 Composition

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

1.2.2 Finished Product Description

- (a) Finished product specifications
- (b) Test methods shall be made available to the cosmetic regulatory agency when requested or necessary

1.2.3 Attestation to support special product claims. Attestation should contain the following information:

- (a) Name, position and specialization of investigator/s performing the test/study.
- (b) Curriculum vitae and/or proof that the investigator/s is/are Board Certified Specialist shall be made available to the cosmetic regulatory agency.
- (c) Name and address of the establishment conducting the test/study
- (d) Result/s and conclusion
- (e) Summary of test report including protocol, as necessary

1.2.4 Information Sheet containing the following information:

- (a) Product description / use
- (b) Methods of administration (Direction for use)
- (c) Precautions to be observed during use of product
- (d) Declaration of shelf life (for all products)
- (e) Method of decoding batch reference
- (f) Pack sizes available
- (g) Name and address of the product owner, manufacturer, or assembler

1.2.5 Company's Notarized Declaration of:

- (a) Absence of prohibited substances
- (b) Compliance with the content limit of restricted substances
- (c) Unattached specimen of the labeling layout per pack size, per variant
- (d) Specimen of the finished commercial product (one specimen to represent the pack sizes,)

B. Imported Cosmetic Products

1. In addition to the administrative and technical documents required of the locally manufactured cosmetic products, any one of the following documents shall be submitted:

- 1.1 Certificate of Free Sale and License to Operate / Manufacture, or
- 1.2 Certificate of Free Sale and Certificate of Good Manufacturing Practice, or
- 1.3 Certificate of Origin, or
- 1.4 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.

2. 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.

3. In the event that there is no issuing regulatory agency in all cases, the documents 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.

C. Listing of Cosmetics Specialties

1. Persons or cosmetic establishments responsible for placing Cosmetics in the market in accordance with Administrative Order No. 29-A, series of 1994 (Subject: Regulation Part D-5 Cosmetic: Listing of Cosmetics Specialties) shall file for Notification using the BFAD Notification Template (see attached copy mark as Annex "A") and must submit the following requirements:

- 1.1 Notarized BFAD Notification Form consisting of the following information:
 - (a) Name of Product/Product Brand
 - (b) Product Type
 - (c) Intended Use
 - (d) Pack Size(s)
 - (e) Name and address of manufacturer
 - (f) Name and address of assembler
 - (g) Name and address of trader/importer/distributor
 - (h) Name and address of person representing the local company and his/her designation in the company
 - (i) Product ingredient list, including full ingredients listing and functions
 - (j) Unattached specimen of the labeling layout
 - (k) Declaration of:
 - i. Absence of substances prohibited in cosmetic products

- ii. Compliance with warning labels and concentration limits of restricted substances
- iii. Absence of non-permissible claims
- iv. Compliance to claims under Bureau Circular No. 5, series of 2004 and its amendments, supported by a technical justification or clinical studies to substantiate label claims
- v. Product/s intended for Local and Export Use

1.2 Valid License to Operate reflecting the Manufacturer/Source of the Applicant

1.3 Specimen of the finished commercial product (one specimen to represent the pack sizes)

1.4 Corresponding fees and charges for notification services rendered by the BFAD in accordance with existing DOH Administrative Orders.

D. Cosmetic Products for Export Only

1. The same administrative and technical requirements of the locally manufactured cosmetics products shall apply for those intended for export only, provided that to allow exporters additional lead-time in the registration of their products in the importing countries, the application shall be prioritized by BFAD.

E. Cosmetics Registered in an ASEAN Member Country with existing Mutual Recognition Agreement with the Philippines

1. The following documents shall be required for cosmetics registered in an ASEAN Member Country with an existing Mutual Recognition Agreement with the Philippines:

1.1 Notarized Notification Letter advising the BFAD that the product will be marketed in the Philippines. The Notification shall consist of the following information:

- (a) Name of Product
- (b) Product Brand
- (c) Product Description - describe the form of cosmetics such as cream, gel, powder, pencil, stick, etc.
- (d) Purpose of Cosmetic or Intended Use - describe the purpose of the cosmetic such as baby product, deodorant, eye lotion, hair dye, hair shampoo, skin moisturizer, etc.
- (e) Product Formula shall consist of full ingredients listing and indicate percentage of restricted ingredients
- (f) Packaging particulars - describe the packaging and their pack sizes, e.g. glass, 10mL, 30mL & 100mL
- (g) Name and address of person responsible for putting the product on the market
- (h) Name and address of manufacturer or contract manufacturer
- (i) Name and address of importer

- (j) Unattached specimen of the labeling layout per pack size, per variant.

1.2 Valid License to Operate of the Applicant

1.3 Certificate of Product Registration certified true copy by the issuing agency

1.4 Specimen of the finished commercial product (one specimen to represent the pack sizes)

2. Within 30 calendar days following receipt of the documents, BFAD shall indicate to the applicant its acknowledgement or confirmation that the product can be marketed or the Bureaus need for clarification on the document submitted.

3. Any dispute on the clarification shall be settled between BFAD and applicant concerned in a timely manner through consultation and verification of compliance based on the ASEAN Cosmetic Product Registration Requirements in Article 2 of ASEAN Harmonized Cosmetic Regulatory Scheme.

V. REGISTRATION PROCEDURE

1. The applicant shall secure with BFAD the following forms, namely: (i) an updated checklist of requirements; (ii) a standard application form; (iii) a product information sheet for all application for cosmetic registration; and (iv) a cosmetic product notification form to facilitate compliance with this Order. The applicant may reproduce these forms, provided that such forms cannot be modified and/or revised without the prior written approval from the Product Services Division.

2. The registration shall be processed and finished preferably within a maximum of thirty (30) working days depending on the availability of resources and from the time that the applicant was able to complete and submit all the required documents.

3. The Product Registration shall be valid for a period of two (2) years from the time of the registration of the cosmetic products. Provided that, the following changes shall require a new product registration:

- (a) Any change in formulations, which affect the function and safety of the product; or
- (b) Any change in the product claims.

VI. LABELING OF 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.

- 1.1 The name of the cosmetic products and its function, unless it is clear from the presentation of the product;
- 1.2 Instructions on the use of the cosmetic products, unless it is clear from the product name or presentation;
- 1.3 Full ingredient listing. The ingredients shall be specified by using the nomenclature from the latest edition of standard references (Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated);
 - 1.3.1 The following shall not, however, be regarded as ingredients:
 - (a) Impurities in the raw materials used;
 - (b) Subsidiary technical materials used in the preparation but not present in the final product;
 - (c) Materials used in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions;
- 1.4 Country of manufacture;
- 1.5 The name and address of the company or person responsible for placing the product on the local market;
- 1.6 The contents given by weight or volume, in either metric or both in metric and imperial system;
- 1.7 The manufacturer's batch number;
- 1.8 The manufacturing date or expiry date of the product in clear terms (e.g. month/year);
- 1.9 Special precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label in Annexes II to VIII", 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:

- (a) There must be a statement (of any format) on the product label that declares the presence of ingredients from animal origin.
- (b) For ingredients from bovine and porcine origin, the exact animal must be declared.
- (c) Ingredients from human placenta must be declared specifically on the product label.

1.10 Registration number from the country of origin (manufacture) or 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 shall 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, namely: (a) the name of the cosmetic products; and (b) the manufacturer's batch number.

3. The particulars should be easily legible, clearly comprehensible and indelible.

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

VII. COSMETIC CLAIMS GUIDELINES

Product claims of cosmetic products shall comply with the ASEAN Cosmetic Claims Guidelines and, in a suppletory manner, shall be subject to rules and regulations relative to Cosmetic Product Claims, as laid down by the BFAD in the different Bureau Circulars and their respective amendments.

VIII. ASEAN COSMETIC INGREDIENT LISTINGS AND ASEAN HANDBOOK OF COSMETIC INGREDIENTS

The BFAD shall adopt the ASEAN Cosmetic Ingredient Listing from Part I to V including all the latest amendments thereto.

IX. IMPLEMENTATION OF THE ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE (CGMP) AND POST MARKET SURVEILLANCE SYSTEM

To further ensure the safety and quality of cosmetic products placed in the market pursuant to the provisions of this circular, the BFAD shall endeavor to strictly implement the ASEAN Guidelines for CGMP and to strengthen the conduct of its post market surveillance system.

X. WORKSHOPS FOR THE UNIFORM INTERPRETATION AND IMPLEMENTATION OF THE GUIDELINES

The BFAD, through the Joint Committee of BFAD and the Cosmetic Industry, shall hold a pre-implementation workshop to ensure a uniform interpretation and implementation of this Order. Any deviation from this Order shall be resolved by the Joint BFAD-Industry Committee subject to the approval of the BFAD Director in the form of a circular to the Industry and all parties concerned.

XI. TRANSITORY PROVISIONS

1. All applications for registration still pending before BFAD shall be processed and completed in accordance with this Order.

2. BFAD shall allow the Cosmetic Industry a transitory period of until December 31, 2007 to comply with the ASEAN Labeling Requirements contained in the ASEAN Harmonized Regulatory Scheme.

XII. SEPARABILITY CLAUSE

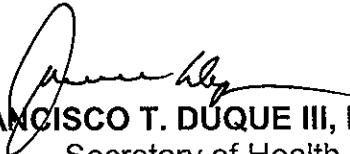
If any part, term or provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable part, term, or provision.

XIII. REPEALING CLAUSE

All administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/or revoked accordingly.

XIV. EFFECTIVITY

This Order shall take effect in fifteen (15) days after publication in a newspaper of general circulation.


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Secretary of Health