

21 April 2005

ADMINISTRATIVE ORDER
NO. 2005-0015

SUBJECT: Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents

I. RATIONALE

The collaboration of the Association of Southeast Asian Nation (ASEAN) Cosmetic Regulatory Authority and Cosmetic Industry since 1998 to align to national standards resulted to an Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme which was signed by the ASEAN Ministers on its 35th ASEAN Economic Ministers Meeting on 02 September 2003. Article 3 of this Agreement requires Member States to "undertake appropriate measure to adopt and implement common technical documents." This Order is issued in compliance with the said undertaking.

II. STATEMENT OF POLICY

The Department of Health (DOH) shall –

1. Support the members of the Cosmetic Industry who are prepared to enter into the ASEAN regional, if not global market of cosmetics by adopting the ASEAN Harmonized Regulatory Scheme including the ASEAN Common Technical Documents; and
2. Encourage and Support the small and medium enterprises to update their technologies to conform to the ASEAN Standards and Requirements and provide them regular technical information dissemination program through the Bureau of Food and Drugs (BFAD) in cooperation with the cosmetic industry association.

III. OBJECTIVES

The objectives of this Order are:

1. To formally adopt and incorporate the ASEAN Harmonized Regulatory Scheme and the ASEAN Common Technical Documents into the National Requirements.
2. To allow a coordinated transition period for both BFAD and the Cosmetic Industry from the previous cosmetic control policies to the ASEAN Harmonized Cosmetic Regulatory Scheme.

IV. SCOPE OF APPLICATION

This Order shall apply to all Cosmetic manufacturers, traders, exporters and importers of all cosmetic product(s).

V. DEFINITION OF TERMS

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.

VI. IMPLEMENTING GUIDELINES

A. ADOPTION OF THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

1. The DOH hereby adopts the ASEAN Mutual Recognition Arrangement of product registration approvals for cosmetics and the ASEAN Cosmetic Directive insofar as they are not in conflict with the national laws.
2. Schedule A and Schedule B of the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme signed by Member States on 02 September 2003 shall be incorporated in this order.

B. ADOPTION OF THE ASEAN TECHNICAL DOCUMENTS

1. The DOH hereby adopts the seven (7) ASEAN Technical Documents insofar as they are not in conflict with the national laws:
 - ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products;
 - ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients;
 - ASEAN Cosmetic Labeling Requirements;
 - ASEAN Cosmetic Claims Guidelines;
 - ASEAN Cosmetic Product Registration Requirements;
 - ASEAN Cosmetic Import/Export Requirements; and
 - ASEAN Guidelines for Cosmetic Good Manufacturing Practice
2. Appendices I to VII Part III of the Agreement Constituting these Seven (7) technical documents shall be incorporated under this order.
3. Said documents to be made accessible at the Bureau of Food and Drugs.

C. AUTHORITY OF THE BUREAU OF FOOD AND DRUGS TO ISSUE IMPLEMENTING DETAILS

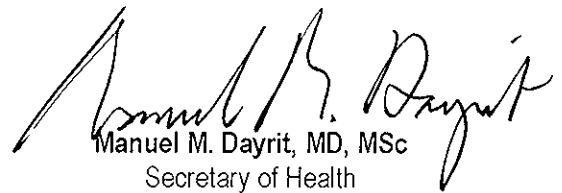
1. The BFAD shall be authorized to issue directive covering the implementation details of this Order provided that the implementation details shall:
 - Allow the Cosmetic Industry a transitory period in compliance to the ASEAN Labeling Requirements from the implementation of this Order to 31 December 2007 to comply with the ASEAN Harmonized Regulatory Scheme.
 - Include regular seminar, workshop or other forms of information exchange to ensure clarity and uniformity of implementation.

VII. REPEALING AND SEPARABILITY CLAUSE

1. All other Administrative Order, Bureau Circulars, Memoranda or parts thereof concerning cosmetic products inconsistent with this Order are hereby repealed
2. In case any provision of this Order is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall remain in force and effect.

VIII. EFFECTIVITY

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


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Secretary of Health