AGREEMENT ON THE ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

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");

MINDFUL that in 1992 the ASEAN Heads of Government declared that an ASEAN Free trade Area shall be established in the region and that in 1998 they agreed to accelerate its implementation to the year 2002;

NOTING the Agreement on the Common Effective Preferential Tariff (CEPT) Scheme for the ASEAN Free Trade Area (AFTA) signed on 28 January 1992 and the Protocol to amend the above Agreement signed on 15 December 1995, which provide for border and non-border areas of cooperation to supplement and complement the liberalization of trade including, among others, the harmonization of standards, reciprocal recognition of tests and certification of products;

REITERATING their commitment to the Agreement on Technical Barriers to Trade (TBT) of the World Trade Organization (WTO), which encourages Contracting Parties to enter into negotiations for the conclusion of agreement for the mutual recognition of results of each other's conformity assessment and mandates, among others, the elimination of unnecessary obstacles to trade, regarding technical regulations;

MINDFUL that the private sector of the cosmetic industry, through the regional and national organizations such as the ASEAN Cosmetics Association (ACA), has participated in the development of the ASEAN Harmonized Cosmetic Regulatory Scheme;

MINDFUL of the desire of ASEAN Member States to encourage and promote cooperation among them in the field of technological development considering the different levels of infrastructure and economic development of ASEAN Member States;

MINDFUL further that the ASEAN Framework Agreement on Mutual Recognition Arrangements signed on 16 December 1998 provides a basis for development of Sectoral MRAs to facilitate the realization of AFTA; and

DESIRING to formulate an agreement to deepen and broaden cooperation on cosmetics to contribute to the realization of AFTA.

HAVE AGREED AS FOLLOWS:

ARTICLE 1
OBJECTIVES

The objectives of this Agreement are:

a) To enhance cooperation amongst Member States in ensuring the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN; and

b) To eliminate restrictions to trade of cosmetic products amongst Member States through harmonization of technical requirements, Mutual Recognition of Product Registration Approvals and adoption of the ASEAN Cosmetic Directive .

ARTICLE 2
ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

1. The ASEAN Harmonized Cosmetic Regulatory Scheme has the following coverage:

   a) The ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics appearing as Schedule A of this Agreement; and

b) The ASEAN Cosmetic Directive appearing as Schedule B of this Agreement.

2. Member States may implement the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics, which shall be effective as of the date when and between the Member States who accede thereto.

3. Member States shall undertake necessary measures to fully implement the ASEAN Cosmetic Directive by 1st January 2008.

4. Member States may implement the ASEAN Cosmetic Directive earlier than the date referred in Paragraph 3 of this Article and this Directive shall be effective as of the date when and between the Member States who may accede thereto beginning 1st January 2003. In this case, the Member States shall inform the ASEAN Secretariat of their decision, who in turn shall promptly notify the other Member States.

ARTICLE 3
TECHNICAL DOCUMENTS FOR COSMETICS

Member States shall undertake appropriate measures to adopt and implement the following common technical documents which appear as Appendices and Annexes to the ASEAN Cosmetic Directive or the ASEAN Mutual Recognition Arrangement of Product Registration Approvals, as the case may be:

a) ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products;
b) ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients;
c) ASEAN Cosmetic Labeling Requirements;
d) ASEAN Cosmetic Claims Guidelines;
e) ASEAN Cosmetic Product Registration Requirements;
f) ASEAN Cosmetic Import/Export Requirements; and
g) ASEAN Guidelines for Cosmetic Good Manufacturing Practice.

ARTICLE 4
OTHER AREAS OF COOPERATION

Member States shall strengthen and enhance existing cooperation efforts in Cosmetics and cooperate in areas that are not covered by existing cooperation arrangements, which include but not limited to the following:

a) Establishing or improving infrastructural facilities; and
b) Encouraging and promoting cooperation in the fields of technological development pertaining to:

   (i) labeling claims, product approvals and manufacturer's license;
   (ii) accreditation and certification;
   (iii) quality assurance and good manufacturing practice;
   (iv) technical information; and
   (v) training.

ARTICLE 5
DISPUTE SETTLEMENT

Any difference between Member States concerning the interpretation or implementation of this Agreement including the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics and the ASEAN Cosmetic Directive, shall be settled amicably by consultation or negotiation among the Member States. If a settlement cannot be reached, thus, it shall be subjected to the Dispute Settlement Mechanism of ASEAN in accordance with the Protocol on Dispute Settlement Mechanism, which was signed on 20 November 1996 in Manila, Philippines.

ARTICLE 6
INSTITUTIONAL ARRANGEMENTS

1. An ASEAN Cosmetic Committee (hereinafter called "the ACC"), is hereby established, which shall be responsible for effective functioning of this Agreement. The ACC shall consist of one official representative from each Member State's regulatory authority responsible for cosmetics. The representative may be accompanied by their

delegation at meetings of the ACC. The ASEAN Cosmetic Industry, such as ACA, will be invited to meetings of the ACC and shall be consulted on all matters concerning the Cosmetic Industry.

2. The ACC, in performance of its functions, shall take its decision by consensus and shall be responsible for but not limited to the following:

   a) coordinating, reviewing and monitoring the implementation of this Agreement, including the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics and the ASEAN Cosmetic Directive; and
   b) reviewing and updating the technical documents in Article 3 of this Agreement.

3. The ACC may establish or consult any body or bodies for purpose of giving advice on any matter of a scientific or technical nature in the field of cosmetic products.

4. The ACC shall adopt its own rules of procedures.

5. The ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Secretariat shall provide support in coordinating and monitoring the implementation of this Agreement, including the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics and the ASEAN Cosmetic Directive and assist the ACC in all matters relating thereto.

ARTICLE 7
FINAL PROVISIONS

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

2. This Agreement shall be effective upon signing by all Member States.

3. This Agreement shall be deposited with the Secretary-General of ASEAN, who shall promptly furnish a certified copy thereof to each Member State.

IN WITNESS WHEREOF, the undersigned, being duly authorized by their respective Governments, have signed this Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme.

DONE in Phnom Penh, Cambodia on this 2nd day of September in the year Two Thousand and Three, in a single copy in the English language.

For the Government of Brunei Darussalam

ABDUL RAHMAN TAIB
Minister of Industry and Primary Resources

For the Government of the Kingdom of Cambodia

CHAM PRASIDH
Minister of Commerce

For the Government of the Republic of Indonesia

RINI M. S. SOEWANDI
Minister of Industry and Trade

For the Government of the Lao People's Democratic Republic

SOULIVONG DARAVONG
Minister of Industry and Handicraft

For the Government of Malaysia

RAFIDAH AZIZ
Minister of International Trade and Industry

For the Government of the Union of Myanmar

BRIGADIER GENERAL DAVID O. ABEL
Minister at the Office of the Chairman of the State Peace
and Development Council

For the Government of the Republic of the Philippines

MANUEL M. DAYRIT
Secretary of Health

For the Government of the Republic of Singapore

B.G. (NS) GEORGE YONG-BOON YEO
Minister for Trade and Industry

For the Government of the Kingdom of Thailand

ADISAI BODHARAMIK
Minister of Commerce

For the Government of the Socialist Republic of Vietnam

TRUONG DINH TUYEN
Minister of Trade

SCHEDULE A

ASEAN MUTUAL RECOGNITION ARRANGEMENT OF PRODUCT REGISTRATION APPROVALS FOR COSMETICS

SCHEDULE A

ASEAN MUTUAL RECOGNITION ARRANGEMENT OF PRODUCT REGISTRATION APPROVALS FOR COSMETICS

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;

DESIRING to implement the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme signed on 2 September 2003.

HAVE AGREED AS FOLLOWS:

ARTICLE 1
OBJECTIVE

The objective of the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics (hereafter referred to as this Arrangement) is to specify requirements and procedures for the implementation of the mutual recognition of product registration approvals for cosmetics amongst the Member States.

ARTICLE 2
MUTUAL RECOGNITION OF THE PRODUCT REGISTRATION APPROVALS

1. The Member States shall mutually recognize the product registration approvals for cosmetic products, issued by a Member State’s Regu-

latory Authority in accordance with the ASEAN Cosmetic Product Registration Requirements and ASEAN Cosmetic Labeling Requirements.

2. Within this Arrangement, "recognition" means the use of certificate of product registration as agreed upon, as a basis for regulatory actions such as approvals or re-issuing the product registration approvals.

ARTICLE 3
PROCEDURES

1. Only cosmetic products registered by a Member State in accordance with Article 2 of this Arrangement can be marketed in the territory of the other Member States.

2. To market cosmetic products meeting requirements of the paragraph 1 of this Article, to the territory of the other Member States, the following documentation is required for submission by the company or person responsible for placing the product in the market (applicant):

   a) Notification Letter informing the other Member States that the product(s) will be marketed in their respective territories. The information required for Notification are detailed in the ASEAN Cosmetic Product Registration Requirements appearing as Appendix IV; and

   b) Certified true copy of the Certificate of Product Registration issued by the regulatory authority responsible for cosmetics.

3. Within 30 calendar days following receipt of the documents under paragraph 2 of this Article, the other Member States shall indicate to the applicant either their confirmation that the product can be marketed or their need for clarification on the documentation submitted.

4. Any dispute on the clarification shall be settled between the Member State 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 this Arrangement.

ARTICLE 4
PARTICIPATION

1. This Arrangement is intended to be multilateral in which all Member States are encouraged to participate. However, two or more Member States may proceed first if other Member States are not ready to participate in this Arrangement or decide to proceed directly to the ASEAN Cosmetic Directive.

2. Any Member State that wishes to participate in this Arrangement shall notify the ASEAN Secretariat of its intention to participate and the date on which its participation will take effect. The ASEAN Secretariat shall send a copy of this notification to the other Member States.

3. Member States shall review regularly the progress of the implementation of this Arrangement through the ACC. Meetings will be convened as required and shall be held in rotation among the Member States, the venue and time of which shall be agreed by the Member States.

ARTICLE 5
FINAL PROVISIONS

1. A Member State may at any time withdraw from this Arrangement after giving all the other Member States at least three months' notice in writing with a copy to the ASEAN Secretariat. The withdrawal shall not affect the validity and duration of any activity made under this Arrangement until the completion of such activity.

2. This Arrangement shall be valid and enforceable until superseded by the ASEAN Cosmetic Directive.

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SCHEDULE B

ASEAN COSMETIC DIRECTIVE

SCHEDULE B

ASEAN COSMETIC DIRECTIVE

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 2 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 10, 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 5 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.