Regulation of Cosmetics in Korea
## Classification in Korea

<table>
<thead>
<tr>
<th>Regulatory classification</th>
<th>Category</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Quasi-drug (QD)</td>
<td>Feminine Care, Hair Care</td>
<td>Sanitary napkins, Anti-hair fall products, Hair dye (Hair colorants), Toothpaste, Mouth Refreshers, Low Concentrated Vitamins &amp; Mineral</td>
</tr>
<tr>
<td></td>
<td>Oral Care, Vitamins</td>
<td>Hand sanitizer</td>
</tr>
<tr>
<td></td>
<td>Anti-perspirant, Anti septic and etc.</td>
<td></td>
</tr>
<tr>
<td>Cosmetics</td>
<td>Skin Care, Hair Care</td>
<td><strong>Functional Cosmetics</strong>&lt;br&gt;1) Whitening product&lt;br&gt;2) Anti-wrinkle product&lt;br&gt;3) Sunscreen products&lt;br&gt;<strong>Regular Cosmetics</strong></td>
</tr>
</tbody>
</table>
Cosmetic in Korea?

Definition of Cosmetic in Korea Cosmetic Law
Items with mild action on the human body for the purpose of cleaning, beautifying, adding to the attractiveness, altering the appearance, keeping/promoting the skin/hair in good condition.

Sub-Items

♦ 12 product categories by usage
  Children, Bath, Cleanser, Eye, Perfume, Hair Tint (Hair color spray), Make-up, Hair, Nail, Shaving, Skincare, Deodorant

♦ 2 regulatory classification by product claims
  Regular cosmetics, Functional cosmetics
Regulatory Agencies for Cosmetic

Registration Agency/Industry Association

MFDS (Ministry of Food and Drug Safety)
- Cosmetic Review Division
- Cosmetic Policy Division

MOH (Ministry of Health)

KPTA (Korean Pharmaceutical Traders Association)

KCA (Korea Cosmetic Association)
Cosmetic Law and Regulation

- Cosmetic Law
- Cosmetic Enforcement Ordinance
- Cosmetic Enforcement Regulations
- MFDS Notifications
Key Features

1. Marketing Authorization Holder system

2. Labeling Requirement in Korea

3. Ingredients in Korea

4. Advertisement and Labeling Substantiation

5. Import of Cosmetics Regulatory Requirements
1. Marketing Authorization Holder System

(Cosmetic Manufacturer and Marketing Authorization Holder System) (Cosmetic Law Article 3)

**Cosmetic Manufacturer**

1. Those who wish to directly manufacture cosmetic products
2. Those who wish to receive contract orders to manufacture cosmetic products

**Marketing Authorization Holder**

1. Those who wish to distribute and sell directly manufactured cosmetic products
2. Those who wish to distribute and sell cosmetic products manufactured by contract
3. Those who wish to distribute and sell imported cosmetic products
4. Those who wish to promote and sell cosmetic products as an online import agent
(Article 11 of the Regulation)

1. Marketing Authorization Holder shall comply with the Quality Control Standards (Annex 1).


4. Marketing Authorization Holder shall prepare and keep import control records on imported cosmetics.

5. Sales after quality control test by batch

6. Import permission by KPTA through the electronic document interchange (EDI) method for customs clearance.

7. New data and information obtained in regards to the safety and efficacy of products which can affect the public health (including case reports of side effects from using cosmetic products) shall be reported and necessary safety measures taken.

8. Products containing any of the ingredients corresponding to following a. to f. in a dosage more than 0.5% shall be kept the stability test results for 1 year from the expiry date of final manufactured product.
   a. Retinol (Vitamin A) and its derivatives
   b. Ascorbic Acid (Vitamin C) and its derivatives
   c. Tocopherol (Vitamin E) e. Peroxide f. Enzyme
Korean labeling on primary package

1. Name of product
2. Name of Marketing Authorization Holder and Manufacturer
3. Lot No.
4. Expiry date or PAO (In case of indicating PAO, mfg. date should be labeled together with PAO)
2. Label Requirements in Korea

Korean labeling on secondary package

1. Name of product
2. Name & address of Marketing Authorization Holder and Manufacturer
3. Name of all ingredients (descending order) for exceeding 50ml(g)
4. Name of designated ingredients* for exceeding 10ml(g) and 50ml(g) and less
5. The volume or weight of contents (It should be ml or g.)
6. Price
7. In case of functional cosmetic, the word of “기능성화장품” (functional cosmetic)
8. Cautions in use that is designated by enforcement regulation of cosmetic law
9. In case of functional cosmetic, efficacy, how to use, cautions approved by MFDS
10. Bar code
11. Call center information and homepage address and phrase( “Exchange or refund if the product has problems” )
2. Label Requirements in Korea

Korean labeling on secondary package

Designated ingredients*

a. Tar pigments.
b. Gold foil.
c. Kinds of phosphate contained in shampoo and rinse (hair conditioner).
d. Alpha- Hydroxy Acid (AHA)
e. In the case of functional cosmetics, its active ingredients
f. Cosmetic ingredients for which maximum ratios have been publicly announced by the MFDS commissioner.
3. Cosmetic ingredients in Korea

- Cosmetic banned ingredient list (negative list) designated by MFDS
- Restricted and positive lists (preservative, colorants, UV filter etc.) designated by MFDS
- Risk assessment system by MFDS to access potentially harmful ingredient will be implemented and added to the banned list
- Marketing Authorization Holders should annually report the ingredient list used in cosmetics to MFDS and MFDS develops DB on ingredient list.
4. Advertisement and Labeling Substantiation

✓ Marketing Authorization Holder is responsible for providing substantiation data for advertisement within 15 days if MFDS requests.

✓ Details on substantiation subject, requirements and scope is decided by MFDS regulation

✓ Banned advertisement: potentially mislead or deceive consumers

✓ Penalty of violation

  - advertisement : advertisement suspension

  - advertisement on product package : sales suspension
Import of Cosmetics
Regulatory Requirements
Prior to import

- Marketing Authorization Holder’s License issued by MFDS
- Pre-market product registration to MFDS for Functional cosmetics
  (lead time: 4~6Ms) or notification to MFDS (1 day)

After import

- Import permission on every shipment by Korea Pharmaceutical Traders Association
- Quality Control test for every lot before release to market
- Korean label
- Report of ingredients list used in cosmetics to MFDS annually
1. EDI submission of import permission request
2. Submit the following documents to KPTA
   - Registration formula, Free sales certificate, BSE certificate, batch Nos
3. Keeping
4. Import Permission
   7 days
5. Attach Korean label on package at warehouse
6. Approval for the products by local Q.C Lab.
7. Sell the products to consumers
1. Documents for MFDS registration

2. Submit registration documents of functional cosmetics to MFDS
   - Specification of finished product
   - Assay and identification method of active ingredients in the product
   - Samples / Formula / Efficacy Data and etc.

3. Approval by MFDS

4. Submit Import documents to KPTA with approval letter by MFDS

5. Submit Import permission (by KPTA) to Customs with B/L, invoice and P/L

6. Keeping

7. Approval for the products by local Q.C Lab.

8. Attach Korean label on package at warehouse

9. Sell the products to consumers
## Functional Cosmetic vs. Regular Cosmetic

<table>
<thead>
<tr>
<th></th>
<th>Regular Cosmetics</th>
<th>Functional Cosmetics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration</strong></td>
<td></td>
<td>MFDS Approval</td>
</tr>
<tr>
<td>MFDS</td>
<td></td>
<td>Notification: 1 day</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td></td>
<td>Registration: 4 ~ 6 Ms</td>
</tr>
<tr>
<td><strong>import permission</strong></td>
<td>1~7days for import permission</td>
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</tr>
<tr>
<td><strong>import</strong></td>
<td></td>
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<tr>
<td><strong>KPTA</strong></td>
<td></td>
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</tr>
<tr>
<td><strong>Required Documents</strong></td>
<td>Certificate of Manufacture / Free Sales Certificate / BSE-free certificate</td>
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</tr>
<tr>
<td></td>
<td>- Efficacy data</td>
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</tr>
<tr>
<td></td>
<td>- Test methods, Spec. and etc.</td>
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</tr>
<tr>
<td><strong>Claim</strong></td>
<td>- Ban claim for anti-wrinkle, whitening, sunscreen</td>
<td>- Anti-Wrinkle claim</td>
</tr>
<tr>
<td></td>
<td>- Beautifying, cleansing and etc.</td>
<td>- Whitening claim</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- SPF/PA claim</td>
</tr>
</tbody>
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감사합니다.