Deciphering China Cosmetic Regulatory Framework and Latest Updates

Hedy He
Cosmetic Regulatory Analyst
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01 China Cosmetic Regulatory Framework

02 China Latest Cosmetic Regulatory Updates

- Finished Products
- New Cosmetic Ingredient
Part 1
China Cosmetic Regulatory Framework

1. China cosmetics market overview
2. Competent authority and regulatory system
3. Cosmetic definition and classification
4. Pre-market requirements
1.1 China Cosmetic Market Overview – Retail market

- **Second largest beauty market**
- **12.7%** market share
- Retail sales reached **189.3 billion RMB** in the first 8 months of 2019
1.1 China Cosmetic Market Overview – Import sector

- Import volume reached 56.1 billion RMB in the first 8 months of 2019
- 42.1% growth rate
- Japan, South Korea, France and the United States have been entrenched in the top four positions in China's cosmetic importing countries
1.1 China Cosmetic Market Overview – Specific product market share

- Skin care products account for more than half of the market share
- Makeups develop rapidly: 22% growth rate
1.2 Competent Authority & Regulatory System

- **Pre-market approval**
  - In-market surveillance
  - Safety management
  - China Food and Drug Administration (CFDA)

- **inspection of**
  - Cosmetic safety
  - Sanitation
  - Quality
  - General Administration of Quality Supervision Inspection and Quarantine (AQSIQ)

- **Regulate trademarks advertising commercial activities**
  - State Administration for Industry & Commerce (SAIC)

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**NMPA**

- Cosmetics
- Drug
- Medical Devices

**CFDA**
1.2 Competent Authority & Regulatory System

Framework

Overarching
- Regulations Concerning the Hygiene Supervision over Cosmetics 1989
  - Safety and Technical Standards for Cosmetics 2015
  - Hygienic Standard for Production Enterprises of Cosmetics
  - Provisions for Application and Acceptance of Administrative Licensing for Cosmetics No.856, 2009
  - Administrative Measures for Filing of Non-special Use Cosmetics (Draft)

Hygiene Standard
- GB 5296.3-2008 General Labeling for Cosmetics

Licensing
- 5296.3-2008 General Labeling for Cosmetics

Ingredient
- IECIC
  - Guidance on Application and Review of New Cosmetic Ingredient

Import & Export
- Administrative Measures on Inspection and Quarantine of Import and Export Cosmetics

Labeling
- Guide to the Naming of Cosmetics

Naming
- Working Rules for Cosmetic Registration and Filing Testing

Testing
- Administrative Measures on Cosmetics Labeling (draft)
1.3 Cosmetic Definition & Classification

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

<table>
<thead>
<tr>
<th>Aspects</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usage</td>
<td>• Surface of human body</td>
<td>Oral administration or injection</td>
</tr>
<tr>
<td></td>
<td>• Smearing, spraying or other similar ways like rubbing</td>
<td></td>
</tr>
<tr>
<td>Applied body parts</td>
<td>Any external part of the human body, such as skin, hair, nails, lips</td>
<td>Oral care products</td>
</tr>
<tr>
<td>Functions and purposes of use</td>
<td>Skin care, to make the body hygienic, to eliminate undesirable odors, to enhance the beauty of the appearance</td>
<td>Prevent and treat diseases Antibacterial products</td>
</tr>
</tbody>
</table>
Cosmetic Definition & Classification

Cosmetics

- Special-use cosmetics
  - anti-spot/whitening
  - UV protection
  - hair dye
  - hair growth
  - hair perm
  - hair removal
  - breast beauty
  - body fitness
  - deodorant

- Non-special use cosmetics
  - skin care
  - hair care
  - nail (toe) care
  - makeup
  - fragrance
## Pre-market Requirements

<table>
<thead>
<tr>
<th>Category</th>
<th>Obligation</th>
<th>Certificate</th>
<th>Validity period</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imported SUC</td>
<td>Pre-market administrative licensing</td>
<td>Administrative license</td>
<td>4 Years</td>
<td>NMPA</td>
</tr>
<tr>
<td>Domestic SUC</td>
<td></td>
<td>Administrative license</td>
<td>4 Years</td>
<td></td>
</tr>
<tr>
<td>Domestic non-SUC</td>
<td>Pre-market filing</td>
<td>No certificate</td>
<td>4 Years</td>
<td>Provincial MPA</td>
</tr>
<tr>
<td>Imported non-SUC</td>
<td></td>
<td>Filing certificate</td>
<td>Permanent, but are subject to annual report to NMPA</td>
<td>NMPA Provincial MPA in the 11 FTZs</td>
</tr>
</tbody>
</table>
Part 2
China Latest Cosmetic Regulatory Updates

1. Finished products
   - Cosmetic new filing policy
   - Status and progress trend of animal testing
   - Special-use cosmetics renewal
   - New testing rules
   - Future trends

2. New Ingredients
   - Definition & Regulation
   - Registration procedures
   - Current status
   - Future trends
2.1.1 Finished Products

- Cosmetic New Filing Policy - Background

- Mar. 1st 2017 to Dec. 21st 2018
  - Pudong became the first pilot city of the new filing policy

- Mar. 12th 2018 to Dec. 21st 2018
  - New filing policy was expanded to 10 other locations

- Nov 10th 2018
  - Expanded nationwide
2.1.1 Finished Products

- Cosmetic New Filing Policy - Procedures

- RP Authorization
  - At least one month

- NMPA Account Application
  - Non-SUC: 2-4 months

- Product Testing
  - Dossier Compilation
    - Format review
      - Yes
        - E-Filing Certificate
      - No
        - Stop importation and sales/Product recall

- Importation
  - Yes
    - Dossier supplement
  - No
    - Technical Review
      - Stop importation and sales/Product recall
### Finished Products

- Cosmetic New Filing Policy – Comparison between RP and RA

<table>
<thead>
<tr>
<th></th>
<th>RA</th>
<th>RP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Registration</td>
<td>Filing</td>
</tr>
<tr>
<td><strong>Requirement</strong></td>
<td>Legal entity registered in Chinese mainland</td>
<td>Legal entity in Chinese mainland needs to be importer with <em>cosmetic business licence</em>,</td>
</tr>
<tr>
<td><strong>Responsibility</strong></td>
<td>For registration ONLY</td>
<td>For all cosmetic activities, including <em>safety issues</em>.</td>
</tr>
<tr>
<td><strong>Exclusiveness</strong></td>
<td>One brand owner shall only have one RA</td>
<td>One product shall only have one RP</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td>Information will not appear on the Chinese label</td>
<td>Name and address must be listed on the Chinese label</td>
</tr>
</tbody>
</table>
| **Change**       | • Can be changed  
                    • Do **not need** to inform previous RA | • Can be changed  
                    • Do need to inform the previous RP and *issue and statement* |
Finished Products

- Cosmetic New Filing Policy - Procedures

- RP Authorization
- NMPA Account Application
- Product Testing
- Dossier Compilation
- Format review
- E-Filing Certificate
- Technical Review
- Importation
- Dossiers supplement

At least one month
Non-SUC: 2-4 months

specification for imported non-special use cosmetics filing documents review

Yes No

Stop importation and sales/Product recall

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Finished Products
• Cosmetic New Filing Policy

2018-11-10
Registration Change to Filing Management Nationwide

Filing Management

Outside 11 FTZs
Do filing to NMPA

11 FTZs:
Tianjin, Liaoning, Shanghai,
Zhejiang, Fujian, Henan,
Hubei, Guangdong,
Chongqing, Sichuan and
Shanxi

Unified the Requirements

Imported Non-SUC
Domestic Non-SUC
Finished Products
• Draft Administrative Measures for Filing of Non-special Use Cosmetics

国家药监局综合司公开征求《非特殊用途化妆品备案管理办法（征求意见稿）》意见

为加强非特殊用途化妆品的备案管理，根据现行化妆品监督管理有关规定，结合国产和进口非特殊用途化妆品备案管理工作实际，国家药监局组织起草了《非特殊用途化妆品备案管理办法（征求意见稿）》，现向社会公开征求意见，请将修改意见于2019年6月15日前，以电子邮件形式反馈我局化妆品监督管理司（电子邮箱：huazhuangpinchu@163.com）。

附件：非特殊用途化妆品备案管理办法（征求意见稿）

国家药监局综合司
2019年5月23日
Finished Products

- Draft Administrative Measures for Filing of Non-special Use Cosmetics

- New Requirements On Documentation
- Post-Market Surveillance
- Animal Testing Exemption
New Requirement on Documentation

- ISO / GMP will be required for all imported Non-SUC.
- Relevant research and experimental data for Chinese consumers shall be submitted.
- Submit commitment on documents authenticity.
- RP alteration: Confirmed online by both sides.
- The acceptance agreement signed by RP and consignee.
- Product designed especially for Chinese market

Finished Products
- Draft Administrative Measures for Filing of Non-special Use Cosmetics

2.1.1
Post-Market Surveillance

Importation and Sale will be suspended under the following circumstances:

- **Testing**
  - Missing required testing item and report;

- **COA**
  - The certificate of analysis of raw material is not qualified;

- **Safety Risk Assessment**
  - The result of safety risk assessment can’t determine the product safety;

- **QC**
  - Product QC including technical requirements does not meet the safety requirements of cosmetics;

- **Others**
  - Other situations that are unable to determine the product safety.
2.1.1 Finished Products

- Draft Administrative Measures for Filing of Non-special Use Cosmetics

**Animal Testing Exemption**

- Manufactured under certified GMP conditions
- The safety risk assessment results are sufficient to prove product safety

**Except in one of the following circumstances:**

- The product is for specific use by children or infants;
- The product uses new raw materials that have been approved or filed, but have not been included in the IECIC;
- The filer, the RP or the actual manufacturing enterprise is listed as the key supervision targets according to the results of credit rating;
- The filer, the RP or the actual manufacturing enterprise was investigated and punished for the quality and safety of cosmetics in the past three years.
### Finished Products

- **Status and progress trend of animal testing in China**

#### Status of Alternative Methods in China

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Testing Method</th>
<th>Testing Item</th>
<th>Range of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 2016</td>
<td>In-vitro 3T3 Neutral Red Uptake Phototoxicity Test Method for Chemicals used in Cosmetics</td>
<td>Phototoxicity</td>
<td>Cosmetic Ingredient</td>
</tr>
<tr>
<td>Aug 2017</td>
<td>In Vitro Skin Corrosion Transcutaneous Electrical Resistance Test (TER) for Chemicals Used in Cosmetics</td>
<td>Skin Corrosion</td>
<td>Cosmetic Ingredient</td>
</tr>
<tr>
<td></td>
<td>Skin Photoallergy Test</td>
<td>Skin Photoallergy</td>
<td><strong>Cosmetic Ingredient &amp; Cosmetic Product</strong></td>
</tr>
<tr>
<td>Mar 2019</td>
<td>Short Time Exposure In Vitro Test Method (STE)</td>
<td>Eye Irritation</td>
<td>Cosmetic Ingredient</td>
</tr>
<tr>
<td></td>
<td>In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)</td>
<td>Skin Sensitization</td>
<td>Cosmetic Ingredient</td>
</tr>
<tr>
<td></td>
<td>Skin Sensitization: Local Lymph Node Assay: DA (LLNA: DA)</td>
<td>Skin Sensitization</td>
<td>Cosmetic Ingredient</td>
</tr>
<tr>
<td></td>
<td>Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA (LLNA: BrdU-ELISA)</td>
<td>Skin Sensitization</td>
<td>Cosmetic Ingredient</td>
</tr>
</tbody>
</table>
Finished Products

- Status and progress trend of animal testing in China

<table>
<thead>
<tr>
<th>Alternative Methods</th>
<th>Safety Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most of them are for cosmetic Ingredients</td>
<td>May replace animal testing in imported Non-SUC filing</td>
</tr>
<tr>
<td>Only one method is for cosmetic product</td>
<td></td>
</tr>
</tbody>
</table>
2.1.3 Finished Products

- Special-use Cosmetics Renewal - Procedures

1. 6 months before the expiry date: Enterprise conduct self-inspection
2. 30 working days before the expiry date: Apply for license renewal
3. 5 working days: Format Examination
4. If the examination passes, proceed to Issue renewed license.
5. If the examination fails, proceed to Reapply.
6. If all dossiers are qualified, proceed to Issue renewed license.
7. If there are disqualified dossiers, return all the dossiers and reapply.
8. If there are incomplete application dossiers or need further explanation, supplement the dossiers.
9. If there is a fake commitment or incomplete dossiers, revoke the license.

License cannot be renewed if it would expire less than 30 working days.
Any testing institutions with CMA certificate, submit relevant institution information through online testing information system and confirmed and published by NMPA can undertake testing work.

Terminate the original designated testing institution system

Standardize the requirements of testing items

Implement the digital information management

Foreshadow the integration of the testing information, registration and the filing management system

Adjust test sample requirements

2.1.4 Finished Products

• New Testing Rules for Cosmetic Registration and Filing
2.1.5 Finished Products

- Future Trends

CSAR

Administrative Rules

Normative Documents

Interpretations and Instructions

Short for Cosmetic Supervision and Administration Regulations – the overarching regulation in China

No legal force

Disclosed by an official of NMPA at the CAFFCI annual meeting
2.1.5 Finished Products

- Future Trends

The New CSAR may be updated by the end of 2019

**Cosmetic Definition:**
Toothpaste may be included in Cosmetics in China.

**Cosmetic Category:**
For SUC narrowed to 5+1: Hair dye, Hair perm, Anti-hair loss, whitening, Sun Screening, products with new efficacy.

**Registration for New Cosmetic Ingredient:**
High risk ingredients shall register while ingredients with low risk only require filing.

**Safety Assessment:**
Should be issued by a qualified safety assessor (With ≥ 5 academic background) for SUC & Non-SUC.

**Efficacy Claim:**
The literature or testing reports are required, and may be exposed to the public on the website.
2.2.1 New Cosmetic Ingredient

- Definition & Regulation

New Cosmetic Ingredient:
A natural or artificial ingredient that is **firstly used** in **cosmetic product** in **China**.

<table>
<thead>
<tr>
<th>Inventory of Existing Cosmetic Ingredients in China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive list</td>
</tr>
<tr>
<td>8783 cosmetic ingredients</td>
</tr>
<tr>
<td>2015 version</td>
</tr>
</tbody>
</table>
2.2.1 New Cosmetic Ingredient
- Definition & Regulation

Pre-Market Approval

- **Article 9** of the <Regulation of Hygienic Supervision on Cosmetics>(1989) requires that any new cosmetic ingredients should be approved by Ministry of Health(MoH), currently National Medical Products Administration(NMPA), prior to firstly being used in cosmetic products for commercial purpose.

Reference document

2.2.2 New Cosmetic Ingredient

- Registration procedures

Applicant → Testing Institution

Competent Authority

Appointing Responsible Agent in China → Document Preparation & Submission

Data gap Analysis → Acceptance

Testing (if necessary) → Technical Review

NMPA reception service center
5 working days

NMPA Expert Committee
90 working days

Dept. of Drug & Cosmetics
Registration management
20+10 working days

Approval
2.2.3 New Cosmetic Ingredient

- Current Status

Statistics of the Applications for New Ingredients in China (2008~2018.9)

- Domestic NCI
- Imported NCI

Calculated from the monthly statistics released by NMPA Assessment Center
2.2.3 New Cosmetic Ingredient

• Current Status

Till now, there are ten ingredients in total being approved for cosmetic application by the former CFDA and the former competent authority, MoH.

<table>
<thead>
<tr>
<th>No.</th>
<th>INCI Name</th>
<th>Trade Name</th>
<th>Applicants</th>
<th>Approved Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Alkyl (C12-C22) trimethyl ammonium, bromide and chloride</td>
<td>-</td>
<td>-</td>
<td>Jun 2004 (MoH)</td>
</tr>
<tr>
<td>2</td>
<td>Potassium Methoxysalicylate</td>
<td>4MSK</td>
<td>Shisheido</td>
<td>Apr 2007 (MoH)</td>
</tr>
<tr>
<td>3</td>
<td>Methylisothiazolinone</td>
<td>Kathon</td>
<td>Rohm Haas</td>
<td>May 2007 (MoH)</td>
</tr>
<tr>
<td>4</td>
<td>Carnitine Tartrate</td>
<td>-</td>
<td>-</td>
<td>Jun 2008 (MoH)</td>
</tr>
<tr>
<td>5</td>
<td>Lathyrus odoratus flower extract</td>
<td>-</td>
<td>-</td>
<td>Aug 2008 (MoH)</td>
</tr>
<tr>
<td>6</td>
<td>Fructooligosaccharides</td>
<td>-</td>
<td>-</td>
<td>Aug 2008 (MoH)</td>
</tr>
<tr>
<td>7</td>
<td>Dimethoxytolyl Propylresorcinol</td>
<td>Nivitol</td>
<td>Unigen</td>
<td>Mar 2012 (CFDA)</td>
</tr>
<tr>
<td>8</td>
<td>Polymethacryloyl Lysine</td>
<td>-</td>
<td>-</td>
<td>Mar 2012 (CFDA)</td>
</tr>
<tr>
<td>9</td>
<td>Phenylethyl Resorcinol</td>
<td>Symwhite 377</td>
<td>Symrise</td>
<td>Dem 2012 (CFDA)</td>
</tr>
<tr>
<td>10</td>
<td>Elaeagnus mollis Oil</td>
<td>琪尔康翅果油</td>
<td>琪尔康</td>
<td>Oct 2014 (CFDA)</td>
</tr>
</tbody>
</table>
2.2.4 New Cosmetic Ingredient
• Future trends

Article 9
• New Cosmetic Ingredient: A natural or artificial ingredient that is firstly used in cosmetic product in China.
• High risk ingredients are required to do registration: preservatives, sunscreen agent, colorant, hair dying agent, whiting agent; Other ingredients only require filing.
• Authority will publish registration/filing results within 10 working days after new cosmetic ingredient application.

Article 10
Applicants are asked to submit semiannual report on ingredient post-market safety condition to authority within 3 years after getting certificate.
• Authority will cancel certificate if there is safety issues.
• The ingredient will be listed in IECIC if there is no adverse events happen within 3 years.
Cosmetics and NCIs will be categorized based on their risk.

Low-risk NCIs will be subject to reduced compliance duties and faster application process.

The *efficacy system will be managed by both the government and public*. The government will implement efficacy evaluation regulation but not endorse any efficacy claims. Efficacy claims will be disclosed to the public and supervised by them.

Cosmetics claiming new efficacy will be managed as *special cosmetics*.

RP of filing and registration shall bear corresponding obligations.

A quantitative rating system will be established. Companies with a bad record will be the key regulatory targets.

Punishment will be specific to a person rather than a company.
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Add: 14F, #3 Bldg., Haichuang Technology Center, Hangzhou, China (311121)
Email: contact@chemlinked.com | Skype: ChemLinked Official
Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566