

## **Cosmetics Act B.E. 2558 (2015)**

BHUMIBOL ADULYADEJ, REX.

Given on the 30<sup>th</sup> Day of August in the Year B.E. 2558 (2015);

Being the 70<sup>th</sup> Year of the Present Reign,

His Majesty King Bhumibol Adulyadej is graciously pleased to proclaim that:  
Whereas it is expedient to revise the law on cosmetics;  
Be it, therefore, enacted by the King, by and with the advice and consent of the National Legislative Assembly, as follows:

### **Article 1**

This Act is called the “Cosmetics Act, B.E. 2558 (2015).”

### **Article 2**

This Act shall come into force as from the day following its publication in the Royal Thai Government Gazette.

### **Article 3**

The Cosmetics Act, B.E. 2535 (1992) shall be repealed.

### **Article 4**

In this Act:

“Cosmetics” means:

- (1) A “cosmetic product” shall mean any substance or preparation intended to be placed in contact (by applying to, massaging or rubbing into, sprinkling or spraying on, dropping onto, introducing into, perfuming, or by any other means,) 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 but shall not include ornaments and clothing which are deemed as accessories outside human body.
- (2) Articles intended for use specifically as a component in the manufacture of cosmetics,  
or
- (3) Other articles classified as cosmetics by Ministerial Regulations;

“Container” means any material used specifically for packing or wrapping cosmetics;

“Statement” means any written message, picture, film, light, sound, symbol, or any other activity intended to convey understanding;

“Advertising” means any activity, undertaken by any means whatsoever, that is intended to make the public see, hear, acknowledge a statement intended for commercial purposes;

“Advertising media” means anything as an advertising medium, e.g. newspapers, printed matter, radio, television, telephone, electronic media, or signage;

“Label” means a picture, imprint, or any statement, which is displayed on cosmetics, containers or packages, or inserted or posted with cosmetics, containers, or packages, and shall include any text or user’s manual accompanying the cosmetic;

“Manufacture” means make, mix, convert, transform, prepare, pack in portions, or repackage;

“Import” means bringing or ordering into the Kingdom;

“Export” means taking or ordering out of the Kingdom;

“Sell” means distribute, dispose of, or exchange, provided that such is for the purpose of trade and shall include possess intending to sell;

“Active ingredient” means a substance used in the manufacture of a cosmetic as prescribed by the Minister under Article 6 (3) or a substance responsible for the cosmetic property(ies) stated in the text on the label or as stated in the notification submitted to the Regulatory Agent as prescribed by the Minister under Article 6 (4);

“Place” means a place, building or any part thereof, and shall include its vicinity;

“Notification receipt” means a notice providing details of each cosmetic product that the Regulatory Body issues to the notifying party;

“Notifying party” means the party who receives a notification receipt for the manufacture for sale, import for sale, or subcontracting for manufacture of cosmetics under this Act;

“Regulatory Body” means the Secretary-General of the Food and Drug Administration or that individual authorized by him/her;

“Committee” means the Cosmetics Committee;

“Secretary-General” means the Secretary-General of the Food and Drug Administration;

“Competent official” mean a person appointed by the Minister for the execution of this Act;

“Minister” means the Minister having charge of the execution of this Act.

## **Article 5**

The Minister of Public Health shall have charge of the execution of this Act and shall be empowered to appoint a competent official who shall issue Ministerial rules pertaining to fees not in excess of those appended to this Act, with the exception of fees and other activities associated with the issuing of orders or announcements integral to the execution of this Act;

In issuing Ministerial rules which set fees as in Paragraph 1 above, fees shall differ, taking into account the type of cosmetic, the size and type of business, and the type of correction or modification;

All such rules, orders and announcements shall come into force as of their date of publication in the Royal Thai Government Gazette.

#### **Article 6**

For the protection of individual safety and health, the Minister in consultation with the Committee shall have the powers to set rules and regulations prescribing the following:

- (1) the name, category, kind or nature of cosmetics which may not be manufactured, imported or sold;
- (2) the name of any substance prohibited for use as an ingredient in cosmetics;
- (3) the name, quantity, or conditions for use of any substance which may be used as an ingredient in cosmetics;
- (4) the name of main ingredients, category, kind or nature of a cosmetic responsible for the property(ies) of a cosmetic product manufactured for sale, import for sale, or contracted for manufacture;
- (5) nature of manufacturing site location, tools, instruments, manufacturing equipment, cosmetics packaging, and nature of importation location;
- (6) rules, procedures and conditions for the manufacture and import of cosmetics;
- (7) rules, procedures and conditions pertaining to notification and reporting of adverse event which may result from the use of a cosmetic product;
- (8) rules, procedures, and conditions pertaining to the collection and storage of information about cosmetics by manufacturers, importers, or contractors for the purpose of inspection;
- (9) any place within the Kingdom served as an inspection check point of cosmetics;
- (10) rules, procedures and conditions pertaining to notification, issuing and amending of notification receipts, and renewal and replacement of notification receipts;
- (11) rules, procedures and conditions for the manufacture or importing of cosmetics under Article 16;
- (12) rules, procedures and conditions for submitting applications and issuing certification for cosmetics;
- criteria for setting the deviation value for substandard cosmetics;
- (13) rules, procedures and conditions for seeking advice on labeling;
- (14) rules, procedures and conditions for seeking advice on advertising;
- (15) rules, procedures and conditions pertaining to the recall, destruction and hand over of cosmetics.

### **Section 1 Cosmetics Committee**

## **Article 7**

There shall be a committee called the “Cosmetics Committee” consisting of the Permanent Secretary of the Ministry of Public Health as Chairperson, the Director-General of the Department of Medical Services, the Director-General of the Department of Disease Control, the Director-General of the Department of Thai Traditional and Complementary Medicine, the Director-General of the Department of Medical Sciences, the Director-General of the Department of Health Service Support, the Director-General of the Department of Health, the Secretary-General of the Food and Drug Administration, a representative from the Department of Science Service, a representative from the Customs Department, a representative from the Office of the Counsel of State, a representative from the Consumer Protection Bureau, two elected members from among the Deans of the Faculties of Pharmaceutical Science at all tertiary institutions, and six qualified members appointed by the Minister, of whom three must represent associations or foundations dedicated to consumer protection, and three members representing businesses engaged in the manufacture, import or sale of cosmetics.

The Secretary-General of the Food and Drug Administration shall appoint a Deputy Secretary-General to serve as a member and committee secretary. The Secretary-General shall also appoint a government official to serve as assistant secretary.

Qualifications, exclusions, and the recruitment and selection of qualified committee members shall comply with the rules, procedures and conditions set by the Minister.

## **Article 8**

Qualified committee members shall hold office for a term of two years and may be reappointed, although no member may serve more than two consecutive two-year terms.

In the event that a qualified member vacates office prior to the end of his/her term, the Minister may appoint a new member to serve out the remaining portion of that term, except when the remaining portion of the term is less than 90 days, in which case the Minister may elect not to appoint a replacement member and the Committee shall consist of the remaining members;

If at the expiration of the term as in Paragraph 1, no replacement member has been appointed, the former member shall remain in his/her position until such time as a replacement has been appointed.

## **Article 9**

In addition to the expiration of his/her term, a qualified committee member vacates his/her post upon:

- (1) death;
- (2) resignation;

- (3) removal by the Minister for reasons of dishonesty in the performance of his/her duties, misconduct, or incompetence;
- (4) failure to comply with the qualifications or exclusions in Article 7 Paragraph 3;
- (5) is bankrupt;
- (6) is incapacitated or quasi-incapacitated;
- (7) has been sentenced to prison in a court of final instance, except for an offense committed through negligence or for a petty offense;

#### **Article 10**

The powers and responsibilities of the Committee are as follows:

- (1) to give advice and consultation to the Minister on matters relating to policies and regulatory measures for cosmetics under this Act;
- (2) to give advice and consultation to the Minister on the issuing of announcements as per Article 6;
- (3) to give advice and consultation on the revocation of notification receipts as per Article 36;
- (4) to approve the revocation of notification receipts as per Article 37;
- (5) to perform other functions as may be prescribed by law or as assigned by the Minister.

#### **Article 11**

At meetings of the Committee, a quorum shall be defined as a majority of the members present.

If at a meeting of the Committee, the Chairperson is absent or unable to perform his/her duties, the present members shall appoint a Chairperson to act in his/her stead.

Motions shall be carried by a majority of votes, with each member having one vote. In the event of a tie, the Chairperson shall cast the deciding vote, which is final.

#### **Article 12**

The Committee is empowered to appoint a sub-committee to consider, study, or conduct research on any matter within the scope of the Committee's powers and duties, or to carry out any other function as assigned by the Committee;

The Committee shall stipulate a quorum and procedures for meetings of the subcommittee as appropriate.

#### **Article 13**

In the performance of their duties under this Act, the Committee or subcommittee under Article 12 shall have the power to issue written summons to any individual for the purpose of giving testimony or submitting documents or other material to supplement their consideration.

## **Section 2**

### **Notification and Receipt of Notification of Cosmetics**

#### **Article 14**

Any individual wishing to manufacture, import for sale, or subcontract for the manufacture and sale of cosmetics must file a notification and only after the issuing of a notification receipt may the individual undertake the manufacture or import of cosmetics.

Notification and the issuing of a notification receipt as in Paragraph 1 shall comply with the rules, procedures and conditions stipulated by the Minister;

The Notifying Party in Paragraph 1 must conform to the rules, procedures and conditions pertaining to the manufacture, import or subcontracting for the manufacture and sale of cosmetics as stipulated by the Minister in Article 6 (5) (6) (7) and (8).

#### **Article 15**

The notification receipt shall remain valid for a period of three years as from the date of issue.

Should the Notifying Party wish to renew the notification receipt, he/she shall submit a renewal request prior to the expiration date. Once the application has been submitted and the renewal fees have been paid, the notification receipt shall remain valid until such time as the Regulatory Body orders that no further renewals will be approved;

Applications for renewal of notification receipts shall comply with the rules, procedures and conditions stipulated by the Minister.

A Notifying Party whose notification receipt has expired for a period of not more than one month may submit a renewal request without penalty provided that he/she shows reason for the failure to apply for a renewal prior to the expiry date and pays the renewal fee. However, a request for renewal without penalty does not exempt the Notifying Party from compliance with the terms of Article 64.

#### **Article 16**

A person who manufactures or imports cosmetic samples for the purpose of an exhibit or promotional display or for purpose of study, research or laboratory analysis shall be exempt from the requirement to obtain a notification receipt for said cosmetics under Article 14;

Any person receiving an exemption as in Paragraph 1 above shall comply with the rules, procedures and conditions stipulated by the Minister.

#### **Article 17**

The Regulatory Body shall not accept notification requests for cosmetics with any one or more of the following characteristics:

(1) the cosmetic is not safe for use under Article 28;

- (2) the cosmetic is sold under a trade name that overstates its properties, or is indecent, or is misleading to consumers;
- (3) the cosmetic is sold under a trade name that conflicts with Thai cultural norms or that degrades the Thai language.

#### **Article 18**

If the notification receipt is seriously damaged, lost or destroyed, the Notifying Party shall obtain a replacement from the Regulatory Body within 15 days; Requests for and issuing of replacement notification receipts shall be in compliance with the rules, procedures and conditions stipulated by the Minister.

#### **Article 19**

Should the Notifying Party wish to change any of the information in the notification receipt, he/she shall apply to the Regulatory Body; Requests to change information in the notification receipt shall be in compliance with the rules, procedures and conditions stipulated by the Minister.

#### **Article 20**

Any party wishing to obtain certification for a cosmetic product shall apply for such from the Regulatory Body; Applications for and issuing of certification as in Paragraph 1 above shall be in compliance with the rules, procedures and conditions stipulated by the Minister.

#### **Article 21**

With regard to decisions concerning the issuing of notification receipts as in Article 14, the changing of information as in Article 19, and the issuing of certification as in Article 20, the Secretary-General, with the approval of the Committee is empowered to publish in the Royal Thai Government Gazette the names of individuals, organizations or agencies with relevant expertise both in Thailand and abroad to evaluate scientific data, inspect places of manufacture, test or analyze cosmetics, and set fees and procedures for such, and the Notifying Party shall be responsible for paying all said fees.

### **Section 3 Cosmetics Labels**

#### **Article 22**

Manufacturers, importers and subcontractors for the manufacture and sale of cosmetics must ensure that all cosmetics have labels;

Labels as in Paragraph 1 above must comply with the following:

- (1) All information contained on the label must be accurate and must not contain any information which could result in a serious misunderstanding; all information must be ethical and in keeping with Thai cultural norms;
- (2) Information must be written in the Thai language and must be of a size that is easily legible; information may also be provided in a foreign language.

Cosmetics imported for sale in the Kingdom are not required to have a Thai-language label on the packaging or wrapping at the time of customs inspection but a Thai-language label must be affixed prior to sale;

- (3) Labels must bear the following information:
- (a) name and trade name of the cosmetic;
  - (b) name and location of the manufacturer if the product is manufactured in the Kingdom; name and location of the importer together with the name of the manufacturer and country of origin in the case of imported cosmetics;
  - (c) quantity, directions for use, cautions, warnings, month and year of manufacture and expiry date, batch number or letter, and the names of all ingredients used in the manufacture of the product;
  - (d) Any other information intended for the benefit of consumer safety in accordance with the rules and conditions stipulated by the Committee in the Royal Thai Government Gazette;

Rules governing the information specified in Paragraphs (2) and (3) above shall be in compliance with the rules, procedures and conditions prescribed by the Committee in the Royal Thai Government Gazette.

#### **Article 23**

If a label does not conform to the terms stipulated in Article 22, the Secretary-General, with the approval of the Committee, is authorized to order the Notifying Party to terminate use of the label or to amend said label.

#### **Article 24**

Any Notifying Party unsure of whether his/her label is in violation of or otherwise does not conform to the terms set down in Article 22 may request that the Committee evaluate the label prior to use, in which case the Committee shall deliberate and inform the Notifying Party of its decision within 90 days as from the day on which the Food and Drug Administration receives the request. If the Committee fails to notify the Notifying Party within this time period, the Committee shall be deemed as having given its approval;

Requests and approvals as in Paragraph 1 above shall comply with the rules, procedures and conditions stipulated by the Minister.

### **Section 4 Controlled Cosmetics**

#### **Article 25**

When an announcement is made as in Article 6 (9), cosmetics imported for sale in the Kingdom must pass inspection at the designated inspection check point.

#### **Article 26**

The Notifying Party must manufacture or import all cosmetics in strict compliance with the information contained in the notification given to the Regulatory Body.



### **Article 27**

The manufacture, importing, and subcontracting for manufacture and sale of the following cosmetics are strictly prohibited:

- (1) cosmetics which are unsafe for use;
- (2) counterfeit cosmetics;
- (3) sub-standard cosmetics;
- (4) cosmetics prohibited by the Minister under Article 6 (1);
- (5) Cosmetics for which the notification receipt has been revoked under Article 36 or Article 37.

### **Article 28**

Cosmetics having any of the following properties or characteristics shall be considered as unsafe for use:

- (1) Any cosmetic product manufactured or packaged under unsanitary conditions such that it poses a threat to consumers;
- (2) Cosmetics containing ingredients that could degrade and become hazardous to consumers;
- (3) Cosmetics containing impurities that could pose a health risk to consumers;
- (4) Cosmetics containing ingredients prohibited for use in cosmetics under Article 6 (2).

### **Article 29**

Cosmetics with any of the following properties or characteristics shall be considered as counterfeit:

- (1) Any cosmetics bearing a label with false information about the **manufacturer, importer, or place of manufacture;**
- (2) Cosmetics containing 20% more or less than the amount specified in the notification of any ingredient or as specified on the label;
- (3) Cosmetics which contain an artificial ingredient in place of any of the main ingredients, or which do not contain any of the active ingredients as reported to the Regulatory Body or as listed on the label;
- (4) Cosmetics for which the notification document contains false information.

### **Article 30**

Cosmetics containing a percentage more or less of any active ingredient exceeding acceptable error margins determined by the Minister and appearing in the Royal Thai Government Gazette but which do not exceed conditions set down in Article 29 (2) shall be considered as sub-standard cosmetics.

### **Article 31**

If it appears that the Notifying Party is in violation of Article 26 or fails to comply with the rules of the Minister under Article 6 (5) (6) (7) or (8), the Regulatory Body is empowered to order that the offender cease all actions which are in violation or take action to ensure compliance, and shall have the authority to make any such

violations or failure to comply with Ministerial rules known to the public in the interest of safety as may be warranted.

### **Article 32**

Sale of the following is strictly forbidden:

- (1) Cosmetics for which notification has not been filed under Article 14 Paragraph 1;
- (2) Cosmetics without labels as prescribed in Article 22 Paragraph 1;
- (3) Cosmetics with labels not in compliance with Article 22 Paragraph 2 (1);
- (4) Cosmetics with labels not in compliance with Article 22 Paragraph 2 (2) or (3);
- (5) Cosmetics with labels which the Minister has ordered terminated under Article 23;
- (6) Cosmetics whose expiry date has already passed.

### **Article 33**

In the interest of the health and safety of an individual, the Minister is empowered to order the Notifying Party to take the following actions:

- (1) report to the Food and Drug Administration on any cosmetics which he/she manufactures or imports;
- (2) provide the Food and Drug Administration with samples of any cosmetic which he/she manufactures or imports.

### **Article 34**

As there is an announcement to allow any substance as an essential ingredient in manufacturing cosmetics in accordance with Section 6 (3), such substance shall be exempted from remaining in force under the law on drugs, food, hazardous substances, medical devices and other related laws.

If any substance specified as an essential ingredient in manufacturing cosmetics in accordance with Section 6 (3) is subsequently announced as a prohibited ingredient in manufacturing cosmetics under Section 6 (2), such announcement shall come into force after one hundred and eighty (180) days following the announcement date. If such substance appears to be very harmful to users, the announcement shall come into force immediately or within the period of less than one hundred and eighty (180) days.

### **Article 35**

In the interest of exporters, manufacturers, or importers, the manufacture or import of cosmetics intended for export may comply with the quality, standards, labeling, or other requirements of the buyer abroad, but in such cases, the manufacturer, importer, or exporter must provide the Regulatory Body with complete details and must comply with the rules, procedures and conditions stipulated by the Secretary-General, approved by the Committee, and published in the Royal Thai Government Gazette;

Manufacturers or importers of cosmetics intended for export abroad as in Paragraph 1 are prohibited from selling such products in the Kingdom.

## **Section 5**

### **Revocation of Notification Receipts for Cosmetics**

#### **Article 36**

The Regulatory Body is authorized to revoke a cosmetics notification receipt if it appears that:

- (1) a cosmetic is subject to Ministerial regulation under Article 6 (1);
- (2) the Notifying Party fails to comply with the terms of Article 26.

#### **Article 37**

To protect consumer health and safety, the Regulatory Body with the approval of the Committee is authorized to revoke a cosmetics notification receipt if it appears that:

- (1) the Notifying Party fails to comply with the rules, procedures and conditions stipulated by the Minister in Article 14 Paragraph 2;
- (2) the cosmetic is deemed unsafe for use under Article 28;
- (3) The Notification party has added or revised any direction of use or the cosmetics are deemed to possess any characteristic of being medicine, food, psychotropic or narcotic substance, hazardous substance, or medical devices.

#### **Article 38**

All orders to revoke the notification receipt of a cosmetic shall be made in writing and sent to the address of the Notifying Party as specified in the notification receipt, as stipulated in Article 39 or Article 40.

#### **Article 39**

When notice of the revocation of a notification receipt is delivered in person, if the Notifying Party refuses to accept the notice or if he/she is not present at the time of delivery, and if delivery is made to an individual legally employed or resident at the location, or in the event that said individual refuses delivery, if the notice is left or posted in a clearly visible place at the location in the presence of a witness, the notice shall be considered as having been delivered and acknowledged.

#### **Article 40**

When notice of revocation of a notification receipt for cosmetics is sent by return mail, the notice shall be considered as having been received as from seven after the day of posting, unless it is found that delivery was not made or was made before or after the specified date.

## **Section 6**

### **Advertising**

#### **Article 41**

Cosmetics advertising must not contain statements intended to deceive consumers or that may have negative effects on society at large. This includes all statements regarding a product's place of origin, condition, quality, quantity or properties;

Statements of the following types are considered as intended to deceive consumers or as having possible negative effects on the society at large:

- (1) statements that are false or overstate the truth;
- (2) statements that cause serious misunderstanding of the product either through the mention of scientific data, statistics, or anything else that is not true or that overstates the truth;
- (3) statements that make medical claims or whose purpose is other than cosmetic;
- (4) statements that lead consumers to believe that the product may enhance libido or sexual performance;
- (5) statements that either directly or indirectly promote the commission of a crime or immoral act, or that have a degrading effect on the nation's morals;
- (6) statements that may cause dissension or disunity among the public;
- (7) any other statements as stipulated by Ministerial rules)

The statement used for the advertisement of the cosmetics and known to the public that is utterly unrealistic shall not be deemed as the prohibited statement in the advertisement of the cosmetics stated in the second paragraph (1).

#### **Article 42**

The advertisement of the cosmetics shall not be conducted in any certain manner that causes trouble to consumers or deemed harmful to consumers' health, mentality and morality.

#### **Article 43**

In case that the Secretary-General shall consider any type of cosmetics to be harmful to consumers, the Secretary-General approved by the Committee shall be authorized to order the Notification party or advertiser to proceed with the following actions:

- (1) append to the advertising a caution or warning regarding proper use or possible dangers associated with use in accordance with the conditions set by the Committee, and the Committee may set different conditions for different advertising media;
- (2) limit the use of advertising for said cosmetics;
- (3) prohibit advertising for said cosmetics;

Items (2) and (3) above shall apply to advertising deemed by the Secretary-General to contravene public morals or national customs and culture.

#### **Article 44**

In case that the Secretary-General shall consider that the advertisement has violated the requirements specified in Article 41 or 42, the Secretary-General shall be authorized to order the Notification party or advertiser to proceed with the following actions:

- (1) amend the statement or method of the advertisement;
- (2) prohibit the use of certain statements contained in the advertisement;
- (3) prohibit advertising or the particular method of advertising;
- (4) Broadcast the amended advertisement for the precision of consumers' understanding in accordance with the requirements stated in the Ministerial Regulations-

In issuing an order as in (4) above, the Secretary-General shall comply with the rules and procedures prescribed by the Committee, taking into account the interests of consumers and the truthfulness of the Notifying Party or the advertiser.

#### **Article 45**

Should the Secretary-General have reasonable cause to believe that any statement contained in an advertisement is false or an overstatement of the truth under Article 41 Paragraph 2 (1), the Secretary-General is empowered to order the Notifying Party or the advertiser to present proof of the truthfulness of their advertising;

In the event that the Notifying Party or the advertiser cites a scientific study, research findings, statistics, certification from an institution or individual, or any other confirmation of the truthfulness of the advertisement, and the Notifying Party or the advertiser is unable to provide proof of the truthfulness of the truthfulness of claims made in their advertising, the Secretary-General, with the approval of the Committee, is empowered to issue such orders as provided in Article 44 above.

#### **Article 46**

If a Notifying Party or advertiser has reason to believe the advertising for a cosmetics product is in violation of or otherwise fails to comply with this Act, he/she may request the Committee to offer an opinion; in which cases, the Committee shall inform the Notifying party or the advertiser of its opinion on the matter within 60 days of the date on which the Food and Drug Administration receives said request. If the Committee does not deliver an opinion within this time frame, the Committee shall be considered as having given its approval.

Requests for an opinion and the issuing of such as in Paragraph 1 above shall be in compliance with the rules, procedures and conditions stipulated by the Minister;

Approval from the Committee does not restrict its right to review and issue a new ruling when it has reasonable cause to do so;

Any action taken with the approval of the Committee or any action considered to have the approval of the Committee as in Paragraphs 1 and 3 above shall not be considered a criminal offense.

### **Section 7 Competent Officials**

#### **Article 47**

For the execution of this Act, the competent official shall have the following powers:

- (1) enter the manufacturing facility, import point, storage facility or place of sales of a given cosmetic during the location's regular working hours, or to enter the vehicle loading area for the purpose of inspecting or ensuring compliance with the terms of this Act;
  - (2) take adequate samples of a given cosmetic or suspected cosmetic not in compliance with the terms of this Act for the purpose of testing and analysis;
  - (3) when there is reasonable cause to believe that there is a violation of the terms of this Act, the competent official may enter any premises or vehicle loading area in order to inspect, search, seize or confiscate cosmetics, equipment, packaging or wrapping, labels, documents, or other matter pertaining to said cosmetics involved in any real or perceived wrongdoing;
  - (4) summon any individual to give testimony or hand over documents or any relevant evidence necessary for the deliberation of the competent official;
- In performing the duties specified in the first paragraph, other related persons shall be involved in the said actions if necessary.

The performance of duties in (3) requires a search warrant. If it has an evidence to believe that it may induce the diversion, concealment, alteration of nature, or spoliation of evidence related to the violation if the search warrant is issued in a delayed manner, it is legally allowed to require no search warrant, but all actions shall comply with the Criminal Code on search and seizure.

#### **Article 48**

If the competent official shall consider that there is the violation under Article 14 Paragraph 1, Article 26, Article 27, or Article 32, the competent official with the permission of the Secretary-General is authorized to order the Notifying Party, the seller, or the owner of the cosmetics to recall and destroy said cosmetics, or hand over the cosmetics to the competent official within a period of time determined by him/her; or if necessary, the competent official may take immediate possession of said cosmetics, and the Notifying Party, seller, or owner shall be responsible for any expenses incurred. All such actions shall be in compliance with the rules, procedures and conditions of the Minister.

#### **Article 49**

The competent official who carries out a search shall keep a complete inventory of all items searched, seized or attached;

Itemized inventories in Paragraph 1 above shall be read to the owner of the facility or vehicle, or to an individual working at the facility or vehicle, or to a witness as the case may be, who shall affix his/her signature. If this individual refuses to sign, the competent official who has made the search shall send the itemized inventory and any attached items to the Food and Drug Administration immediately.

#### **Article 50**

Seized or attached items under this Act shall become the property of the Ministry of Public Health, which shall dispose of them in accordance with its rules and rules, when it appears that:

- (1) there is no apparent owner or when no one appears to take possession of the items within 90 days of their seizure or attachment;
- (2) when there are no legal proceedings and the owner does not request return of the items within 90 days of the day on which it is announced that no legal action will be taken;
- (3) in the event that legal action is pursued and an officer of the prosecutor's office or the court rules against seizure, and the owner does not request return of the seized items within 90 days as from the date on which the final ruling against further legal action comes down, or the day on which the court issues a final ruling, depending on circumstances.

#### **Article 51**

In the event that items seized or attached under this Act are perishable or near their designated expiration date, or if items are at risk of spoiling in storage, or if the cost of storage exceeds the value of the items, the Food and Drug Administration shall place the items up for sale on the market prior to the conclusion of the case, or before the items become the property of the Ministry of Public Health. Money from the sale of said items after all expenses shall be seized instead of the items and deposited in a government bank;

Actions taken in accordance with Paragraph 1 above shall comply with the rules of Ministry of Public Health.

#### **Article 52**

In the execution of Article 47 (1) (2) or (3), all actions shall be carried out in the presence of the owner of the premises or vehicle or in front of witnesses, as the case may be, to ensure that actions are carried out in a proper manner, and the competent official at the scene shall record whether the individual or individuals confirm or refuse to confirm that proper protocol has been observed;

(4) Any items seized or attached shall be shown to the owner of the facility or vehicle, or to an individual working at the facility or vehicle, or to a witness, depending on circumstances.

, to verify that proper protocol has been observed, and the competent official at the scene shall record whether the individual or individuals confirm or refuse to confirm that proper protocol has been observed;

Items seized or attached shall be packed or wrapped and stamped or otherwise marked for identification purposes.

#### **Article 53**

In the execution of this Act, the competent official shall be a competent official under the Criminal Code;

If there are reasonable grounds to do so, the Secretary-General may order the competent official to conduct a joint investigation in cooperation with other investigating officers in accordance with the rules of the Ministry of Public Health and with the approval of the National Police Bureau;

and in such cases, the competent official shall have the status of investigating officer under the Criminal Procedure Code.

#### **Article 54**

In performing duties, the competent official is required to display an identity card to persons related the performance of duties.

The identity card owned by the competent official shall comply with requirements prescribed in the Ministerial Regulations

#### **Article 55**

In the interest of public health and safety, the Secretary-General with the approval of the Committee shall be empowered to make public the findings of any inspection or analysis of cosmetics or suspected cosmetics not in compliance with this Act which have been inspected or analyzed under Article 47 (2); in such instances, the owner of the cosmetics shall have the opportunity to challenge or respond to the findings and to present supporting evidence, depending on cases.

### **Section 8 Appeals**

#### **Article 56**

Should the Regulatory Body not issue a notification receipt or fail to issue a renewal of such, the Applicant either filing a notification or requesting a renewal of such may make a written appeal to the Minister within 30 days as of the date on which he/she receives notice that no notification receipt or no renewal of such will be issued;

The Minister's decision shall be final;

Before such time as the Minister rules on the appeal as in Paragraph 1 above, he/she is empowered to permit a business to continue operating until a ruling is given, should the party making the appeal make such a request.

#### **Article 57**

A Notifying Party whose notification receipt has been revoked may submit a written appeal to the Minister within 30 days of the date on which he/she receives notice of revocation under Article 38;

The Minister's decision shall be final;

The notice of appeal stated in the first paragraph shall not limit the enforcement of the revocation of the Notification receipt.

#### **Article 58**



In the event that an individual does not agree with an order from the Secretary-General under Article 23, Article 33, Article 43, Article 44, or Article 45, he/she has the right to file a written appeal to the Minister within 30 days of receipt of the order;

The decision of the Minister shall be final;

The notice of appeal stated in the first paragraph shall not limit the enforcement of the revocation of the Notification receipt.

#### **Article 59**

The Minister shall rule on appeals made under Article 56, Article 57, and Article 58 within 90 days of the date on which the appeal is filed. If circumstances prevent the Minister from issuing a ruling within this time period, the party making the appeal shall be notified of such prior to the end of the 90-day period. In such cases, the time for deliberation may be extended for not more than 90 days as from the end of the initial 90-day period.

### **Section 9 Penalties**

#### **Article 60**

Any manufacturer, importer, or subcontractor for the manufacture of cosmetic products who violates announcements made by the Minister under Article 6 (1) shall be subject to imprisonment for a period not to exceed two years or a fine not to exceed 200,000 baht or both;

Any individual who sells cosmetics in violation of the announcements made by the Minister under Article 6 (1) is subject to imprisonment for a period not to exceed 6 months or a fine not to exceed 50,000 baht or both.

#### **Article 61**

Any individual who does not make a statement or submit documents or other materials when ordered to do so by the Committee or sub-committee under Article 13 or by a competent official under Article 47 (4) is subject to imprisonment for a period not to exceed one month or a fine not to exceed 10,000 baht or both.

#### **Article 62**

Any individual who not comply with the terms of Article 14 Paragraph 1 is subject to imprisonment for a period not to exceed 6 months or a fine not to exceed 50,000 baht or both.

#### **Article 63**

Any Notifying Party who does not comply with the rules, procedures, or conditions prescribed in Article 14 Paragraph 3 is subject to a fine not to exceed 50,000 baht.

#### **Article 64**

A Notifying Party who submits a request for renewal of a notification receipt after the expiration date but within the grace period allowed under Article 15 Paragraph 4 is subject to a fine assessed daily at a rate of 500 baht for each day the request is late.

**Article 65**

Any individual who does not comply with the terms of Article 16 Paragraph 2 is subject to a fine not to exceed 10,000 baht.

**Article 66**

Any individual who does not comply with the terms of Article 18 Paragraph 1 is subject to a fine not to exceed 1,000 baht.

**Article 67**

Any manufacturer, importer or subcontractor for the manufacture of cosmetic products who does not comply with the terms of Article 22 Paragraph 1 or who uses a label not in compliance with the terms prescribed in Article 22 Paragraph 2 (1) is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both;

Any individual who sells cosmetics with labels in breach of Article 22 Paragraph 1, which is in violation of Article 32 (2), or who sells cosmetics with labels in breach of Article 22 Paragraph 2 (1), which is in violation of Article 32 (3) is subject to imprisonment for a period not to exceed three months or a fine not to exceed 30,000 baht or both.

**Article 68**

Any manufacturer, importer or subcontractor for the manufacture and sale of cosmetic products with labels in breach of Article 22 Paragraph 2 (2) or (3) is subject to imprisonment for a period not to exceed three months or a fine not to exceed 30,000 baht, or both;

Any individual who sells cosmetics with labels in breach of Article 22 Paragraph 2 (2) or (3), which is in violation of Article 32 (4), is subject to imprisonment for a period not to exceed one month or a fine not to exceed 10,000 baht or both.

**Article 69**

Any Notifying Party who continues to use a label which the Secretary-General has ordered discontinued under Article 23 is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both;

Any individual who sells cosmetics found to be in violation of Article 32 (5) is subject to imprisonment for a period not to exceed three months or a fine not to exceed 30,000 baht or both.

**Article 70**

Any individual who does not comply with the terms of Article 25 is subject to a fine not to exceed 20,000 baht.

#### **Article 71**

Any Notifying Party who does not comply with the terms of Article 26 is subject to a fine not to exceed 20,000 baht.

#### **Article 72**

Any individual in violation of Article 27 (1) who manufactures, imports or subcontracts to manufacture for sale cosmetic products determined to be unsafe for use under Article 28 (1) or (2) is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht or both;

Any individual in violation of Article 27 (1) who sells cosmetic products determined to be unsafe for use under Article 28 (1) or (2) is subject to imprisonment for a period not to exceed three months or a fine not to exceed 30,000 baht or both.

#### **Article 73**

Any individual in violation of Article 27 (1) who manufactures, imports or subcontracts to manufacture for sale cosmetic products determined to be unsafe for use under Article 28 (3) is subject to imprisonment for a period not to exceed two years or a fine not to exceed 200,000 baht or both;

Any individual in violation of Article 27 (1) who sells cosmetic products determined to be unsafe for use under Article 28 (3) is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both.

#### **Article 74**

Any individual in violation of Article 27 (1) who manufactures, imports or subcontracts to manufacture for sale cosmetic products determined to be unsafe for use under Article 28 (4) is subject to imprisonment for a period not to exceed five years or a fine not to exceed 500,000 baht or both;

Any individual in violation of Article 27 (1) who sells cosmetic products determined to be unsafe for use under Article 28 (4) is subject to imprisonment for a period not to exceed three years or a fine not to exceed 300,000 baht or both.

#### **Article 75**

Any individual in violation of Article 27 (2) who manufactures, imports or subcontracts to manufacture for sale counterfeit cosmetic products under Article 29 (1) or (2) is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht or both;

Any individual in violation of Article 27 (2) who sells counterfeit cosmetic products under Article 29 (1) or (2) is subject to imprisonment for a period not to exceed three months or a fine not to exceed 30,000 baht or both.

#### **Article 76**

Any individual in violation of Article 27 (2) who manufactures, imports or subcontracts to manufacture for sale counterfeit cosmetic products under Article 29 (3) or (4) is subject to imprisonment for a period not to exceed two years or a fine not to exceed 200,000 baht or both;

Any individual in violation of Article 27 (2) who sells counterfeit cosmetic products under Article 29 (3) or (4) is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both.

#### **Article 77**

Any individual in violation of Article 27 (3) who manufactures, imports or subcontracts to manufacture for sale substandard cosmetic products under Article 30 is subject to a fine not to exceed 40,000 baht;

Any individual in violation of Article 27 (3) who sells substandard cosmetic products under Article 30 is subject to a fine not to exceed 50,000 baht or both.

#### **Article 78**

Any individual who sells cosmetics for which no notification has been made in violation of Article 32 (1) is subject to a fine not to exceed 20,000 baht;

If the action in Paragraph 1 above is committed by a manufacturer, importer, or subcontractor to manufacture for sale, he/she is subject to imprisonment for a period not to exceed two months or a fine not to exceed 20,000 baht or both.

#### **Article 79**

Any individual who sells cosmetics which have passed their expiration date in violation of Article 32 (6) is subject to a fine not to exceed 10,000 baht;

If the action in Paragraph 1 above is committed by a manufacturer, importer, or subcontractor to manufacture for sale, he/she is subject to a fine not to exceed 5,000 baht.

#### **Article 80**

Any Notifying Party who does not comply with an order issued by the Secretary-General under Article 33 is subject to imprisonment for a period not to exceed two months or a fine not to exceed 20,000 baht or both.

#### **Article 81**

Any manufacturer or importer intending to export cosmetic products abroad in violation of Article 35 Paragraph 1 is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both;

Any manufacturer or importer intending to export cosmetic products abroad in violation of Article 35 Paragraph 2 is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht or both.

#### **Article 82**

Any individual who manufactures, imports, or subcontracts to manufacture for sale cosmetic products for which the notification receipt has been revoked under Article 36 (1) or Article 37 (2) or (3) is subject to imprisonment for a period not to exceed five years or a fine not to exceed 500,000 baht;

Any individual who sells cosmetic products for which the notification receipt has been revoked under Article 36 (1) or Article 37 (2) or (3) is subject to imprisonment for a period not to exceed three years or a fine not to exceed 300,000 baht.

#### **Article 83**

Any individual who manufactures, imports or subcontracts to manufacture for sale cosmetic products for which the notification receipt has been revoked under Article 36 (2) or Article 37 (1) is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht;

Any individual who sells cosmetic products for which the notification receipt has been revoked under Article 36 (2) or Article 37 (1) is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht.

#### **Article 84**

Any individual who advertises cosmetic products in violation of Article 41 or who does not comply with the terms of Article 42 is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht or both.

#### **Article 85**

Any individual who does not comply with an order from the Secretary-General under Article 43 or Article 44 is subject to imprisonment for a period not to exceed one year or a fine not to exceed 100,000 baht or both.

#### **Article 86**

Any individual who does not reasonably accommodate a competent official in the performance of his/her duties under Article 47 is subject to imprisonment for a period not to exceed one month or a fine not to exceed 10,000 baht or both.

#### **Article 87**

Any individual who violates or otherwise does not comply with the order of a competent official under Article 48 is subject to imprisonment for a period not to exceed six months or a fine not to exceed 50,000 baht or both.

#### **Article 88**

In the case of any ongoing violation of Article 84 or Article 85, the offender is subject to a fine not to exceed 10,000 baht assessed daily for the period in which he/she remains in violation or fails to take action to ensure compliance.

#### **Article 89**

When the court rules that an individual is in breach of Article 14 Paragraph 1 or Article 27, the court shall order the seizure of cosmetics, packaging, labels, and all other items relevant to the breach of said Articles, unless these assets are the property of another individual who is not a knowing party to the violation;

In the event that the court orders the seizure of assets under Paragraph 1 above, it appears that subsequent to the seizure the true owner of the assets was not a knowing party to the violation, the court shall order the return of said assets, in which case, the true owner must submit a request to the court within 90 days of the day on which the court issues its final ruling;

Assets seized by order of the court under Paragraph 1 above shall become the property of the Ministry of Public Health to destroy or dispose of as the Ministry sees fit.

### **Article 90**

For any violation of this Act for which the penalty is a fine alone or a term of imprisonment not to exceed one year, the Secretary-General or an individual appointed by him/her shall have comparative power, in accordance with the rules governing comparative power set by the Committee;

When the offender has paid the fine assessed within 30 days as from the day on which comparative power has been exercised, the case shall be considered concluded under the Criminal Proceedings Code;

The party with comparative power shall consider appropriate action to take with regard to any assets which may have been seized under the law, but in the following instances, comparative power may be exercised only when:

(1) The belongings deemed to be involved in the violation or misconduct, since the violator or misconducting person has agreed to keep the belongings in possession of the Food and Drug Administration;

(2) The belongings deemed to be involved in the violation or misconduct and legally prohibited for distribution and such violation or misconduct can be amended for correction, since the violator or misconducting person has agreed and amended the violation or misconduct of the said belongings;

(3) The belongings deemed to be involved in the violation or misconduct and legally prohibited for distribution and such violation or misconduct can be amended for correction, since the violator or misconducting person has agreed to keep the belongings in possession of the Food and Drug Administration, where all costs incurred from the demolition of such belongings shall be responsible by the violator or misconducting person.

## **Transitional Provisions**

### **Article 91**

Initially, a Committee consisting of members appointed under Article 7 with the exception of deans representing the faculties of Pharmaceutical Science at tertiary institutions shall execute the provisions of this Act until such time as the deans and

qualified members under this Act are in place; however, this period shall not exceed 180 days as from the day on which this Act comes into force.

#### **Article 92**

Notification applications pertaining to controlled cosmetics under the Cosmetics Act B.E. 2535 (1992) and which are still under consideration shall be considered as notification applications under this Act *mutatis mutandis*, and the Regulatory Body is empowered to order the Applicant to submit additional information or to amend the information contained in his/her notification request for controlled cosmetics as needed.

#### **Article 93**

Notification receipts for controlled cosmetics issued under the Cosmetics Act B.E. 2535 (1992) prior to the date on which the present Act comes into force shall be considered as notification receipts under this Act and shall remain valid for an additional three years as from the date on which this Act comes into force.

#### **Article 94**

All Ministerial rules, regulations or announcements issued under the Cosmetics Act B.E.2535 (1992) which are in force on the day prior to the day on which this Act comes into force shall remain in force provided that they do not contradict or conflict with the provisions of this Act until such time as new Ministerial rules, regulations and announcements issued under this Act come into force;

The issuing of Ministerial rules, regulations and announcements as in Paragraph 1 above shall be completed within two years as from the day on which this Act comes into force; should this not be possible, the Minister shall submit a written explanation to the Cabinet.

Countersigner of the Royal Proclamation  
General Prayuth Chan-ocha  
Prime Minister

#### Schedule of Fees

(1) Notification receipt for manufacture of cosmetics	5,000 baht
(2) Notification receipt for import of cosmetics	5,000 baht
(3) Notification receipt for subcontracting to manufacture for sale	5,000 baht
(4) Replacement notification receipt	1,000 baht
(5) Notification application	500 baht
(6) Request to modify notification receipt	500 baht
(7) Certification under Article 20	1,000 baht

(8) Request for advisement under Article 24	10,000 baht
(9) Request for advisement under Article 46	10,000 baht
(10) Renewal of notification receipt equivalent to fee for issuance of notification receipt by type	
(11) Other applications	100 baht

*Remarks:* As explanation for the enactment of this new law, the Cosmetics Act B.E. 2535 (1992) has been in force for many years and a number of its provisions are no longer adequate to meet current conditions. Also, as a member of ASEAN, Thailand must amend its laws pertaining to cosmetics to ensure that they are consistent with those of other member states of the Association, i.e. the notification procedures prior to the manufacture or import of cosmetic products. Amending the laws to reflect present-day circumstances will also enhance the competitiveness of Thailand's cosmetics industry in international markets. Furthermore, by prohibiting the manufacture, import and sale of certain types of cosmetics, the new law provides for more effective measures to ensure consumer safety. The new law stipulates which substances may not be used as ingredients in the manufacture of cosmetic products; it sets standards for cosmetic manufacturing facilities and packaging; it requires the reporting of ingredients used in the manufacture of cosmetics; it sets labeling and advertising requirements and restrictions, and includes measures intended to protect consumers from cosmetic products deemed unsafe for use. It aims to ensure fairness for consumers through measures against counterfeit and substandard cosmetics. Finally, the new law sets penalties and fees more in line with present-day realities. It is therefore required to enforce this Act.