Overview of Cosmetic Regulatory Status and Trends in China

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Status Quo

Cosmetic Registration

- Regulatory Background and Competent Authority
- Clarification of roles and responsibilities
- Procedures and timeline
- Formula and label requirement
- Testing requirements
- Introduction of Pudong filing
Status Quo

Cosmetic Registration
Definition and Classification of Cosmetics in China

**Cosmetics:**

“a kind of daily-used chemical product intended to be applied on the surface of human body (skin, hair, nails, lips, etc.) by rubbing, spraying or otherwise similar ways for the purpose of cleansing, correcting body odors, protecting, beautifying and altering the appearance.”

![Diagram showing the classification of cosmetics in China]

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

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

**Domestic Notification**
- Hair Growth
- Hair Dye
- Hair Perm
- Hair Removal
- Beauty Breast
- Body Fitness
- Deodorant
- Anti-spot
- Whitening
- UV protection

**CFDA Pre-market registration**
- Initially imported non-special use cosmetics filing
Regulatory System

Cosmetic Hygienic and Management Regulation, 1989

Detailed Rules

Inventory of Existing Cosmetic Ingredient in China, IECIC 2015

Safety and Technical Standard for Cosmetic STSC No.268, 2015-12

Provisions for Application and Acceptance of Administrative Licensing for Cosmetics No.856, 2009

Instruction for Use of Consumer Products – General Labelling for Cosmetics, GB 5296.3-2008, 2008-06

Rules and Guidance Naming for Cosmetics No.72, 2010-02

Draft of Cosmetic Supervision and Administration Regulation, 2014, 2015, 2018…
Competent Authorities

China Food and Drug Administration, CFDA

General Administration of Quality Supervision, Inspection and Quarantine, AQSIQ

State Administration for Industry & Commerce, SAIC
Competent Authorities

- Pre-market approval on food, cosmetics and medical devices.
- In-market surveillance (quality + safety)
- Safety management

China Food and Drug Administration, CFDA

General Administration of Quality Supervision, Inspection and Quarantine, AQSIQ

State Administration for Industry & Commerce, SAIC
Competent Authorities

- China Food and Drug Administration, CFDA
  - Import and Export Commodity Inspection
  - Counterfeit products inspection...

- General Administration of Quality Supervision, Inspection and Quarantine, AQSIQ

- State Administration for Industry & Commerce, SAIC
Competent Authorities

- China Food and Drug Administration, CFDA
- General Administration of Quality Supervision, Inspection and Quarantine, AQSIQ
- State Administration for Industry & Commerce, SAIC

- Company Law
- Cosmetic advertising
- Trade mark registration
- Commercial activities management
- Law on Protection of Consumer Rights and Interests……
Competent Authorities

- Unify information record system and set information publicizing and sharing mechanism
- Organize the law enforcement of comprehensive market supervising work
- Shoulder the law duty of comprehensive anti-monopoly action
- Standardize and maintain market order
- Organize and implement quality control
- Shoulder the duty of products and devices safety and quality supervision
- Unify the counting standard
- Shoulder the duty of product permission (registration or filing certification) and inspection and quarantine

CFDA renamed as CNDA, subordinated to SAMR
Clarification of roles and responsibilities

- Manufacturers/applicants
- Responsible agent/responsible person
- Importers/distributors

Introduction of registration documents

- Formula & production
- Packaging & label
- Testing reports
- Other supporting documents

Suggestion on time arrangement

- Typical timeline
- General registration V.S new filing system

Regulatory Updates

- Draft of Cosmetic Supervision and Administration Regulation
- Safety and Technical Standard for Cosmetic
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## Clarification of roles and responsibilities

<table>
<thead>
<tr>
<th>Party</th>
<th>Roles and responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td><strong>For manufacturer/brand owner</strong></td>
</tr>
<tr>
<td></td>
<td>• Responsible for the safety of products</td>
</tr>
<tr>
<td></td>
<td>• The applicant of registration</td>
</tr>
<tr>
<td></td>
<td>• Provide accurate required documents</td>
</tr>
<tr>
<td></td>
<td>• Name and address will be listed on the certificate</td>
</tr>
<tr>
<td></td>
<td><strong>For real manufacturer (OEM/ODM/OBM)</strong></td>
</tr>
<tr>
<td></td>
<td>• Provide accurate required documents</td>
</tr>
<tr>
<td><strong>Responsible Agent</strong></td>
<td><strong>(General registration)</strong></td>
</tr>
<tr>
<td></td>
<td>• Shall be a legal entity registered in China</td>
</tr>
<tr>
<td></td>
<td>• Responsible for product registration ONLY</td>
</tr>
<tr>
<td></td>
<td>• Name and address will not be shown on the label</td>
</tr>
<tr>
<td></td>
<td>• Name and address will be listed on approval license, but not on the label</td>
</tr>
<tr>
<td><strong>Responsible Person</strong></td>
<td><strong>(Initially imported non-special use cosmetics filing)</strong></td>
</tr>
<tr>
<td></td>
<td>• Shall be a legal entity registered in Pudong New Area or other 10 free trade zones</td>
</tr>
<tr>
<td></td>
<td>• Responsible for product filing, quality and safety</td>
</tr>
<tr>
<td></td>
<td>• Must be the importer</td>
</tr>
<tr>
<td></td>
<td>• Name and address will be listed on the filing certificate.</td>
</tr>
<tr>
<td><strong>Distributor</strong></td>
<td>• Collaborations with good sales channels</td>
</tr>
<tr>
<td><strong>Importer</strong></td>
<td>• Products importation</td>
</tr>
</tbody>
</table>

10/19/2018  www.reach24h.com  13
Clarification of roles and responsibilities

- **Real Manufacturer**
  - Contracted manufacturing

- **Manufacturer**

- **Importer**

- **Distributor**

- **Responsible Agent**
  - Provide information for registration
  - Authorization
  - Work together for registration
  - Certificate for custom clearance

- **CNDA**
  - Review and Approval
  - Dossier Submission
Status Quo

Cosmetic Registration
Clarification of roles and responsibilities

- Manufacturers/applicants
- Responsible agent/responsible person
- Importers/distributors

Introduction on registration documents

- Formula & production
- Packaging & label
- Testing reports
- Other supporting documents

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Regulatory Updates

- Draft of Cosmetic Supervision and Administration Regulation
- Safety and Technical Standard for Cosmetic
## Introduction on registration documents

### Safety
- Formula
- Safety assessment report of impurities with safety concern
- Quality control
- Manufacture process
- Testing Reports

### Wording
- Chinese naming statement
- Original package
- Chinese label

### Supporting
- Application form
- Authorization letter
- Certificate of free sale and production
- BSE statement
- OEM agreement
- GMP/ISO of OEM
Introduction on registration documents

Safety
- Formula
- Safety assessment report of impurities with safety concern
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- Manufacture process
- Testing Reports

Wording
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Supporting
- Application form
- Authorization letter
- Certificate of free sale and production
- BSE statement
- OEM agreement
- GMP/ISO of OEM
CNDA regulates the cosmetic ingredients in the following way,

I. **Cosmetic Hygienic standards (Safety and Technical Standards for Cosmetics 2015)** presents the list of prohibited & restricted ingredient, preservatives, hair dyes, colorants, and UV filters.

II. **Inventory of Existing Cosmetic Ingredients in China (IECIC 2015)**: the list of ingredients allowable to be used, and the determinant of new ingredients.
## Introduction on registration documents

### Formula

<table>
<thead>
<tr>
<th>No.</th>
<th>C-INCI Name</th>
<th>INCI Name</th>
<th>Ratio in finished product(%)</th>
<th>Ratio in compound ingredients(%)</th>
<th>Actual Weight(%)</th>
<th>Function</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>非复配原料1</td>
<td>Non-compound ingredient 1</td>
<td>96</td>
<td>100</td>
<td>96</td>
<td>Function 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>复配原料1</td>
<td>Compound ingredient 1</td>
<td></td>
<td>40</td>
<td>1.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>复配原料2</td>
<td>Compound ingredient 2</td>
<td>3</td>
<td>32</td>
<td>0.96</td>
<td>Function 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>复配原料3</td>
<td>Compound ingredient 3</td>
<td></td>
<td>28</td>
<td>0.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>非复配原料1</td>
<td>Non-compound ingredient 2</td>
<td>1</td>
<td>100</td>
<td>1</td>
<td>Function 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total amount</td>
<td></td>
<td>100</td>
<td></td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Introduction on registration documents

#### Testing

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Hygienic chemistry</th>
<th>Microbiology</th>
<th>Toxicology</th>
<th>Human trial</th>
<th>Additional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-special use</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>△</td>
</tr>
<tr>
<td>Special use</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>△</td>
</tr>
</tbody>
</table>

Animal testing
Chinese label

I. Original Label + Chinese Label

II. Newly designed Chinese label for China market

Some claims can’t be used for cosmetics: medical terms, clinical terms, exaggeration, etc.

Product name: XXX绿茶洗发露
Country of origin: 西班牙
Manufacturer name and address (not mandatory):
Importer/Distributor/Agent’s name and address:
LOT number and the day before use, or Manufacturing date and shelf life:
L005543, 2021/10/30 or 生产日期2018/10/31, 保质期3年
Certificate approval number:
Ingredients: Chinese INCI
Directions of use:
Cautions:
Storage condition:
Net Content:
Introduction (optional):
Clarification of roles and responsibilities
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- Importers/distributors

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Suggestion on time arrangement
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Suggestion on time arrangement

- At least one month

- Testing must be conducted in CNDA accredited labs in China.
  - For non-special use products: 2~4 months*
  - For special use products: 5~8 months

- At least 3 months, uncontrolled
- Importation & sales
Suggestion on time arrangement

- At least one month
- Testing must be conducted in CNDA accredited labs in China.
  - For non-special use products: 2~4 months*
  - For special use products: 5~8 months
- Importation and Sales

1. Responsible Person
2. CNDA account application
3. Product Analysis (formula, label)
5. Submit
6. Notification
7. Technical review within 3 months
8. REACH24H & Manufacturer
9. Testing Lab
10. CNDA

* Note: Times are approximations and may vary depending on specific circumstances.
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Regulatory Updates

Draft of Cosmetic Supervision and Administration Regulation, 2014, 2015, 2018

Reduce pre-market approval

• Accelerate approval procedures of initially imported non-special use cosmetics
• Redefine special use cosmetics: hair dye, hair perm, anti-freckle&whitening, UV protection and those claiming new efficacy or functions
  
  【hair removal, hair growth, beauty breast, body fitness might be defined as drugs and deodorant might drop into non-special use cosmetics】
• Change the current approval mechanism on new cosmetic ingredients (NCI):
  1. Notification for General NCI: like emollient, humectant, skin conditioner…
  2. Registration for NCI of very high concern: preservative/antiseptic, UV filter, anti-freckle/depigmenting, colorant, hair dyes…

Safety and Technical Standards for Cosmetics, STSC No.268, 2015-12

• Expected to be updated annually.
• Companies need to pay close attention to the transitional period and process.
FAQ & Case Study
• Ingredients

a) If there is an ingredient not listed in IECIC, what should I do?

b) Can I only provide a range concentration?
<table>
<thead>
<tr>
<th>No</th>
<th>INCI Name</th>
<th>CN INCI Name</th>
<th>Concentration</th>
<th>Ingredient Ratio (%)</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Water (AQUA)</td>
<td>水</td>
<td>77</td>
<td>100</td>
<td>SOLVENTE</td>
</tr>
<tr>
<td>2</td>
<td>BUTYLENE GLYCOL</td>
<td>丁二醇</td>
<td>6</td>
<td>100</td>
<td>HUMECTANT</td>
</tr>
<tr>
<td>3</td>
<td>VITIS VINIFERA (GRAPE) SEED OIL</td>
<td>葡萄(VITIS VINIFERA)籽油</td>
<td>5</td>
<td>100</td>
<td>SKIN CONDITIONING AGENT</td>
</tr>
<tr>
<td>4</td>
<td>GLYCERIN</td>
<td>甘油</td>
<td>4</td>
<td>100</td>
<td>HUMECTANT</td>
</tr>
<tr>
<td>5</td>
<td>BETAIN</td>
<td>甜菜碱</td>
<td>3</td>
<td>100</td>
<td>HUMECTANT</td>
</tr>
<tr>
<td>6</td>
<td>STEARETH-21</td>
<td>硬脂醇聚醚-21</td>
<td>1.3</td>
<td>100</td>
<td>EMULSIFYING AGENT</td>
</tr>
<tr>
<td>7</td>
<td>BENZYL ALCOHOL</td>
<td>苯甲醇</td>
<td>1.1</td>
<td>87</td>
<td>PRESERVATIVE</td>
</tr>
<tr>
<td>8</td>
<td>TOCOPHEROL</td>
<td>生育酚(维生素E)</td>
<td>1</td>
<td>65</td>
<td>SKIN CONDITIONING AGENT</td>
</tr>
<tr>
<td>8</td>
<td>GLYCINE SOJA (SOYBEAN) OIL</td>
<td>野大豆(GLYCINE SOJA)油</td>
<td>1</td>
<td>34</td>
<td>SKIN CONDITIONING AGENT</td>
</tr>
<tr>
<td>9</td>
<td>PHENOXYETHANOL</td>
<td>苯氧乙醇</td>
<td>0.9</td>
<td>100</td>
<td>PRESERVATIVE</td>
</tr>
<tr>
<td>10</td>
<td>PORTULACA OLERACEA EXTRACT</td>
<td>马齿苋(PORTULACA OLERACEA) 提取物</td>
<td>0.6</td>
<td>100</td>
<td>EMULSIFYING AGENT</td>
</tr>
<tr>
<td>11</td>
<td>Fragrance (Perfume)</td>
<td>香精</td>
<td>0.1</td>
<td>100</td>
<td>FRAGRANCE INGREDIENT</td>
</tr>
<tr>
<td>12</td>
<td>CARBOMER</td>
<td>卡波姆</td>
<td>0.17</td>
<td>100</td>
<td>VISCOSITY CONTROLLING</td>
</tr>
<tr>
<td>13</td>
<td>ETHYLHEXYLGLYCERIN</td>
<td>乙基己基甘油</td>
<td>0.1</td>
<td>100</td>
<td>HUMECTANT</td>
</tr>
<tr>
<td>14</td>
<td>PORTULACA PILOSA EXTRACT</td>
<td>/</td>
<td>0.02</td>
<td>100</td>
<td>SKIN CONDITIONING AGENT</td>
</tr>
</tbody>
</table>
• Tests
  a) Is there any way to avoid animal testing?

• Package
  a) Can we claim organic cosmetic in China?

• Procedures
  a) Can we apply CNDA registration and Pudong filing at the same time?
**REACH24H Consulting Group**, based in Hangzhou, with office in Taiwan, Ireland and USA, has served more than 5000 companies with its extensive experience in expediting global market access. It provides global regulation compliance solutions to assist manufacturers, importers and downstream users to effectively manage their responsibilities.

**Cosmetic Division** is one of the key strategic divisions in REACH24H. We are devoted to providing professional global market access consultation and customized regulatory compliance services for all cosmetics related companies.

Flawless Coverage of Asia–Pacific Regulatory Affairs.
THANK YOU!

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