The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Vietnam, Member States of the Association of Southeast Asian Nations (hereinafter referred to as “ASEAN”);

HAVING regard to the Principles of Harmonization of Cosmetic Regulations, the Common Technical Documents for Cosmetics and the progress made in its implementation; and

DESIRING to implement the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme signed on the ______ of September 2003.

HAVE ADOPTED THIS DIRECTIVE:

ARTICLE 1
General Provisions

1. Member States shall undertake all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive, its Annexes and Appendices may be placed in the market.

2. Notwithstanding to Article 4 and without prejudice to Article 5 and Article 11, a Member State may not, for reasons related to the requirements laid down in this Directive, its Annexes and Appendices, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive, its Annexes and Appendices thereto.

3. The company or person responsible for placing the cosmetic products in the market, shall notify the regulatory authority responsible for cosmetics (hereafter referred to as regulatory authority) of each Member State where the product will be marketed of the place of the manufacture or of initial importation before the product is placed in the market.

4. The company or person responsible for placing the cosmetic products in the market shall for control purposes keep the product’s technical and safety information readily accessible to the regulatory authority of the Member State concerned.
ARTICLE 2
Definition and Scope of Cosmetic Product

1. A “cosmetic product” shall mean 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.

2. The products to be considered as cosmetic products within the meaning of this definition are listed in Appendix I.

3. Cosmetic products containing any substances in Annex V shall be excluded from the scope of this Directive. Member States may take measures as they deem necessary with regard to those products.

ARTICLE 3
Safety Requirements

1. A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product’s presentation, its labeling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market.

2. The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.

ARTICLE 4
Ingredient Listings

1. Member States shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments.

2. Member States shall prohibit the marketing of cosmetic products containing:

   a) substances listed in Annex II;

   b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;

   c) colouring agents other than those listed in Annex IV, Part 1 with the exception of cosmetic products containing colouring agents intended solely to colour hair;
d) colouring agents listed in Annex IV, Part 1 used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

e) preservatives other than those listed in Annex VI, Part 1;

f) preservatives listed in Annex VI, Part 1 beyond the limits and outside the conditions laid down therein, unless other concentrations are used for specific purposes apparent from the presentation of the product;

g) UV filters other than those listed in Annex VII, Part 1; and

h) UV filters listed in Annex VII, Part 1 beyond the limits and outside the conditions laid down therein.

3. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 3.

4. Member States shall allow the marketing of cosmetic products containing:

a) the substances and other ingredients listed in Annex III, Part 2 within the limits and under the conditions laid down, up to the dates in column (g) of that Annex;

b) the colouring agents listed in Annex IV, Part 2, used within the limits and under the conditions laid down, until the admission dates given in that Annex;

c) the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product;

d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

At these dates, these substances, colouring agents, preservatives and UV filters shall be:

- definitively allowed, or
- definitively prohibited (Annex II), or
- maintained for a given period specified in Part 2 of Annexes III, IV and VII, or
- deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.
ARTICLE 5
ASEAN Handbook of Cosmetic Ingredients

1. Notwithstanding the Article 4, a Member State may authorize the use within its territory of other substances, not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

a) the authorization must be limited to a maximum of three years;

b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;

c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the ASEAN Secretariat and to the other Member States the text of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the ACC a request for the inclusion in the list of permitted substances (Annex VIII – the ASEAN Handbook of Cosmetic Ingredients) given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. A decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the ACC or of a Member State, as to whether the substance in question may be included in a list of permitted substances (Annex VIII – the ASEAN Handbook of Cosmetic Ingredients) or whether the national authorization should be revoked. Notwithstanding paragraph 1(a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

ARTICLE 6
Labeling

1. Member States shall take all necessary measures to ensure that cosmetic products may be marketed only if product label is in full compliance with the ASEAN Cosmetic Labeling Requirements appearing as Appendix II and the information required thereunder, shall be in legible and visible lettering.

2. 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 III, IV, VI, VII and VIII, which must appear on the label, as well as any special precautionary information on cosmetic products.
3. Member States shall take all measures necessary to ensure that, in labeling, putting up for sale and advertising of cosmetic products, text names, trademarks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have.

ARTICLE 7
Product Claims

1. Member States shall take all necessary measures to ensure that product claims of cosmetic products comply with the ASEAN Cosmetic Claims Guideline, appearing as Appendix III. In general, product claims shall be subjected to national control.

2. As a general rule, claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the cosmetic formulation or preparation itself. The company or person responsible for placing the cosmetic product in the market will be allowed to use their own scientifically accepted protocols or designs in generating the technical or clinical data provided there is justification why such design is used.

ARTICLE 8
Product Information

1. The company or person responsible for placing the cosmetic product in the market shall keep the following information readily accessible to the regulatory authority of the Member State concerned at the address specified on the label in accordance with Article 6 of this Directive:

   a) the qualitative and quantitative composition of the product; in case of perfume compositions, the name and code number of the composition and the identity of the supplier;

   b) specifications of the raw materials and finished product;

   c) the method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines For Cosmetic Good Manufacturing Practice appearing as Appendix VI; the person responsible for manufacture or importation into the market must possess adequate knowledge or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or importation;

   d) assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure;
e) existing data on undesirable effects on human health resulting from use of the cosmetic product; and

g) supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect.

2. The information referred to in paragraph 1 of this Article must be available in the national language or languages of the Member State concerned, or in a language readily understood by the regulatory authority.

3. A Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the regulatory authority which shall ensure that this information is used only for the purposes of such treatment.

ARTICLE 9
Methods of Analysis

The following documents shall be made available by the company or person responsible for placing the cosmetic products in the market, to the cosmetic regulatory authority:

a) the available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the Certificate of Analysis; and

b) the criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products and/or methods for checking compliance with those criteria.

ARTICLE 10
Institutional Arrangements

1. The ASEAN Cosmetic Committee (ACC) shall coordinate, review and monitor the implementation of this Directive.

2. The ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Secretariat shall provide support in coordinating and monitoring the implementation of this Directive and assist the ACC in all matters relating thereto.

3. The ACC may establish an ASEAN Cosmetic Scientific Body (ACSB) to assist the ACC in reviewing the ingredient lists, technical and safety issues. The ACSB shall consist of representatives from the regulatory authorities, the industry and the academe.
ARTICLE 11
Special Cases

1. Member State may provisionally prohibit the marketing of a cosmetic product in its territory or subject it to special conditions, if the Member State finds out that on the basis of a substantiated justification, the cosmetic product, although complying with the requirements of the Directive, represents a hazard to health or for reasons specific to religious or cultural sensitivity. Certain product claims may be permitted or prohibited in accordance with national requirements. Furthermore, the Member State for reasons related to its local organization and laws, may designate a specific competent authority and subject to a different control, a specific cosmetic product which comply with the requirements of this Directive and Annexes thereto. It shall immediately inform the other Member States with a copy to the ASEAN Secretariat stating the grounds for its decision.

2. The ASEAN Secretariat shall notify the ACC, which shall, as soon as possible, consult the Member countries concerned, and deliver its opinion without delay and take the appropriate steps.

3. Member State, which places a restriction or temporary ban on specific cosmetic products shall notify the other Member States with a copy to the ASEAN Secretariat of such measures taken, providing reasons together with particulars of the remedies available under its laws in force and the time limits allowed for the exercise of such remedies.

ARTICLE 12
Implementation

1. Member States shall undertake appropriate measures to implement this Directive.

2. Member States may, however, for a period of 36 months from effective of the Directive, authorize the marketing in their territory of cosmetic products, which do not conform to the requirements of the Directive.

3. Member States shall undertake appropriate measures to ensure that the technical infrastructures necessary are in place to implement this Directive.

4. Member States shall ensure that the texts of such provisions of national laws, which they adopt in the field governed by this Directive are communicated to the other Member States with a copy to the ASEAN Secretariat, who shall promptly notify the ACC.

5. Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with this Directive.

6. The provisions of this Directive may be amended by written agreement of all Member States. All amendments shall become effective upon acceptance by all Member States.