### (National Coat-of-Arms) KINGDOM OF CAMBODIA Nation Religion King

Royal Government of Cambodia No. 122 S.E.

# **SUBDECREE**

#### On

#### **Cosmetic Product Control**

#### The Royal Government

#### *Pursuant to:*

- The Constitution of the Kingdom of Cambodia;
- Royal Decree No. NS/RD/0704/124, dated July 15, 2004, on the Appointment of the Royal Government of the Kingdom of Cambodia;
- Royal *Kram* No. 02/NS/94, dated July 20, 1994, promulgating the Law on the Organization and Functioning of the Council of Ministers;
- Royal *Kram* No. NS/RK/0196/06, dated January 24, 1996, promulgating the Law on the Establishment of the Ministry of Health;
- Royal *Kram* No. CS/RK/0696/02, dated June 17, 1996, promulgating the Law on Pharmaceutical Management;
- Royal *Kram* No. NS/RK/0600/001, dated June 21, 2000, promulgating the Law on the Control of the Quality, Safety of Products, Goods and Services;
- Royal *Kram* No. NS/RK/0202/006, dated February 7, 2002, promulgating the Law on Brands, Trade Names and Unfair Competition;
- Subdecree No. 67 S.E., dated October 22, 1997, on the Organization and Functioning of the Ministry of Health;
- Approval from the Council of Ministers during a plenary session held on August 8, 2008;

## Hereby decides:

Chapter 1 General Provisions

# Article 1.-

This subdecree aims to control cosmetic products of all types being traded in the Kingdom of Cambodia.

# Article 2.-

The purposes of this subdecree are to protect, prevent the production, circulation, importation of counterfeit cosmetic products, cosmetic products of damaged quality, illegal cosmetic products to ensure quality and safety for consumers and to facilitate the trade of cosmetic products.

# Article 3.-

The terms used in this subdecree shall have the following meanings:

Cosmetic products refer to products that are compounded of chemical substances, bio-products, plants or minerals and are to be applied to the external parts of the human body (skin, hair, nail, lips and external parts of sex organs) or applied to teeth and the soft tissue of the palate with the aim of cleaning, protecting, maintaining, scenting, altering the external image or eliminating body odor.

A counterfeit or false cosmetic product refers to a product that has compound substances of inadequate quality, that is different in level or inappropriate according to the compound elements described by producers in the record filed with the company or formula defined on the label of a product that is produced or packed by a physical person or legal entity without any license from the competent institutions, or a product with a label or packaging, display of style, or identity similar to that of another cosmetic product that is the genuine cosmetic product.

A cosmetic product of damaged quality refers to a product that is not stored properly according to the technical conditions and a product with an expired shelf life.

An illegal cosmetic product refers to a product that has no notification number.

A notification applicant refers to the physical person or legal entity responsible for the quality and safety of cosmetic products being traded in the Kingdom of Cambodia.

Notification refers to the completion of the formalities of registration in a simple way to provide information about the product to the competent institutions controlling cosmetic products.

# Chapter 2

## Article 4.-

Imported or cosmetic products produced for trade in the Kingdom of Cambodia shall have notification numbers from the Ministry of Health.

Cosmetic products imported for exhibition, research study and for souvenirs shall be exempted from notification, but shall request authorization from the Ministry of Health.

Formalities and procedures for the issuance of notification numbers shall be defined by a *prakas* of the Minister of Health.

The cost of issuance of notification numbers shall be determined by a joint *prakas* of the Minister of Health and the Minister of Economy and Finance.

### Article 5.-

The Ministry of Health shall be entitled to revoke notification numbers in case the said cosmetic product causes harm to consumers.

### Article 6.-

In case of inspection by the competent institutions controlling cosmetic products, the notification applicant shall prepare technical documents and relevant documents about the safety of the cosmetic product such as:

- Product formula specifying the name and quantity of substances contained in the cosmetic product. As for cosmetic products containing compound substances as aromatic substances, the names of the substances, code numbers and names of suppliers shall be specified;

- The method of examination of chemical substances shall be attached with the certificate of quality control;

- All conditions in the analytical research for microorganisms in cosmetic products will determine the purity of chemical substances as well as control methods in response to scheduled conditions;

- The specifications for compound substances of cosmetic products and final products;

- Production methods that comply with the principle of good production practice in the production of cosmetic products;

- Assessment of safety inspection of final products, compound substances, chemical structure and determination of impacts on external parts of the human body;

- Specify the side effects for users should they consume the products;

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- Shall have adequate data specifying the effectiveness of cosmetic products.

Relevant technical documents about the safety of cosmetic products shall be written in Khmer and English or French.

## Article 7.-

A physical person or legal entity responsible for trading cosmetic products on the market shall comply with the formalities of trade defined by a *prakas* of the Minister of Health.

# Chapter 3 Conditions of Safety Guarantee

### Article 8.-

Cosmetic products being traded on the market of the Kingdom of Cambodia shall be produced in enterprises that have complied with the principle of good production practice in producing cosmetic products or the principle of minimum good production practice in producing cosmetic products acceptable to competent institutions that control cosmetic products.

#### Article 9.-

Cosmetic products being traded on the market of the Kingdom of Cambodia shall comply with the following conditions:

- Shall be safe and of good quality, and will not be harmful to consumers;

- Shall have labels and bulletins providing instructions on the methods of use, storage and caution in consumption.

#### Article 10.-

The Ministry of Health shall issue warnings to a physical person or legal entity that produces, imports, distributes and sells cosmetic products against any conditions to be determined by a *prakas* of the Minister of Health.

In case the above cosmetic product causes harm to consumers, the physical person or legal entity shall be subject to punishment in accordance with the Law on Pharmaceutical Management and the laws in force.

# Chapter 4 List of Cosmetic Product Substances

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#### Article 11.-

The list of substances as well as the limit of the level of each substance authorized for use in the production of cosmetic products and the list of prohibited substances in the production of cosmetic products shall be determined by a *prakas* of the Minister of Health.

# Chapter 5 Cosmetic Product Labels

#### Article 12.-

All cosmetic products authorized for trading shall have a label according to the formalities to be determined by a *prakas* of the Minister of Health.

## Chapter 6 Control Competency

#### Article 13.-

Cosmetic products of all types shall be under the control of the Ministry of Health. The Ministry of Health shall prepare:

- The formalities of cosmetic product notification;

- The formalities and conditions for requesting to open and close a cosmetic product import – export establishment;

- The formalities and conditions for advertising a cosmetic product;

- The classification of cosmetic products stipulated in the final classification list of ASEAN.

Classification of cosmetic products other than [those on] the final classification list of ASEAN shall be determined by a joint *prakas* between the Minister of Health and the Minister of Industry, Mines and Energy.

#### Article 14.-

The instructions and inspection related to cosmetic products shall be [within] the competence of the Ministry of Health. The Ministry of Health shall assign the inspection team as well as health agents who are judicial police officers to conduct inspections at establishments trading cosmetic products and cosmetic product import – export establishments in order to:

- Examine the technical documents of cosmetic products;
- Extract sample cosmetic products for quality analysis, if necessary including cosmetic products being locally produced;

- Temporarily detain exhibits related to offences [committed in] flagrante delicto and prepare the case file to be forwarded to the court.

### Article 15.-

Use of trade names, pictures that affect national culture or text, style with the aim of exaggerating the quality of a cosmetic product via advertisement shall be prohibited.

## Article 16.-

The Ministry of Health shall be entitled to halt or completely terminate the circulation, distribution and trade of cosmetic products if it is observed that those cosmetic products cause harm to the health of consumers even though those cosmetic products meet the conditions and formalities specified in the said subdecree.

# Chapter 7 Transitional Provisions

### Article 17.-

Any cosmetic products currently circulating and trading in the Kingdom of Cambodia shall be authorized to continue to be circulated and traded for a further period of 36 (thirty-six) months after the said subdecree takes effect should the Ministry of Health observe that those cosmetic products cause no harm to consumers.

As regards cosmetic products that are produced after the said subdecree takes effect, they shall meet the conditions and formalities specified in the said subdecree.

# Chapter 8 Final Provisions

#### Article 18.-

Subdecree No. 33 S.E., dated April 22, 2002, on the Control of Cosmetic Products and other provisions contrary to the said subdecree shall be abrogated.

#### Article 19.-

The Minister of the Office of the Council of Ministers; the Minister of Economy and Finance; the Minister of Health; ministers; secretaries of state of all

*By JICA HRD* ministries and relevant institutions shall implement this subdecree from the date of signature onwards.

Phnom Penh Capital, August 28, 2008
Prime Minister

(Signature and stamp)

**Unofficial Translation** 

Ministry of the Royal PalaceGeneral Secretariat of the Constitutional Council

CC:

- General Secretariat of the Senate
- General Secretariat of the National Assembly
- Secretary-General of the Royal Government
- Cabinet of *Samdech* Prime Minister
- Cabinet of His Excellency the Deputy Prime Minister
- As stipulated in Article 19
- Royal Gazettes
- Records Archives

# Samdech Akka Moha Sena Padei Techo HUN SEN