Chinese Cosmetic Regulation

Contents
1. Regulatory Framework
2. Definition
3. Classification
5. Imported Cosmetics
6. Ingredients
7. Limits for Toxic Substances
8. Naming
9. Labeling
10 Advertisement
11. Summary of expected changes
# Regulatory Framework for Cosmetics in China

**Competent Authority:** CFDA  
*(China Food and Drug Administration)*

<table>
<thead>
<tr>
<th>Regulations Concerning the Hygiene Supervision over Cosmetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics</td>
</tr>
<tr>
<td>Requirements for Application and Acceptance of Administrative Licensing for Cosmetics</td>
</tr>
<tr>
<td>Administrative Measures on Cosmetics Labeling</td>
</tr>
<tr>
<td>Guide to the Naming of Cosmetics</td>
</tr>
<tr>
<td>Administrative Measures on Inspection and Quarantine of Import and Export Cosmetics</td>
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<tr>
<td>Other CFDA Announcements</td>
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</tbody>
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**Definition of Cosmetic Products**

**Definition:**

Cosmetic products refer to chemical products for daily use intended to be applied on any external part of human body (such as skin, hair, nails, lips etc.) by spreading, spraying or other similar ways to keep the body clean, eliminate unpleasant odor, protect skin, and improve appearance and beauty.

(Regulations Concerning the Hygiene Supervision over Cosmetics)
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(Regulations Concerning the Hygiene Supervision over Cosmetics)

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
- Teeth and mucous membranes of the oral cavity will be included into cosmetic products

### Cosmetics

- **Special use**
  - Domestic
  - Imported
- **Non-special use**
  - Domestic
  - Imported

Administrative license
Online filing
Filing
### Classification of Cosmetic Products

**Special use:**

<table>
<thead>
<tr>
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<th>Definition</th>
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<tr>
<td>Hair growth (育发)</td>
<td>Helps hair growth, reduces thinning and loss of hair.</td>
</tr>
<tr>
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</tr>
<tr>
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<td>Perms and maintains the hair.</td>
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<td>Breast beauty (美乳)</td>
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</tr>
<tr>
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**Non-special use:** Wrinkle-care, Anti-perspirant (prevents body odor), Nail care, Make-up and other cosmetic products that are not special-use
## Classification of Cosmetic Products

### Special use:

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
- Hair dye, Hair perming, Whitening, Sunscreens, Other special cosmetics deemed by the CFDA

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- General cosmetics

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
Imported Cosmetics—Responsible Agent in China

**Designation of a Responsible Agent:** must be a Chinese legal entity.

- A power of attorney needs to be signed and filed with CFDA before starting the registration process.
- When registering, changing, and extending the license, a copy of the power of attorney and business license of the Responsible Agent need to be included.
- The Responsible Agent bears legal responsibility for the registration documents.

**Information that need to be included in the power of attorney:**

1. Signature of overseas cosmetic company and the Responsible Agent
2. If the power of attorney is in foreign language, it should be translated into Chinese and notarized.
3. The power of attorney should include: name and address of the overseas cosmetic company, name and address of the Responsible Agent, range of entrusted products and authority.

(Requirements for Application and Acceptance of Administrative Licensing for Cosmetics)
Imported Cosmetics – License /Filing Procedure

Special use cosmetics administrative license registration:

1. Application form
2. Product formula
3. Chinese instructions for use
4. Product sample
5. CDC test report
6. Human safety test report
7. Safety assessment report (for risk-concern substance)
8. Document to prove manufacture and sale of the product in the country of origin
9. Original packaging (including label and instructions for use) and its Chinese translation.
10. Chinese product naming statement
11. Quality control specification
12. Power of Attorney and business license of the responsible person in China
13. Statement on animal derived ingredients
+ Multi-shade product application and formula comparison

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13. Product Technical Specification
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8. Document to prove manufacture and sale of the product in the country of origin
9. The proof of manufacture and sales of the product in the country of origin can be substituted with the results from research on Chinese customers.
10. [2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
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8. Original packaging (including label and instructions for use) and its Chinese translation.
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11. Power of Attorney and business license of the responsible person in China
12. -> Filing process for imported non-special use cosmetics will be simplified. (Filing 10 days before the import)
13. [2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
Imported Cosmetics – Product Technical Specification

Product Technical Specification 2011.04.01 enforced

E-file upload on license application webpage + Submit printed hard copy document
- Product name: Chinese name
- Formula: Chinese name of the ingredients, purpose
- Procedure: Simple explanation
- Sensory specifications: Color, appearance, fragrance
- Hygienic chemical/microbiological specifications
- Testing methods
- Instructions for use, storage conditions (Should be the same as the license document)
- Period of warranty (months or years)
## Imported Cosmetics – Registration Duration, Period of Validity

### Registration Duration

<table>
<thead>
<tr>
<th></th>
<th>Non-special use</th>
<th>Special use</th>
</tr>
</thead>
</table>
| **Hygiene safety testing institution (CDC)**  
- Microbiological test, hygienic chemical test, toxicological test | 3 months        | 3 months                                      |
| **Human safety testing institution**            | X               | Human safety testing and sunscreen efficacy test: 3 months  
(For waterproof +3 months) |
| **Registration review center (CFDA)**           | 3 months        | 6 months                                      |

### Period of validity: 4 years
## Registration Duration

<table>
<thead>
<tr>
<th></th>
<th>Non-special use</th>
<th>Special use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hygiene safety testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>institution (CDC)</td>
<td>3 months</td>
<td>3 months</td>
</tr>
<tr>
<td>- Microbiological test, hygienic chemical test, toxicological test</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Human safety testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>institution</td>
<td>X</td>
<td>Human safety testing and sunscreen efficacy test: 3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(For waterproof +3 months)</td>
</tr>
<tr>
<td><strong>Registration review</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>center (CFDA)</td>
<td>3 months</td>
<td>6 months</td>
</tr>
</tbody>
</table>

### Period of validity: 4 years

- -> 5 years

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
### Inventory of Existing Cosmetic Ingredients in China:

8783 ingredients that have been used as cosmetics in China
## Ingredients

<table>
<thead>
<tr>
<th>List</th>
<th>Total Number of Ingredients</th>
<th>Change</th>
<th>Number of Ingredients Added/Deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety and Technical Standards for Cosmetics 2015 (To be enforced 2016.12.01)</strong></td>
<td><strong>Hygienic Standard for Cosmetics 2007</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prohibited</td>
<td>1388</td>
<td>1286</td>
<td>Added</td>
</tr>
<tr>
<td>Restricted</td>
<td>47</td>
<td>73</td>
<td>Added</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Deleted</td>
</tr>
<tr>
<td>Preservatives Permitted</td>
<td>51</td>
<td>56</td>
<td>Deleted</td>
</tr>
<tr>
<td>UV Filters Permitted</td>
<td>27</td>
<td>28</td>
<td>Deleted</td>
</tr>
<tr>
<td>Colorants Permitted</td>
<td>157</td>
<td>156</td>
<td>Added</td>
</tr>
<tr>
<td>Hair Dyes Permitted</td>
<td>75</td>
<td>93</td>
<td>Deleted</td>
</tr>
</tbody>
</table>

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics] - Permitted list of whitening agents will be added.

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### Inventory of Existing Cosmetic Ingredients in China:
8783 ingredients that have been used as cosmetics in China
## Limits for Toxic Substances

<table>
<thead>
<tr>
<th>Toxic Substance</th>
<th>Limit (mg/kg)</th>
<th>Safety and Technical Standards for Cosmetics 2015 (To be enforced 2016.12.01)</th>
<th>Hygienic Standard for Cosmetics 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercury</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Lead</td>
<td>10</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>2</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Methanol</td>
<td>2000</td>
<td>2000</td>
<td></td>
</tr>
<tr>
<td>Cadmium</td>
<td>5</td>
<td>(Prohibited)</td>
<td></td>
</tr>
<tr>
<td>Dioxane (1,4-dioxane)</td>
<td>30</td>
<td>30</td>
<td>(Prohibited)</td>
</tr>
<tr>
<td>Asbestos</td>
<td>Must not be detected</td>
<td></td>
<td>(Prohibited)</td>
</tr>
</tbody>
</table>

**Note:** The limits for Toxic Substances are based on the Safety and Technical Standards for Cosmetics 2015 (To be enforced 2016.12.01) and the Hygienic Standard for Cosmetics 2007.
Naming

**Brand name + Generic name** (main ingredient, usage, body part) + **Attribute name**
(physical characteristics)

* For imported cosmetics: The Chinese name should match the foreign name as close as possible

**Prohibited:**
1) False, exaggerative, absolute words
   - Ex) absolutely natural, professional, special effect, best, wrinkle removing
2) Medical terminology
   - Ex) medicine, antibacterial, hair-growing
3) Names of medical celebrities
   - Ex) Li Shizhen
4) Terminology that is difficult to understand
   - Ex) infrared light, intelligence
5) Vulgar or superstitious terms
   - Ex) Ghost, spirits
6) Pharmaceutical names officially approved in China
   - Ex) Bumanyoungh
7) Alphabet, Pinyin, number, symbols
   - (Except when used for UV index, color, serial number, brand name)
8) Other misleading terms

**Allowed to use:**
1) Non-special use cosmetics
   - All terms defined in line of cosmetics
   - Ex) soft, moisture, beauty, protect
2) Special use cosmetics
   - Terms that match the special use characteristics
   - Ex) slimming, freckle

(Guide to the Naming of Cosmetics)
Labeling

Cosmetics label should be factual, accurate, scientific, and abiding to the regulations.

1. Product name
2. Name and address of manufacturer (For imported cosmetics: Country of origin + Name and address of the importer)
3. Production date + shelf life, or lot number + expiration date
4. Net content
5. List of ingredients
   - Should start with the title: 成分 and separate the listed ingredients with ＂、＂
   - Listed in descending order of quantity for ingredients over 1% concentration.
   - For multi-shade products, list the colorants at the end, as “可能含有的着色剂”
   - Must be indicated with Chinese INCI name, name in Chinese Pharmacopoeia, chemical or botanical name.
   - Fragrance and its components can be written as: “香精”

(Administrative Measures on Cosmetics Labeling)
6. Manufacture license number (Domestic)
7. License/Filing certificate number
8. Prohibited in cosmetic label:
   - Functions or features that the product do not possess
   - Medicinal or therapeutic functional claims
   - Misleading wordings
   - Other forbidden terms

* SPF, PA Claim:
Range of SPF that can be claimed: SPF2~50+
Can claim SPF 50+ if the test result is higher than 50.

Claiming waterproof:
   1. Write SPF value before and after bath
   2. Write SPF value after bath

UVA Protection:
   - PFA 2~3: PA+
   - PFA 4~7: PA++
   - PFA 8~15: PA+++  
   - PFA 16+: PA++++

(Administrative Measures on Cosmetics Labeling), (总局关于发布防晒化妆品防晒效果标识管理要求的公告(2016年第107号))
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- PFA 2~3: PA+
- PFA 4~7: PA++
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- PFA 16~: PA+++++

(Administrative Measures on Cosmetics Labeling), (总局关于发布防晒化妆品防晒效果标识管理要求的公告(2016年第107号))
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<th>Content</th>
<th>Surface area ≤10cm² &amp; net content ≤ 15g/mL</th>
<th>Giveaway, Not for sale (Should have appropriate label for being free or not for sale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Manufacturer’s name and address</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>(Imported cosmetics: Country of origin, importer’s name and address)</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Production date + period after opening, or production lot number + expiry date</td>
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<td>O</td>
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<tr>
<td>Net content</td>
<td>O</td>
<td>X</td>
</tr>
<tr>
<td>List of ingredients</td>
<td>Can be written on the instructions for use</td>
<td>X</td>
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- Cosmetic label should not be separated from the case.
- The label should be on the minimum packaging unit.
- The label should be clear and easy to see, and should be durable.
- All of the contents except the brand name should be in Chinese.
- When the surface area of the product case is larger than 20cm²: font size should be larger than 1.8mm.

(Administrative Measures on Cosmetics Labeling)
### Labeling

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(Administrative Measures on Cosmetics Labeling)

> Label must be on the minimum packaging unit + container in direct contact with the content.

[2015.07 draft - Regulations concerning the Supervision and Administration over Cosmetics]
Prohibited for advertisement:

- False or exaggerative terms about the cosmetics name, procedure, ingredients, and effect
  (Ex) Special effect, strong effect, most, best, changes the skin, removes wrinkles
- Using a person’s name to guarantee the product’s quality, or terms that mislead the customers about the product’s effect.
- Vulgar terminology
- Related to medical effect
  (Ex) medical, medicine, Chinese medicine, cure, anti-bacterial, hair growth
- Demeaning other products that belong to the same category.
- Data regarding the effect or sales of the cosmetics
  (When using statistical data or research results in advertisement, there must be proof)
- Other terminology prohibited by law

* If there is genuine scientific evidence:
  Non-special use cosmetics: Can use all terms defined in line of cosmetics
  Special use cosmetics: Can use terms that match the special use characteristics

(Methods on the Administration of Advertising for Cosmetics)
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[Methods on the Administration of Advertising for Cosmetics]
### Summary of Expected Changes to Chinese Cosmetic Regulation

**[2015.07.20 Draft] Regulations concerning the Supervision and Administration over Cosmetics**

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<th>Expected Change</th>
<th>Impact on industry</th>
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<td>Definition</td>
<td>Teeth and mucous membranes of the oral cavity will be included into cosmetic products.</td>
<td>Classification of teeth and mouth-related products into special use and non-special use.</td>
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| Classification    | - Special use cosmetics: Hair dye, Hair perming, Whitening, Sunscreens, Other special cosmetics deemed by the CFDA  
                     - Non-special use cosmetics → general cosmetics | Follow up on classification of products into “other special cosmetics deemed by the CFDA”  
                                                                                         Reclassification of cosmetic products with the new classification system. |
| Registration      | The proof of manufacture and sales of the product in the country of origin can be substituted with the results from research on Chinese customers. | May allow import of cosmetics made by foreign companies exclusively for Chinese customers. |
| Registration      | Filing process for imported non-special use cosmetics will be simplified. (Filing 10 days before the import) | Establishment of the new simplified process. |
| Registration      | License period of validity 4 years → 5 years                                      | 1 year added to the period of validity of license. |
| Ingredient        | Permitted list of whitening agents will be added                                  | Need to check if the whitening agents being used in the industry are on the list. |
| Label             | Label must be on the minimum packaging unit + container in direct contact with the content. (both 1st and 2nd packaging) | Packaging process extended. (Increase in cost and time) |
| Claiming effects  | The relevant reference materials for effect-related claims will be published on designated websites. | Concerns with release of confidential ingredient information. |