

# COSMETICS ACT

Wholly Amended by Act No. 11014, Aug. 4, 2011

Amended by Act No. 11690, Mar. 23, 2013

Act No. 11985, Jul. 30, 2013

Act No. 12497, Mar. 18, 2014

Act No. 13117, Jan. 28, 2015

Act No. 14027, Feb. 3, 2016

Act No. 14264, May 29, 2016

## Article 1 (Purpose)

The purpose of this Act is to contribute to improving national health and developing the cosmetics industry by prescribing matters concerning the manufacture, importation, sale, etc. of cosmetics.

## Article 2 (Definitions)

The terms used in this Act shall be defined as follows: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14264, May 29, 2016>

1. The term "cosmetic" means any item intended to be used by means of spreading, rubbing, spraying on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or brightening the appearance, or maintaining or improving the health of skin and hair, which have light effects on the human body: Provided, That goods constituting medicines defined in subparagraph 4 of Article 2 of the Pharmaceutical Affairs Act shall be excluded herefrom;
2. The term "functional cosmetics" means cosmetics prescribed by Ordinance of the Prime Minister, falling under any of the following:
  - (a) Products aiding in the whitening of the skin;
  - (b) Products aiding in improving wrinkles in the skin;
  - (c) Products aiding in tanning skin gently or protecting skin from ultraviolet rays;
  - (d) Products aiding in changing or removing the color of hair, or nourishing hair;
  - (e) Products aiding in preventing or improving dryness, splits, loss, cornification, etc. resulting from weakened functions of skin or hair;
3. The term "organic cosmetics" means cosmetics manufactured from organic materials, plants and animals, or materials, etc. derived therefrom, which comply with standards prescribed by the Minister of Food and Drug Safety;

4. The term "safe containers or packaging" means containers or packaging designed or planned with child-proof lids for children under the age of five;
5. The term "use-by date" means the minimum period from date of manufacture during which consumers can safely use a cosmetic with its unique characteristics preserved in appropriate storage conditions;
6. The term "primary package" means packaging containers which come into direct contact with the contents of cosmetics at the time of manufacturing;
7. The term "secondary package" means one or more packages, protecting materials, and packages for the purpose of labeling (including attached documents, etc.) that encase the primary package;
8. The term "labeling" means letters, numbers or figures written on the containers and packages of cosmetics;
9. The term "advertisement" means conduct to display or notify information on cosmetics by means of radio, television, newspapers, magazines, voice, sound, videos, the Internet, printings or billboards, or by other means.

### **Article 3 (Registration, etc. of Manufacture or Sales Business)**

(1) Each person who intends to manufacture all or part of cosmetics (excluding the process of secondary packaging or labeling only), (hereinafter referred to as "manufacturer"), and who intends to distribute or sell, or supply or award for the purpose of import agency business, the manufactured cosmetics (including manufactured cosmetics by consignment) and imported cosmetics (hereinafter referred to as "manufacturer-seller") shall file for registration with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. The same shall also apply to any modification of important matters prescribed by Ordinance of the Prime Minister, among registered matters. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016>

(2) None of the following persons shall obtain registration of manufacturing or manufacturing-selling business: Provided, That subparagraphs 1 and 3 shall apply to manufacturing business only: <Amended by Act No. 12497, Mar. 18, 2014; Act No. 14027, Feb. 3, 2016>

1. A mentally ill person defined in subparagraph 1 of Article 3 of the Mental Health Act: Provided, That the foregoing shall not apply to a person determined suitable as a manufacturer by a specialized medical doctor;
2. An incompetent person under the adult guardianship or a person declared bankrupt and not yet reinstated;
3. An addict to drugs or other harmful substances;
4. A person for whom his/her imprisonment without labor or greater punishment declared by a court for violating this Act or the Act on Special Measures for the Control of Public Health Crimes was not completed or the non-execution of the sentence has not become final;
5. A person for whom one year has not elapsed since the date registration was revoked (excluding cases where the registration was revoked on grounds of subparagraphs 1 through 3) pursuant to Article 24.

(3) A manufacturer who intends to file for registration pursuant to paragraph (1) shall be equipped with proper facilities, as prescribed by Ordinance of the Prime Minister: Provided, That he/she may be allowed to be equipped with only part of the facilities in cases prescribed by Ordinance of the Prime Minister, such as partial engagement in the process of manufacturing cosmetics. <Amended by Act No. 11690, Mar. 23, 2013>

(4) A seller referred to in paragraph (1) who intends to file for registration of manufacture-sale business shall meet appropriate standards prescribed by Ordinance of the Prime Minister for quality control and post-manufacture and sale safety control and shall assign a manager capable of managing such standards (hereinafter referred to as "manufacture-sales manager"). <Amended by Act No. 11690, Mar. 23, 2013>

(5) Matters necessary for procedures for registration, etc. or qualification requirements, duties, etc. of manufacture-sales managers under paragraphs (1) through (4) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 4 (Examination, etc. of Functional Cosmetics)**

(1) A person who intends to manufacture or sell functional cosmetics by manufacturing or importing them shall undergo an examination by the Minister of Food and Drug Safety or shall submit a report to the Minister of Food and Drug Safety for safety and effectiveness of each product. The same shall apply to any revision to the examined matters. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Examinations of effectiveness under paragraph (1) shall be limited to the efficacy and effects provided for in the items of subparagraph 2 of Article 2.

(3) A person who intends to undergo an examination under paragraph (1) shall submit data necessary for such examination to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) Matters necessary for the scope of and procedures, etc. for examinations or submission of reports under paragraphs (1) and (2) shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 5 (Obligations, etc. of Manufacturer-Sellers, etc.)**

(1) A manufacturer-seller shall conform to matters prescribed by Ordinance of the Prime Minister concerning the quality control, post-manufacture and sale safety control of cosmetics and other issues related to manufacture-sale. <Amended by Act No. 11690, Mar. 23, 2013>

(2) A manufacturer shall observe matters prescribed by Ordinance of the Prime Minister concerning manufacturing of cosmetics. <Amended by Act No. 11690, Mar. 23, 2013>

(3) A manufacturer-seller shall report data, such as a track record of manufacturing or importing cosmetics and a list of raw materials used in the process of manufacturing cosmetics, to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) Manufacture-sales managers shall undergo training for securing safety and quality management of cosmetics every year. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016>

(5) Where deemed necessary for the prevention of hazards to public health, the Minister of Food and Drug Safety may order manufacturers and manufacturer-sellers to undergo training concerning cosmetics-related statutes and institution (including matters necessary for securing safety and quality management of cosmetics). <Newly Inserted by Act No. 14027, Feb. 3, 2016>

(6) Where persons required to undergo training pursuant to paragraph (5) are engaged in manufacturing or manufacturing-sales in two or more places, a person may be designated as the person-in-charge and required to undergo training, among his/her employees prescribed by Ordinance of the Prime Minister. <Newly Inserted by Act No. 14027, Feb. 3, 2016>

(7) Necessary matters concerning institutions providing training, details of training, persons required to undergo training, training fees, etc. under paragraphs (4) through (6) shall be determined by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016>

#### **Article 5-2 (Recall of Hazardous Cosmetics)**

(1) Where cosmetics currently in market violate Article 7, 9, 15 or 16 (1) and are likely to cause harm to national health, the manufacturer or manufacturer-seller shall, without delay, recall or take necessary measures to recall the relevant cosmetics.

(2) A manufacturer or manufacturer-seller who intends to recall or take necessary measures to recall the relevant cosmetics pursuant to paragraph (1) shall report a recall plan to the Minister of Food and Drug Safety in advance.

(3) The Minister of Food and Drug Safety may reduce or remit the administrative disposition set forth under Article 24 to be imposed on the manufacturer or manufacturer-seller who has carried out conscientiously the recall or necessary measures for recall set forth under paragraph (1) because of the relevant cosmetics, as prescribed by Ordinance of the Prime Minister.

(4) Matters necessary for the cosmetics subject to the recall, reporting of a recall plan, recall procedures, etc. set forth under paragraph (1) and (2) shall be prescribed by Ordinance of the Prime Minister.

#### **Article 6 (Reporting on Business Closure, etc.)**

In any of the following cases, a manufacturer-seller or manufacturer of cosmetics shall report the event to the Minister of Food and Drug Safety within 20 days from the date of occurrence of the relevant event: Provided, That the same shall not apply where he/she suspends his/her business for less than one month or resumes his/her business after suspension for less than one month: <Amended by Act No. 11690, Mar. 23, 2013>

1. Where he/she closes or suspends the business;
2. Where he/she resumes the business after suspension;
3. Where any other matter prescribed by the Ordinance of the Prime Minister are revised.

#### **Article 7 (International Trade, etc. in Endangered Species of Wild Fauna and Flora)**

When a person who intends to import or bring in or export cosmetics or raw materials for cosmetics containing processed products of animals or plants prescribed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora shall obtain permission from the Minister of Food and Drug

Safety, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 8 (Safety Standards, etc. for Cosmetics)**

(1) The Minister of Food and Drug Safety shall designate and publicly announce raw materials which cannot be used for manufacturing cosmetics. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The Minister of Food and Drug Safety shall designate and publicly announce standards for usage regarding raw materials, such as sterilization preservatives, coloring and sunblocks which require a specific restriction on usage, and no sterilization preservatives, coloring and sunblocks whose standards for usage are not designated and publicly announced shall be used. <Amended by Act No. 11690, Mar. 23, 2013>

(3) As for raw materials of cosmetics, etc. that are likely to pose risks to public health, such as those known to contain harmful materials in Korea or overseas, the Minister of Food and Drug Safety shall promptly assess the hazards of such materials and determine whether such materials are hazardous, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) After completing hazard assessment under paragraph (3), the Minister of Food and Drug Safety shall designate the relevant raw materials of cosmetics as unusable in manufacturing cosmetics or shall prescribe the standards for usage of such materials. <Amended by Act No. 11690, Mar. 23, 2013>

(5) The Minister of Food and Drug Safety may publicly announce other safety control standards for distributed cosmetics. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 9 (Safe Containers, Packaging, etc.)**

(1) When a manufacturer-seller sells manufactured or imported cosmetics, he/she shall use child-proof containers and packages to prevent children from being poisoned by misuse.

(2) Items requiring child-proof containers and packages under paragraph (1) and standards, etc. for containers and packages shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 10 (Matters Required to be Stated in Packages of Cosmetics)**

(1) Each of the following matters shall be stated and labeled on the primary or secondary package of cosmetics, as prescribed by the Ordinance of the Prime Minister: Provided, That in cases of packages prescribed by Ordinance of the Prime Minister including packages of cosmetics with a small quantity of contents, matters other than the name of a cosmetic, the trade name of a manufacturer-seller, the price, the manufacturing number and the use-by date (where the best-before date after opening is stated, the manufacturing date shall also be stated; hereafter the same shall apply in this Article) shall not be stated and labeled thereon: <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14027, Feb. 3, 2016>

1. Name of a cosmetic;
2. Trade name and address of a manufacturer or manufacturer-seller;
3. All ingredients used in manufacturing the relevant cosmetic (excluding ingredients prescribed by Ordinance of the Prime Minister, such as trace ingredients that are not harmful to the human body);

4. Volume or weight of contents;
5. Manufacturing number;
6. Use-by date or best-before date after opening;
7. Price;
8. The words "functional cosmetics" in cases of functional cosmetics;
9. Cautions for use;
10. Other matters prescribed by Ordinance of the Prime Minister.

(2) Notwithstanding the main body, other than the subparagraphs of paragraph (1), each of the following matters shall be stated in the primary package:

1. Name of the cosmetic;
2. Trade name of the manufacturer or manufacturer-seller;
3. Manufacturing number;
4. Use-by date and best-before date after opening.

(3) The name of a product and the trade name of a manufacturer or manufacturer-seller may be also stated in Braille for visually-impaired persons when placing matters required to be stated under paragraph (1) on the containers and packages of cosmetics.

(4) Standards for and methods of labeling and other matters shall be determined by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 11 (Price Indication of Cosmetics)**

(1) Prices referred to in Article 10 (1) 7 shall be indicated by a person who directly sells cosmetics to consumers (hereinafter referred to as "seller").

(2) Methods of indication prescribed in paragraph (1) and other necessary matters shall be determined by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 12 (Cautions for Statements or Labeling)**

Matters prescribed in Articles 10 and 11 shall be stated or labeled in a more conspicuous place than a place where other characters or sentences are and shall be accurately stated or labeled in easily readable and comprehensible Korean characters, as prescribed by Ordinance of the Prime Minister, and scripts in Chinese characters and foreign languages may also be placed. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 13 (Prohibition of Wrongful Labeling and Advertisements)**

(1) No manufacturer, manufacturer-seller or seller shall make any of the following labeling or advertisements:

1. Labeling or advertisements likely to mislead consumers into thinking the cosmetics are medicines;
2. Labeling or advertisements exceeding the scope of the examination undergone on the safety and effectiveness of functional cosmetics, or labeling or advertisements different from such examination results;
3. Labeling or advertisements likely to mislead consumers into thinking the cosmetics are functional cosmetics or organic cosmetics;

4. Other labeling or advertisements likely to deceive or mislead consumers by misrepresentation.

(2) The scope of labeling and advertisements under paragraph (1) or other necessary matters shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

#### **Article 14 (Demonstration of Contents of Labeling and Advertisements)**

(1) A manufacturer, manufacturer-seller or seller shall be able to demonstrate matters of relevant factors in labeling and advertisements which he/she has placed.

(2) If the Minister of Food and Drug Safety deems it necessary to demonstrate labeling or advertisements placed by a manufacturer, manufacturer-seller or seller pursuant to paragraph (1) as it or they fall under Article 13 (1) 4, he/she may request the manufacturer, manufacturer-seller or seller to submit relevant data specifying the details thereof. *<Amended by Act No. 11690, Mar. 23, 2013>*

(3) A manufacturer, manufacturer-seller or seller in receipt of a request to submit the demonstration data under paragraph (2) shall submit it to the Minister of Food and Drug Safety within 15 days after receipt of such request: Provided, That the period for submission may be extended when the Minister of Food and Drug Safety deems extenuating circumstances exist. *<Amended by Act No. 11690, Mar. 23, 2013>*

(4) When a manufacturer, manufacturer-seller or seller continues placing labeling or advertisements without submitting the demonstration data within the period for submission prescribed in paragraph (3) even after having been requested to do so under paragraph (2), the Minister of Food and Drug Safety shall issue an order to suspend the labeling or advertisements until he/she submits such verification data. *<Amended by Act No. 11690, Mar. 23, 2013>*

(5) A manufacturer, manufacturer-seller or seller may refuse the submission of verification data requested by other organizations under other Acts, such as the Act on Fair Labeling and Advertising when he/she has submitted verification data requested by the Minister of Food and Drug Safety pursuant to paragraphs (2) and (3). *<Amended by Act No. 11690, Mar. 23, 2013>*

(6) The Minister of Food and Drug Safety shall comply with other organizations' request for the submitted verification data, made under other Acts, such as the Act on Fair Labeling and Advertising, except in extenuating circumstances. *<Amended by Act No. 11690, Mar. 23, 2013>*

(7) Necessary matters concerning those subject to verification, scopes of, and requirements for verification data, and methods of submission under paragraphs (1) through (4) shall be determined by Ordinance of the Prime Minister. *<Amended by Act No. 11690, Mar. 23, 2013>*

#### **Article 15 (Prohibition of Manufacture-Sale)**

No person shall sell (including supplying or awarding for the purpose of import agency business) any of the following cosmetics or manufacture, import, store or display them for the purpose of sale: *<Amended by Act No. 14264, May 29, 2016>*

1. Functional cosmetics that fail to undergo an examination or no report on which has not been submitted, as prescribed in Article 4;
2. Fully or partially deteriorated cosmetics;

3. Cosmetics contaminated by pathogens;
4. Cosmetics mixed or mingled with foreign substances;
5. Cosmetics using raw materials that cannot be used for cosmetics as prescribed in Article 8 (1) and (2), or cosmetics that fail to meet safety control standards for distributed cosmetics under paragraph (5) of the same Article;
6. Cosmetics using the horns of rhinoceros or bones of tigers, or the extracts thereof;
7. Cosmetics manufactured either under unsanitary conditions which are likely to cause harm to health and sanitation, or in facilities which fail to satisfy facility standards under Article 3 (3);
8. Cosmetics which are likely to cause harm to health and sanitation due to poor containers and packages;
9. Cosmetics which have forged or falsified the use-by date or best-before date after opening (including the date of manufacture stated) prescribed in Article 10 (1) 6.

**Article 15-2 (Prohibition of Distribution or Sale of Animal-Tested Cosmetics)**

(1) A manufacturer-seller may not distribute or sell cosmetics for which, or cosmetics manufactured (including manufacturing by consignment) or imported using raw materials for which, animal testing under Article 2 (1) of the Laboratory Animal Act was conducted: Provided, That the foregoing shall not apply to cases falling under any of the following:

1. Where animal testing is needed to determine the standards for usage for raw materials requiring a specific restriction on usage, such as sterilization preservatives, coloring or sunblocks under Article 8 (2), or to assess hazards of cosmetics raw materials, etc. posing risks to public health pursuant to paragraph (3) of the same Article;
2. Where animal testing is needed because no alternative to animal testing (referring to non-animal testing or testing on a limited number of animals or reducing animal pains, and recognized as such by the Minister of Food and Drug Safety; hereafter the same shall apply in this Article) exists;
3. Where animal testing is needed to export cosmetics in accordance with the statutes of the export partner country;
4. Where animal testing is needed for product development in accordance with the statutes of the importing country;
5. Where raw materials developed through animal testing conducted under other statutes is used for manufacture, etc. of cosmetics;
6. Where conducting alternatives to animal testing is otherwise impractical, as cases prescribed by the Minister of Food and Drug Safety.

(2) The Minister of Food and Drug Safety shall endeavor to develop alternatives to animal testing, and shall take necessary measures to enable manufacturer-sellers, etc. to utilize the alternatives to animal testing.

**Article 16 (Prohibition of Sale, etc.)**



(1) No person shall sell any of the following cosmetics, or store or display them for the purpose of sale: Provided, That this shall be limited to cosmetics to be sold to consumers in the case of subparagraph 3: <Amended by Act No. 14264, May 29, 2016>

1. Cosmetics sold after being manufactured (including manufacturing by consignment) or imported by a person who has not obtained registration under Article 3 (1);
2. Cosmetics in violation of Articles 10 through 12 or cosmetics with statements or labeling likely to mislead consumers into thinking the cosmetics are medicines;
3. Cosmetics manufactured or imported for consumers to test and use in advance not for the purpose of sale but for publicity and sales promotions;
4. Cosmetics, the package of which or statements or labeling on which have been damaged, forged or falsified.

(2) No one shall sell contents divided from a container of a cosmetic.

#### **Article 17 (Establishment)**

Manufacturer-sellers or manufacturers may establish an association to guarantee their independent activities and common interests and to contribute to improving national health.

#### **Article 18 (Reporting, Inspections, etc.)**

(1) When the Minister of Food and Drug Safety deems it necessary, he/she may order manufacturer-sellers, manufacturers, sellers or other persons who handle cosmetics for their business to file necessary reports, or order the relevant public officials to enter the places of manufacturing cosmetics, places of business, warehouses, stores or other places handling cosmetics in order to inspect relevant facilities, books, documents or other goods, or to ask questions to relevant persons. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The Minister of Food and Drug Safety may collect the minimum amount of a cosmetic necessary to inspect the propriety of quality or safety standards, or statements or labeling on packages, etc. <Amended by Act No. 11690, Mar. 23, 2013>

(3) The Minister of Food and Drug Safety may operate a monitoring system on sale of products, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

(4) In the case of paragraph (1), a relevant public official shall produce an identity card indicating his/her authority to relevant persons.

(5) Qualification of relevant public officials under paragraphs (1) and (2) and other necessary matters shall be prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 19 (Corrective Orders)**

If deemed necessary, the Minister of Food and Drug Safety may issue a corrective order to persons who fail to comply with this Act. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 20 (Inspection Orders)**

If deemed necessary, the Minister of Food and Drug Safety may order manufacturer-sellers or manufacturers to undergo an inspection performed by a cosmetics testing and inspection institution

prescribed in Article 6 (2) 5 of the Act on Testing and Inspection in the Food and Drug Industry, on cosmetics they have handled. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 11985, Jul. 30, 2013>*

**Article 21 Deleted.** *<by Act No. 11985, Jul. 30, 2013>*

**Article 22 (Orders to Repair Facilities)**

If the Minister of Food and Drug Safety deems that facilities held by a manufacturer are likely to compromise the safety and quality of cosmetics because such facilities fail to satisfy the facility standards referred to in Article 3 (3) or are decrepit or damaged, he/she may order the manufacturer to repair the facilities or prohibit the use of all or part of the facilities until finishing repair. *<Amended by Act No. 11690, Mar. 23, 2013>*

**Article 23 (Orders, etc. to Recall or Discard Goods)**

(1) The Minister of Food and Drug Safety shall order manufacturer-sellers, manufacturers, sellers or other persons handling cosmetics for business to take measures such as recalling and discarding the relevant goods, where the cosmetics that they have sold, stored, displayed, manufactured, or imported in violation of Article 7, 9, 15 or 16 (1), or the raw materials, ingredients, etc. (hereinafter referred to as "goods") are likely to cause harm to national health. The manufacturer-seller, manufacturer, seller or any other person handling cosmetics for business who has received a recall order shall report a recall plan to the Minister of Food and Drug Safety in advance. *<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13117, Jan. 28, 2015>*

(2) The Minister of Food and Drug Safety may order relevant public officials to discard the relevant goods or take other necessary measures in any of the following cases: *<Amended by Act No. 11690, Mar. 23, 2013>*

1. When a person who has received an order prescribed in paragraph (1) fails to comply with it;
2. When other urgent measures are necessary for national health.

(3) Matters necessary for the recall or discard procedures and plans, follow-up measures, etc. set forth under paragraph (1) shall be prescribed by Ordinance of the Prime Minister. *<Newly Inserted by Act No. 13117, Jan. 28, 2015>*

**Article 23-2 (Publication of Hazardous Cosmetics)**

(1) In any of the following cases, the Minister of Food and Drug Safety may order the relevant business entity to make the fact public:

1. Where the cosmetics violating Article 7, 9, 15, or 16 (1) are likely to cause harm to national health;
2. Where a recall plan set forth under Article 5-2 (2) has been received.

(2) Matters necessary for the method of and the procedures, etc. for the publication set forth under paragraph (1) shall be prescribed by Ordinance of the Prime Minister.

**Article 24 (Revocation of Registration and Suspension, etc. of Manufacturing Products)**

(1) If a manufacturer-seller or manufacturer falls under any of the following, the Minister of Food and Drug Safety may revoke the registration thereof or prohibit him/her from manufacturing, importing and selling (including supplying or awarding for the purpose of import agency business) products, or suspend all or part of his/her business for a prescribed period not exceeding one year: Provided, That if he/she falls under subparagraph 1 or 14, the Minister of Food and Drug Safety shall revoke the registration thereof:

<Amended by Act No. 11690, Mar. 23, 2013; Act No. 13117, Jan. 28, 2015; Act No. 14264, May 29, 2016>

1. When he/she falls under any subparagraph of Article 3 (2);
2. When he/she fails to equip the facilities under Article 3 (3);
3. When he/she manufactures or imports cosmetics that caused or are likely to cause harm to national health;
4. When he/she fails to file for registration of cosmetics manufacture-sale or manufacture business, any revision thereto, or to report business closure, etc. required under Article 3 or 6;
5. When he/she sells, upon manufacturing or importation, functional cosmetics over which he/she fails to undergo an examination or submit a report, in violation of Article 4;
6. When he/she fails to comply with matters to be observed, in violation of Article 5;
7. When he/she imports, or brings into Korea, cosmetics containing processed animal or plant products prescribed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora, in violation of Article 7;
8. When he/she violates the standards for safety containers and packages under Article 9;
9. When he/she places statements or labeling on the containers or packages of cosmetics and attached documents, in violation of Articles 10 through 12;
10. When he/she labels or advertises cosmetics, in violation of Article 13 or any suspension order issued under Article 14 (4);
11. When he/she sells cosmetics, or manufactures, imports, stores, or displays cosmetics for the purpose of sale, in violation of Article 15;
12. When he/she refuses or interferes with an inspection, questioning, collection, etc. pursuant to Article 18 (1) and (2);
13. When he/she fails to comply with a corrective order, inspection order, repair order, recall order, discard order or publication order issued under Article 19, 20, 22, the former part of Article 23 (1), or Article 23-2;
- 13-2. When he/she fails to or falsely report the recall plan set forth under the latter part of Article 23 (1);
14. When he/she performs business during a period of business suspension.

(2) Standards for administrative dispositions under paragraph (1) shall be determined by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

**Article 25 Deleted.** <by Act No. 11985, Jul. 30, 2013>

**Article 26 (Succession to Status of Manufacturers, etc.)**

When a manufacturer-seller or manufacturer dies or transfers his/her business, or a merger between corporate manufacturer-sellers or manufacturers takes place, the successor, transferee, corporation surviving such merger or corporation incorporated in the course of such merger shall succeed to the status of the manufacturer, etc.

**Article 27 (Hearings)**

The Minister of Food and Drug Safety shall hold a hearing when he/she intends to issue an order to revoke registration or prohibit manufacturing, importing or selling (including supplying or awarding for the purpose of import agency business) products or suspend all business under Article 24. <Amended by Act No. 11690, Mar. 23, 2013; Act No. 14264, May 29, 2016>

#### **Article 28 (Penalty Surcharges)**

(1) When a manufacturer-seller or manufacturer is subject to a disposition of business suspension under Article 24, the Minister of Food and Drug Safety may impose penalty surcharges not exceeding 50 million won in lieu of a disposition of business suspension. <Amended by Act No. 11690, Mar. 23, 2013>

(2) Amounts of penalty surcharges, based on the types, degrees, etc. of violations subject to penalty surcharges under paragraph (1), and other necessary matters shall be prescribed by Presidential Decree.

(3) When a person required to pay a penalty surcharge under paragraph (1) fails to pay it by a payment deadline, the Minister of Food and Drug Safety may revoke the imposition of the penalty surcharge under paragraph (1), as prescribed by Presidential Decree, and order the relevant person to suspend business under Article 24 (1) or collect the said penalty surcharge in the same manner as delinquent national taxes are collected: Provided, That when the Minister of Food and Drug Safety cannot order the relevant person to suspend business under Article 24 (1) due to business closure, etc. under Article 6, the penalty surcharge shall be collected in the same manner as delinquent national taxes are collected. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 28-2 (Publication of Violations)**

(1) The Minister of Food and Drug Safety may release to the public matters related to dispositions and prescribed by Presidential Decree concerning the person against whom an administrative disposition has been determined pursuant to Article 22, 23, 23-2, 24 or 28, such as the reason for and details of the disposition, the name, address and name of representative of the person subject to the disposition and the name of the relevant items.

(2) Matters necessary for the publication such as the methods of the publication set forth under paragraph (1) shall be prescribed by Presidential Decree.

#### **Article 29 (Support for Voluntary Management)**

The Minister of Food and Drug Safety may provide administrative or financial support to manufacturer-sellers or manufacturers in order for them to settle and spread a voluntary management system under which they voluntarily endeavor to comply with criteria for labeling, advertisements, quality control.

<Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 30 (Exception to Products for Exportation)**

Products for exportation only that are not sold domestically may be in compliance with provisions of an importing country, notwithstanding Articles 4, 8 through 12, and 14, subparagraphs 1 and 5 of Article 15, Article 16 (1) 2 and 3, and Article 16 (2). <Amended by Act No. 14264, May 29, 2016>

#### **Article 31 (Re-issuance of Certificate of Registration Completion)**

When a manufacturer-seller or manufacturer loses his/her certificate of registration or a notice on the examination results of functional cosmetics, or such certificate or notice becomes unusable, he/she may be re-issued such certificate, as prescribed by Ordinance of the Prime Minister. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 32 (Fees)**

A person who intends to register or undergo an examination under this Act shall pay fees, as prescribed by Ordinance of the Prime Minister. The same shall apply to revisions to registered or examined matters. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 33 (Support for Cosmetics Industry)**

The Minister of Health and Welfare and the Minister of Food and Drug Safety shall establish the foundation for promoting the cosmetic industry and formulate and implement policies necessary for enhancing competitiveness, and he/she shall secure finances thereof and grant support necessary for developing technology, survey and research projects, and building an international cooperation system. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 34 (Entrustment or Delegation of Authority)**

(1) Part of the authority of the Minister of Food and Drug Safety vested under this Act may be delegated to the Commissioner of the local Korea Food and Drug Administration, the Special Metropolitan City Mayor, a Metropolitan City Mayor, or a Do Governor, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

(2) The Minister of Food and Drug Safety may entrust some of his/her duties related to cosmetics vested under this Act to an association established pursuant to Article 17, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

#### **Article 35 (Penalty Provisions)**

(1) Any person who violates Article 7 shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won. <Amended by Act No. 12497, Mar. 18, 2014>

(2) Imprisonment with labor and fines under paragraph (1) may be imposed concurrently.

#### **Article 36 (Penalty Provisions)**

(1) Any of the following persons shall be punished by imprisonment with labor for not more than three years or by a fine not exceeding 30 million won: <Amended by Act No. 12497, Mar. 18, 2014>

1. A person who violates the former part of Article 3 (1);
2. A person who violates the former part of Article 4 (1);
3. A person who violates Article 15;
4. A person who violates Article 16 (1) 1 or 4.

(2) Imprisonment with labor and fines under paragraph (1) may be imposed concurrently.

#### **Article 37 (Penalty Provisions)**

(1) Any person who violates Article 9, 13, or 16 (1) 2 or 3 or Article 16 (2), or who fails to comply with a suspension order issued under Article 14 (4) shall be punished by imprisonment with labor for not more

than one year or by a fine not exceeding ten million won. <Amended by Act No. 11985, Jul. 30, 2013; Act No. 12497, Mar. 18, 2014>

(2) Imprisonment with labor and fines under paragraph (1) may be imposed concurrently.

#### **Article 38 (Penalty Provisions)**

Any of the following persons shall be punished by a fine not exceeding two million won:

1. A person who violates Article 5 (1) and (2);
2. A person who violates Article 10 (1), (2) and Article 11;
3. A person who violates any order issued under Articles 18 through 20, Article 22 or 23, or refuses, interferes with or evades an inspection, collection or disposition by a relevant public official.

#### **Article 39 (Joint Penalty Provisions)**

If the representative of a corporation or an agent or employee of, or any other person employed by, a corporation or an individual commits any violation under Articles 35 through 38 in connection with the business affairs of the corporation or individual, not only shall the violator be punished, but also the corporation or individual shall be punished by a fine under the relevant provisions: Provided, That the same shall not apply where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant business affairs to prevent such violation.

#### **Article 40 (Administrative Fines)**

(1) Any of the following persons shall be subject to an administrative fine not exceeding one million won: <Amended by Act No. 14027, Feb. 3, 2016>

1. A person who fails to file for registration of any revision, in violation of the latter part of Article 3 (1);
2. A person who fails to undergo an examination of revised matters, in violation of the latter part of Article 4 (1);
3. A person who fails to report the track record of producing or importing cosmetics or a list of materials of cosmetics, in violation of Article 5 (3);
4. A person who violates any order issued under Article 5 (4);
5. A person who fails to report business closure, in violation of Article 6;
6. A person who fails to file a report, in violation of Article 18;
7. A person who distributes or sells animal-tested cosmetics or cosmetics manufactured (including manufacturing by consignment) or imported cosmetics using animal-tested raw materials in violation of Article 15-2 (1).

(2) Administrative fines under paragraph (1) shall be imposed and collected by the Minister of Food and Drug Safety, as prescribed by Presidential Decree. <Amended by Act No. 11690, Mar. 23, 2013>

### ADDENDA

#### **Article 1 (Enforcement Date)**

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Articles 21, 25 and 37 (limited to the provisions concerning inspection reports under Article 21 (2)) shall enter into force one year after the date of its promulgation.

**Article 2 (General Transitional Measures)**

Dispositions, procedures and other acts taken or done pursuant to the previous Cosmetics Act before this Act enters into force shall be deemed taken or done pursuant to the provisions of this Act corresponding thereto.

**Article 3 (Transitional Measures concerning Registration of Manufacturer-Sellers)**

A person who intends to obtain registration as a manufacturer-seller pursuant to amended provisions of Article 3 (1) among manufacturers of cosmetics who filed a report pursuant to previous Article 3 (1) shall file registration, after fulfilling the requirements therefor, within one year after this Act enters into force.

**Article 4 (Transitional Measures concerning Registration of Manufacturers)**

Manufacturers who have filed a report under previous Article 3 (1) as at the time this Act enters into force shall renew the report as registration within one year after this Act enters into force.

**Article 5 (Transitional Measures concerning Statements on Packages of Cosmetics)**

Packages (including labeling) on which statements referred to in Article 10 are indicated as at the time this Act enters into force may be used for manufacturing relevant cosmetic items by the date on which two years pass after this Act enters into force.

**Article 6 (Transitional Measures concerning Designation of Inspection Institutions)**

Any inspection institutions designated by the Commissioner of the Korea Food and Drug Administration pursuant to the previous provisions as at the time this Act enters into force shall be deemed an inspection institution designated pursuant to the amended provisions of Article 21.

**Article 7 (Transitional Measures concerning Penalty Provisions, etc.)**

The application of penalty provisions and administrative fines to any act committed before this Act enters into force shall be governed by the previous provisions.

**Article 8 Omitted.**

ADDENDA <Act No. 11690, Mar. 23, 2013>

**Article 1 (Enforcement Date)**

- (1) This Act shall enter into force on the date of its promulgation.
- (2) Omitted.

**Articles 2 through 7 Omitted.**

ADDENDA <Act No. 11985, Jul. 30, 2013>

**Article 1 (Enforcement Date)**

This Act shall enter into force one year after the date of its promulgation.

**Articles 2 through 5 Omitted.**

ADDENDA <Act No. 12497, Mar. 18, 2014>

**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation.

**Article 2 (Transitional Measures concerning Incompetent Persons)**

Incompetent persons under the adult guardianship referred to in the amended provisions of Article 3 (2) 2 shall be deemed to include persons for whom a declaration of incompetency remains in effect under Article 2 of the Addenda to the Civil Act (Act No. 10429).

**Article 3 (Transitional Measures concerning Quasi-Incompetent Persons)**

Notwithstanding the amended provisions of Article 3 (2) 2, the previous provisions shall apply to persons for whom a declaration of quasi-incompetency remains in effect under Article 2 of the Addenda to the Civil Act (Act No. 10429).

ADDENDUM <Act No. 13117, Jan. 28, 2015>

This Act shall enter into force six months after the date of its promulgation: Provided, That the amended provisions of Article 28-2 shall enter into force on the date of its promulgation.

ADDENDA <Act No. 14027, Feb. 3, 2016>

**Article 1 (Enforcement Date)**

This Act shall enter into force one year after the date of its promulgation: Provided, That the amended provisions of Article 3 shall enter into force on the date of its promulgation.

**Article 2 (Applicability to Animal-Tested Cosmetics, etc.)**

The amended provisions of Article 15-2 shall apply starting with cosmetics for which animal testing was conducted, or manufactured (including manufacturing by consignment) or imported (based on the date of customs clearance) using raw materials for which animal testing was conducted, after this Act enters into force.

ADDENDA <Act No. 14264, May 29, 2016>

**Article 1 (Enforcement Date)**

This Act shall enter into force on the date of its promulgation: Provided, That the amended provisions of subparagraph 2 of Article 2, Article 16, the main sentence of Article 24 (1), and Article 27 shall enter into force one year after the date of its promulgation.

**Article 2 (Applicability to Revocation of Registration)**

The amended provisions of Article 24 (1) 14 shall also apply where any person under a period of business suspension as at the time this Act enters into force performs business after this Act enters into



force.

**Article 2 (Transitional Measures concerning Products for Export)**

Notwithstanding the amended provisions of Article 30, the previous provisions shall apply to cosmetics manufactured before this Act enters into force and intended for export only: Provided, That the amended provisions of Article 30 (limited to the portion concerning Article 4) shall apply to functional cosmetics for which examinations of safety or effectiveness under Article 4 are underway.

