Understanding Korea’s Cosmetic Regulations

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Korean Cosmetic Association
Regulatory Affair Team
Ja-Eun Song
Definition of Cosmetic(I)

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.
Definition of Cosmetic(II)

Functional cosmetics

- To help in the *whitening* of the skin
- To help in improving *wrinkles* in the skin
- To help *tanning* skin gently or protecting skin from ultraviolet rays

[ Implementation date: May 30 2017 ]

- Having the function of *changing* the color of the hair
- With the ability to *remove* hair
- To help *alleviate* hair loss symptoms
- To help *alleviate* acne-prone skin (body cleaning product)
- To help *alleviate* dryness caused by atopic skin
- To help *thinning* red lines caused by stretch marks

Functional cosmetics shall *undergo an examination or report* to the Minister of Food and Drug Safety for safety and effectiveness of each product before manufacture or import.

※ Toothpaste, mouthwash ☞ Quasi-drugs
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

MFDS notification, “Regulation on standard of organic cosmetics”

<contents>

- Definition of ingredient: organic, natural, animal, mineral etc.
- Scope of ingredients
- Manufacturing process, Factories and Production Facilities, Packaging, Storage
- Criteria of organic cosmetic products
Types of Cosmetics

- Baby products
  ※ less than 3 years old
- Body cleansing products
  ※ exclude soap
  ※ include wet tissue
- Fragrance preparations
- Make-up preparations
- Products for finger nails and toe nails
- Skin care preparations
- Bath preparations
- Eye make-up preparations
- Hair coloring preparations
- Hair preparations
- Shaving preparations
- Deodorants
- Depilatories
Cosmetics Regulation System

- Manufacturer/Marketing Authorization Holder
  - R & D
    - Prohibited ingredients
    - Restricted ingredients
    - Colorants
    - Cites
    - Functional Cosmetics
  - Raw materials/Packaging materials
  - Facility Standards
    - Raw materials test
    - Safe containers & Packaging for children
    - Test & inspection
    - Preparation of records
    - Ban on manufacturing

- Manufacturer
  - Production
    - Quality test
    - Compliance of quality control & safety control
    - Responsible person for quality & safety management
    - Screening of Functional Cosmetics
    - Reporting on production/importation & ingredients list
    - Ban on manufacturing & sales

- Marketing Authorization Holder
  - Distribution
    - Labeling of Cosmetic prices
    - Ban on sales

- Sales
  - Monitoring
  - Penalties

- Consumer
# Manufacturer & Marketing Authorization Holder

<table>
<thead>
<tr>
<th></th>
<th><strong>Manufacture</strong></th>
<th><strong>Marketing Authorization Holder</strong></th>
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<tbody>
<tr>
<td><strong>Manufacture</strong></td>
<td>• Manufacture whole or part of cosmetics</td>
<td>• Distribute or sell the manufactured cosmetics (including manufactured cosmetics by consignment) and imported cosmetics</td>
<td>• Proper facilities for manufacture</td>
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<td>‣ Including the process of primary packaging or labelling</td>
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<td>※ excluding the process of secondary packaging or labeling</td>
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<td><strong>Marketing Authorization Holder</strong></td>
<td>• Meet appropriate standards for quality control and post-manufacture and sale safety control</td>
<td>• Assign a &quot;person responsible for quality &amp; safety Management&quot;</td>
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Manufacturer

- Each person who intends to manufacture all or part of cosmetics (excluding the process of secondary packaging or labeling only)

**Persons required to be registered**

- A person who intends to directly manufacture cosmetics
- A person who intends to manufacture cosmetics on consignment
- A person who intends to only make a packaging or labelling process only
Marketing Authorization Holder

- Each person 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

Persons required to be registered

- A person who intends to distribute and sell cosmetics directly manufactured
- A person who intends to distribute and sell cosmetics manufactured by outsourcing the manufacturing thereof
- A person who intends to distribute and sell imported cosmetics
- A person who intends to recommend or provide cosmetics for the purpose of vicarious importation (only for electronic transactions)
Manufacture-Sales Manager

- **Standards for Qualifications for Manufacture-Sales Manager**
  - A medical doctor or a pharmacist
  - A person who obtained a bachelor's degree or higher and who majored in a natural sciences, engineering or a cosmetics-related field
  - A person who is a graduate from a junior college and has at least one year’s experience in the affairs of the manufacture, or quality management of cosmetics
  - Other person who has at least two years’ experience in the affairs of the manufacture, or quality control of cosmetics

- **Affairs of a manufacture-sales manager**
  - Affairs of quality control in conformity with standards for quality control
  - Affairs for ensuring safety under standards for safety management
  - Affairs for managing and supervising a manufacturer with respect to necessary tests, inspections, or examinations from the warehousing of raw materials and other materials to the release of finished products.
Matters to be Observed by Manufacturer(I)

- To comply with the guidance, supervision and requests of a manufacturer-seller in accordance with the standards for quality control
- To prepare and preserve written manufacture management standards, a written manufacture management record and a written quality control record (including forms of an electronic document)
- To hygienically manage and keep uncontaminated the manufacturing factory, facilities and apparatuses so as not to cause injuries to health and hygiene
- To periodically check the facilities and apparatuses necessary for the manufacture of cosmetics to prevent impeding the operations
- Not to leave in a workplace, any articles likely to cause injury, and not to leak or emit any substance hazardous to citizens' health and the environment from a manufacturing factory
- To submit, to a manufacturer-seller, matters necessary for quality control, among matters falling under subparagraph 2: Provided, That in any of the following cases, such matters may be omitted to be submitted
  (a) Where the manufacturer and the manufacturer-seller are identical
  (b) Where the manufacturer manufactures a product by designing, developing and producing it and such manufacturing methods falls under trade secrets in accordance with a mutual contract between the manufacturer and the manufacturer-seller to the extent not effecting the quality and safety management
Matters to be Observed by Manufacturer(II)

- To conduct necessary tests, inspections or examinations, from the warehousing of raw materials and other materials to the release of finished products.
- To thoroughly manage and supervise the consignee to secure that the manufacture or quality inspections are properly performed, and to receive, keep and manage the records of the manufacture or quality inspections, in cases of outsourcing the manufacture or quality inspections.

※ In addition to matters to be observed pursuant to paragraph (1), the Minister of Food and Drug Safety may recommend manufacturers to comply with such standards for managing manufacturing good cosmetics as determined and publicly notified by the Minister of Food and Drug Safety.
Obligations of Marketing Authorization Holder

• Conform to matters concerning the quality control, post-manufacture and sale safety control of cosmetics

• Report data, such as a track record of manufacturing or importing cosmetics (Except standard customs clearance forecast report)

• A list of raw materials used in the process of manufacturing cosmetics (Except standard customs clearance forecast report)

• Recall of Hazardous Cosmetics

• Reporting on Business Closure
Matters to be Observed by Marketing Authorization Holder(I)

- To comply with standards for **quality control**
- To comply with standards for **safety management** after manufacturing and sales
- To prepare and preserve written **manufacture management standards**, a **written manufacture management record** and a **written quality control record**
- To state the following matters on **imported cosmetics** or prepare and preserve the attached **written import and management record**:
  - The product name, and the name intended to be used in selling the imported cosmetics
  - The standards and ingredients
  - The manufacturing country and the name and location of the manufacturing company
  - A copy of the written notification of the findings from examination of the functional cosmetics
  - The certificate of manufacturing and sales
  - A copy of the product guide written in the Korean language.
  - The initial importing date
  - Dates and quantities of importation by manufacturer serial number
  - Quality inspection dates and results by manufacturer serial number
  - Selling stores, and the date and quantities of sale
To distribute products after conducting a quality inspection by manufacturer batch numbers
※ That the a quality inspection may be omitted in cases where the manufacturer and the manufacturer-seller are same and the same or where having obtained the results of quality inspections by outsourcing the quality inspections to any institute falling

Where outsourcing the manufacture of the cosmetics or outsourcing the quality inspections to the manufacturer, thoroughly manage and supervise a consignee for securing that the manufacture or quality inspection of cosmetics is properly performed, to receive, keep and manage the records of the manufacture or quality inspections, and to thoroughly control the quality of the end products
• Omit a quality inspection in the Republic of Korea where it is recognized that the standards for quality control of the manufacturing company in the manufacturing country have been mutually certified between the Republic of Korea and the manufacturing country, or that such standards are equal to or higher than the standards for manufacture management. In such cases, the results of quality inspection shall be replaced by the written record of quality management.

• A person who intends to distribute and sell imported cosmetics shall comply with the guidance on the export and import under the Foreign Trade Act and to make a standard customs clearance forecast report.
To make a report and prepare necessary safety countermeasures upon becoming aware of the new data, information (including the occurrences of side effects caused by the uses of the cosmetics), etc. concerning safety and efficacy, which is liable to directly effect the citizens' health with respect to the product.

In cases of a product containing the content of which is at least 0.5 percent, to preserve test data on safety of the relevant item for one year from the expiry date of the usable period of the finally manufactured product:

※ Retinol (Vitamin A) and its derivatives, Ascorbic acid (Vitamin C) and its derivatives, Tocopherol (Vitamin E), Hydrogen peroxide, and Enzyme.
Ingredients & Safety Standards

- **Ingredients**
  - Prohibited ingredients
  - Positive list
    - restricted ingredients, preservatives, UV-filters
    - colorants

※ No preservatives, coloring and UV-filters whose standards for usage are not designated and publicly announced shall be used

- **Safety Control Standards for distributed cosmetics**
  - **Trace**: lead, arsenic, mercury, antimony, cadmium, dioxane, methanol, formaldehyde, phthalate
  - Microbiological limits, pH, contents etc.
## Labelling(I)

<table>
<thead>
<tr>
<th><strong>Primary package (necessary)</strong></th>
<th><strong>Primary or Secondary package (including attached documents)</strong></th>
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<tbody>
<tr>
<td>• Name of a cosmetic</td>
<td>• Name of a cosmetic</td>
</tr>
<tr>
<td>• Name and address of a manufacturer and marketing authorization holder</td>
<td>• Name and address of a manufacturer &amp; marketing authorization holder</td>
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<tr>
<td>• Batch number</td>
<td>• All ingredients used in manufacturing cosmetic</td>
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<tr>
<td>• Use-by date or best-before date after opening (the date of manufacture shall be also entered when the best-before date after opening is entered)</td>
<td>• Volume or weight of contents</td>
</tr>
<tr>
<td></td>
<td>• Batch number</td>
</tr>
<tr>
<td></td>
<td>• Use-by date or best-before date after opening (the date of manufacture shall be also entered when the best-before date after opening is entered)</td>
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<td></td>
<td>• Price</td>
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<td></td>
<td>• The words &quot;functional cosmetics&quot; in cases of functional cosmetics</td>
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<td></td>
<td>• Cautions for use</td>
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<td></td>
<td>• Other matters prescribed by Ordinance of the Prime Minister</td>
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<tr>
<td></td>
<td>- Bar codes</td>
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<td>- In cases of functional cosmetics, the efficacy and effects, and method of use and optimal dosages reviewed or reported</td>
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<td>- Where the name of any ingredient is used as a part of the name of a product, the name and the ingredient (excluding Aromatic products)</td>
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<td>- Where human cell or tissue material is contained in any cosmetics, their content</td>
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<td>- In cases of labeling &quot;organic farming&quot; on any cosmetics and advertising the cosmetics to that effect, the content of such materials</td>
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<td>- In cases of imported cosmetics, the name of the manufacturing country (in cases of marking the country of origin under the Foreign Trade Act, the name of the manufacturing country may be omitted), and the name and location of manufacturing company</td>
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Labelling(II)

- **Exception Marking, Labelling, on Package of Cosmetics**
  - The primary or secondary packages on which descriptions other than product names, names of manufacturer-seller, price, batch number and use-by date may be omitted
    - A package of cosmetics the net contents is not less than 10ml or 10g
    - A package of cosmetics manufactured or imported so as for customers to try and use them in advance to choose, etc. a product, not for sale
      (Price → ‘sample’, 'not for sale', etc.)
  ※ Where intending to omit to mark the telephone number or homepage address or To always keep, in selling stores, printed materials marking all ingredients

- **Precautions Marking, Labelling, on Package of Cosmetics**
  - To make marks and labels easy to be readable in the Korean language
    (Provided, That Chinese characters or foreign languages may be used together, and in cases of a product for export, the language of the export target country may be used)
  - To use standardized common names in labelling ingredients of cosmetics
Labelling(III)

All ingredients (※ Injection agent included)
- Ingredients eliminated in the course of manufacture and do not remain in a final product
- Ingredients which are incidental ingredients, such as a stabilizer and a preservative, and are present in any raw materials themselves, and contained in amounts of less than the amounts displaying their effects

Over 50mL(g)
Marking ingredients

Over 10mL(g) Less than 50mL(g) (package)
- Tar colors*, Gold foils, Kinds of phosphates contained in shampoo and rinse, Alpha hydroxy acid (AHA), Raw materials displaying efficacy and effects in cases of functional cosmetics, Raw materials, the compound limits of which are publicly notified by the Minister of Food and Drug Safety*

Below 10mL(g) (package, sample, tester, not for sale)
- All components omitted

- To mark the telephone number or homepage address so as for customers to immediately confirm all ingredients
- To always keep, in selling stores, printed materials marking all ingredients

• To use standardized common names in labelling ingredients of cosmetics (www.kcia.or.kr/cid)

Font size 5 or bigger
Labelling(IV)

- **Use-by date or best-before date after opening**
  - The word “use-by date” shall be indicated along with "00 year 00 months" or "till 00 year 00 months”
  - The word “best-before date after opening” shall be indicated along with "00 months" or symbols and periods.
  
  (In case of products required to be used within twelve months after opening)

- **Price**
  - Prices shall be indicated by a person **who directly sells cosmetics to consumers (“seller”)**
Prohibition of Manufacture-Sale

No person shall sell any of the following cosmetics or manufacture, import, store or display them for the purpose of sale:

- Functional cosmetics that fail to undergo an examination or no report on which has not been submitted
- Fully or partially deteriorated cosmetics
- Cosmetics contaminated by pathogenic microorganisms
- Cosmetics mixed or mingled with foreign substances
- Cosmetics using raw materials that cannot be used for cosmetics or cosmetics that fail to meet safety control standards
- Cosmetics using the horns of rhinoceros or bones of tigers, or the extracts thereof
- 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
- Cosmetics which are likely to cause harm to health and sanitation due to poor containers and packages
- Cosmetics which have forged or falsified the use-by date or best-before date after opening (including the date of manufacture stated)
Prohibition of Sale

- No person shall sell any of the following cosmetics, or store or display them for the purpose of sale

  - Cosmetics sold after being manufactured (including manufacturing by consignment) or imported by a person, other than registered marketing authorization holder
  - Cosmetics in violation of Articles 10 through 12 or cosmetics with statements or labeling likely to mislead consumers into thinking the cosmetics are medicines
  - Cosmetics manufactured or imported for consumers to test and use in advance not for the purpose of sale (but for publicity and sales promotions)
  - Cosmetics, the package of which or statements or labeling on which have been damaged, forged or falsified

- No one shall sell contents divided from a container of a cosmetic
Thank you