Regulation of Cosmetics in China

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History of Cosmetics in China

Everybody appreciates his/her own beauty. Dating back to Yin and Shang Dynasty (1046-1600 BC), it was recorded that rouge was made from the extract of safflower leaves for cheek rouging. Inscriptions on oracle bones have the earliest Chinese writings of the character of “沐” which means hair and face washing according to the explanation in Shuo Wen Jie Zi. This might be the earliest record for cleaning and beauty in ancient times.

In 1972, Mawangdui Tumulus was excavated in Changsha, Hunan Province with the existence of a classic book Prescriptions of Fifty-two Diseases which maintained the record of Chinese medicine for beauty. The history can be traced back to Zhou Dynasty (1100BC), Spring and Autumn Period.

According to a folktale, Xishi, a fairest beauty in ancient China, was washing her clothes at the shore of a river. As she washed, the cosmetics she wore fell from her face into the water. The fish were attracted and addicted to the cosmetics which made them beautiful after taking for a long time. Villagers strived to catch the fish. It seemed only a legend that fish wore cosmetics, explained by experts. However another answer explains that Xishi started wearing make-up in her early age.

Modern beauty and cosmetic industry in China starts its development in the 1980s. It has become the world’s largest market after decades of rapid development. In 2008, total sales for the certain industry ranked to RMB 120 billion (USD 18B). It is predicted that the sales will reach RMB 140 billion (USD 20B) in 2010.
Outlines

1. Regulatory framework in China
2. Preservatives and microbiology
3. Regulatory Issues

Definition and categorization of cosmetic

Definition
The Regulations for Hygiene Supervision over Cosmetics (1989) defines a cosmetic product as:

‘those daily used chemical products applied on surface of any part of the human body (such as skin, hair, nails and lips) by way of anointing, spraying or other similar methods for cleansing, getting rid of undesirable smell, protecting the skin, beautifying the face or altering the appearance’. 
Definition and categorization of cosmetic

Categorization

Under the Regulations for Hygiene Supervision over Cosmetics, cosmetics are divided into two categories:

- Non-special Use Cosmetics (Ordinary Cosmetics)
- and Special Use Cosmetics.

And Special Use Cosmetics are defined as cosmetics with fixed purpose of uses including:

- Hair Growth
- Hair Dyes
- Hair Wave
- Depilatories
- Breast Enhancement
- Body Shaping
- Antiodorants
- Breast Enhancement
- Whitening
- Sun Protection

Regulation of cosmetics

- General introduction
- Regulatory bodies and responsibilities
- Controls over ingredients
- Labeling and claims
- Pre-market requirements
- Post-market surveillance
Regulation of cosmetics

General Introduction
Major contents covered in China cosmetic regulations:
- Safety and liability: manufacturers and regulatory authorities
- Control over ingredients
- Labeling and claims
- Product registration/notification
- Registration of manufacturing facilities
- Post-market surveillance
Acronyms

- **SFDA**: State Food and Drug Administration
- **AQSIQ**: General Administration of Quality Supervision, Inspection and Quarantine
- **SAIC**: State Administration for Industry and Commerce
- **MOH**: Ministry of Health
- **QTS**: Quality and Technology Supervision Bureau under AQSIQ
- **CIQ**: Entry-Exit Inspection and Quarantine under AQSIQ

Regulations of cosmetics

<table>
<thead>
<tr>
<th>Authorities</th>
<th>Legal Ground</th>
<th>Responsibilities</th>
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<td>Hygiene permission on cosmetics (SFDA) and domestic manufacturing facilities (local FDA)</td>
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<td>Particulars of Implementation of Regulations for Hygiene Supervision over Cosmetics (1991)</td>
<td>In-market surveillance on cosmetic products and routine inspection on manufacturing facilities</td>
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<td><strong>AQSIQ</strong></td>
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<td>Production permission on domestic manufacturing facilities (AQSIQ)</td>
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<td>Detailed Rules for Implementation of Production Licensing Procedure for Cosmetics (2001)</td>
<td>Standardization Administration of PRC is responsible for standard approval and issuance.</td>
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<td>Regulations on Cosmetic Labeling (2006)</td>
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<td>Administration Regulations on Supervision and Inspection of Imported and Exported Cosmetics (2000)</td>
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<td>Regulations For The Implementation Of The Standardization Law (1994)</td>
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<tr>
<td><strong>SAIC</strong></td>
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<td>In-market surveillance on quality and advertisement of cosmetics</td>
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<tr>
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<td>Advertising Law of the People’s Republic of China (1994)</td>
<td>Establishment of relevant regulations</td>
</tr>
<tr>
<td></td>
<td>Regulations on Administration of Cosmetic Advertisement (1999)</td>
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</tr>
</tbody>
</table>
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- General introduction
- Regulatory bodies and responsibilities
- Controls over ingredients
- Labeling and claims
- Pre-market requirements
- Post-market surveillance

Controls over Ingredients

Registration requirements for new ingredients

- Under the Regulations for Hygiene Supervision over Cosmetics, new ingredients of cosmetics are subject to review and approval by SFDA.

- Procedures and required dossiers for new ingredient registration are prescribed in the Provisions for the Hygiene Permission on Cosmetics.

- The national standard of Safety Assessment Procedures and Methods of Cosmetics (GB 7919) specifies the procedures and methods for safety evaluation on cosmetic ingredients.

- Toxicological testing methods for safety assessment are prescribed in the Hygiene Standard for Cosmetics.
Regulation of cosmetics

Controls over Ingredients

Restrictions and prohibitions on ingredient

Restrictions and prohibitions on ingredients that can be used in cosmetics are included in various lists under the *Hygiene Standards for Cosmetics*:

- Annex II (1) lists over 1208 substances that are prohibited for use in the composition of cosmetic products;
- Annex II (2) lists 78 plants (extracts and products) that are prohibited for use in the composition of cosmetic products;
- Annex III lists over 73 substances which cosmetic products may contain when comply with the restrictions and conditions laid down;
- Annex IV is a positive list of over 56 preservatives that are permitted in cosmetic products;
- Annex V is a positive list of over 28 ultraviolet (UV) filters that are permitted in cosmetic products;
- Annex VI is a positive list of over 156 colorants permitted for use in cosmetic products; and
- Annex VII is a positive list of over 93 hair dyes permitted for use in cosmetic products.
Regulation of cosmetics

Labeling and Claims

Related regulations and standards

- **Labeling requirements**
  - Law of the People’s Republic of China on Product Quality (AQSIQ)
  - Regulations on Product Labeling (AQSIQ)
  - Regulations on Cosmetic Labeling (AQSIQ)
  - Use Instruction for Consumables—General Labeling Requirements on Cosmetics (AQSIQ)
  - Supervision Regulations on Measurement of Quantitative Packaged Commodity (AQSIQ)
  - Hygiene Standards for Cosmetics (MOH)

- **Regulatory requirements on claims**
  - The Regulations for Hygiene Supervision over Cosmetics (MOH)
  - The Guidelines for Cosmetic Naming (SFDA)
  - The Regulation for Cosmetic Naming (SFDA)
  - The Advertising LAW (SAIC)
  - Regulations on Administration of Cosmetic Advertisement (SAIC)
  - Regulations on Cosmetic Labeling (AQSIQ)

### Regulation of cosmetics

**Labeling requirements**

<table>
<thead>
<tr>
<th>Contents</th>
<th>Where</th>
<th>Front Size</th>
<th></th>
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<td>Production Place or Country of Original</td>
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<td>Production License Number, Hygiene License Number of Domestic Manufacturer</td>
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<td>SUC License Number, or Notification Number (applicable to imported ordinary cosmetics), and/or Product Standard Number (applicable to domestic cosmetics)</td>
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<tr>
<td>Directions for Use, Condition for Storage (when necessary)</td>
<td>Visible panels</td>
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</tr>
</tbody>
</table>
Regulation of cosmetics

- General introduction
- Regulatory bodies and responsibilities
- Controls over ingredients
- Labeling and claims
- Pre-market requirements
- Post-market surveillance

Regulations of cosmetics

Pre-market requirements:

- Administration of finished products
- Administration of manufacturing facilities
Pre-market requirements:

Administration on Finished Products

- Under the Regulations for Hygiene Supervision over Cosmetics, imported cosmetics and domestic Special Use Cosmetics are subject to pre-market review and approval by SFDA, while domestic ordinary cosmetics are subject to post-market notification to local authorities.

- The required tests, including physical & chemical test, microbiological test, toxicological test and human test for cosmetics are prescribed in the Requirements on Testing for Cosmetic Hygiene Permission.

- The hygiene specifications of finished cosmetics are prescribed in the Hygiene Standards for Cosmetics, including the limitation of microbe, heavy metals and methanol. Additionally detailed methods for physical & chemical tests, microbiological tests, toxicological tests and human tests are provided in this Standard.

The Flow Chart for Registering Domestic Special Use Cosmetics

1. Production Ability Review → Local FDA → 18 or 30 working days
2. Testing → Labs authorized by SFDA → 140 days for sunscreens and 80 days for anti-hyperpigmentation products
3. Submission of the registration dossiers → SFDA Acceptance Centre → 5 working days
4. Review/Evaluation → SFDA Expert Panel → 90 working days
5. Approval → SFDA → About 30 working days
6. Issuing the SUC license → SFDA Acceptance Centre → About 10 working days
The Flow Chart for Registering Imported Special Use Cosmetics

1. Testing
   - Labs authorized by SFDA

2. Submission of the registration dossiers
   - SFDA Acceptance Centre
   - 5 working days

3. Review/Evaluation
   - SFDA Expert Panel
   - 90 working days

4. Approval
   - SFDA
   - About 30 working days

5. Issuing the SUC license
   - SFDA Acceptance Centre
   - About 10 working days

140 days for sunscreens and 80 days for anti-hyperpigmentation products

The Flow Chart for Notifying Imported Non-special Use Cosmetics

1. Testing
   - Labs authorized by SFDA
   - 25 to 60 days

2. Submission of the registration dossiers
   - SFDA Acceptance Centre
   - 5 working days

3. Review/Evaluation
   - SFDA Expert Panel
   - 20 working days

4. Approval
   - SFDA
   - About 10 working days

5. Issuing the SUC license
   - SFDA Acceptance Centre
   - About 10 working days
### Testing requirements - Hygienic & Chemical Test

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<thead>
<tr>
<th>Item</th>
<th>Non-SUC</th>
<th>SUC</th>
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<tbody>
<tr>
<td></td>
<td>Hair Growth</td>
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<td>Antibiotics and Metronidazole</td>
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<td>Antiseptic and Antifungicides</td>
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### Testing requirements - Microbiological Test

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<th>Item</th>
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<td>Mold and Yeast Count</td>
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### Testing requirements-Toxicological Test

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<td>Cosmetics for Eye</td>
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#### Toxicological test for SUC

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<thead>
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<th>Item</th>
<th>Hair Growth</th>
<th>Hair Dyes</th>
<th>Hair Wave</th>
<th>Depilatories</th>
<th>Breast Enhancement</th>
<th>Body Shaping</th>
<th>Antiodorants</th>
<th>Whitening</th>
<th>Sun Protection</th>
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<tr>
<td>Acute Eye Irritation Test</td>
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<tr>
<td>Acute Dermal Irritation Test</td>
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<tr>
<td>Chronic Dermal Irritation Test</td>
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<td>○</td>
<td>○</td>
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<td>○</td>
<td>○</td>
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<tr>
<td>Skin Sensitisation Test</td>
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### Testing requirements-other test

#### Safety Test-in Vivo

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<thead>
<tr>
<th>Item</th>
<th>Hair Growth</th>
<th>Depilatories</th>
<th>Breast Enhancement</th>
<th>Body Shaping</th>
<th>Antiodorants</th>
<th>Whitening</th>
<th>Sun Protection</th>
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<tr>
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<td>○</td>
</tr>
<tr>
<td>In-use clinical study</td>
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<td>○</td>
<td>○</td>
<td>○</td>
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#### Evaluation of Efficacy of Sun Protection

<table>
<thead>
<tr>
<th>Item</th>
<th>SPF Detection</th>
<th>PFA Detection</th>
<th>Water Resistance Detection</th>
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<tbody>
<tr>
<td>Tests in vivo of UV Protection Efficacy of Cosmetic Sunscreens</td>
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<td>○</td>
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</tbody>
</table>
Regulation of Cosmetics

Pre-market requirements:

Administration on manufacturing facilities

Before being allowed to produce cosmetics in China, the manufacturing facilities are required to be evaluated and approved and licensed with Production License and Hygiene License by AQSIQ and provincial FDA respectively.

- Under the Regulations for Hygiene Supervision over Cosmetics, domestic cosmetic manufacturers shall obtain hygiene license before producing cosmetics. Detailed requirements for the hygiene permission are provided in the Hygiene Standards for Cosmetic Manufacturers. It’s divided into four units for this license, i.e. hair care, skin care, shaded, and perfume.

- According to the Regulation on Administration of Production Licensing for Industry Products, domestic cosmetic manufacturers are subject to production licensing. Detailed requirements are provided in the Detailed Rules for Implementation of Production Licensing Procedure for Cosmetics. It’s divided into five units for the license, i.e. emulsions, water-base, alcohol-base, wax-base and powders.

Regulation of Cosmetics

Pre-market requirements:

Administration on manufacturing facilities

- The Hygiene Standards for Cosmetic Manufacturers sets requirements on location of the plant, equipment and premises, raw materials and packaging components, production, stock handling and control, and sanitation and hygiene, which are similar to GMP requirements. Under this regulation, a quality control system is required to establish to ensure the products are manufactured under proper conditions according to standard operating procedures.

- Under the Detailed Rules for Implementation of Production Licensing Procedure for Cosmetics, similar requirements are set as compared to those set in the Hygiene Standards for Cosmetic Manufacturers.

- For licensing purpose, local provincial FDA and AQSIQ would come to the facilities to carry on on-site audit for compliance, and take samples for quality testings. Generally it takes about half a year for Production permission, while it takes about three months for Hygiene permission.
Regulation of cosmetics

- General introduction
- Regulatory bodies and responsibilities
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- Pre-market requirements
- Post-market surveillance

Post-market Surveillance

After product launch, both the cosmetic products and the manufacturers' facilities are subject to supervision and inspection by regulatory authorities, like local FDA, QTS and AIC through:

- Checking Hygiene License, Production License and certificates for individual products: local FDA comes to manufacturers and distributors to check the validity of Hygiene License, while the local QTS to check the validity of Production License.
- Checking the regulatory compliance of labeling claims: Local QTS focuses on compliance of labeling, while local branch of SAIC and local FDA focus on compliance of claims.
- Inspecting manufacturing facilities: local FDA and local QTS conduct inspection periodically and aperiodically on manufacturing facilities to correct any non-compliance with requirements of licensing facilities.
- Taking samples for testing from both plant and market: local branch of SAIC, local FDA and QTS have the right of taking samples for inspection. Usually, QTS takes samples from plants, while local AIC and FDA takes samples from both plant and market.
- Requesting for report on AE complaints: It is SFDA’s responsibilities to monitor AE caused by using cosmetics. Aperiodically SFDA would request the manufacturers to report AE situation.
Outlines

1. Regulatory framework in China

2. Preservatives and microbiology

3. Regulatory Issues

Preservative and Microbiology

In China, regulation requirements associated with preservatives and microbiology are mainly prescribed in the following three regulations:

- Hygiene Standards for Cosmetics
- Hygiene Standard for Cosmetic Manufacturers
- Requirements on Testing for Cosmetic Hygiene Permission
Preservative and Microbiology

In 1999, China MOH issued the Hygiene Standards for Cosmetics based on The Cosmetics Directive of the Council European Communities. The Standards was revised in 2002 and 2007 based upon the latest changes of the related regulations in USA, EU, Japan and other countries.

- Positive list of preservatives: It only referred to 76/768/EEC and the amendment before Nov. 21st, 2005. The usage of the 56 preservatives shall be in accordance with all the restrictions in the regulation, including maximum allowable concentration in cosmetics, scope of usage, application condition and labeling requirements.
- Microbiological limitation on cosmetic products:

<table>
<thead>
<tr>
<th>Items</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total APC</td>
<td>≤ 500 (CFU/mL or CFU/g)</td>
</tr>
<tr>
<td>(for children products and cosmetics applied on eye area, lips and mucous membranes)</td>
<td></td>
</tr>
<tr>
<td>Fecal Coliforms</td>
<td>Negative by test</td>
</tr>
<tr>
<td>staphylococcus Aureus</td>
<td></td>
</tr>
<tr>
<td>Pseudomonas Aeruginosa</td>
<td></td>
</tr>
<tr>
<td>Yeast and Mold Count</td>
<td>≤ 100 (CFU/mL or CFU/g)</td>
</tr>
</tbody>
</table>

- Methods of Microbiological Tests: Details of the microbiological test methods and the general principles for cosmetic testing are stipulated in Chapter 4 of the Standards, including the methods for Aerobic Bacterial Count, Fecal Coliforms, staphylococcus Aureus, Pseudomonas Aeruginosa, Fecal Coliforms, staphylococcus Aureus, Pseudomonas Aeruginosa, Moulds and Yeast Count.

Preservative and Microbiology

The Hygiene Standards for Cosmetic Manufacturers stipulates hygiene requirements on location, premises, equipment, raw materials and packaging components, production, storage and in-out stock, bylaw, and personnel for cosmetic production.

- Microbiological limitation:

<table>
<thead>
<tr>
<th>Items</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>During production, the air quality in the</td>
<td>Total APC ≤ 1000 (CFU/m³)</td>
</tr>
<tr>
<td>storage area of hold tank, filling area,</td>
<td></td>
</tr>
<tr>
<td>storage area of cleaning containers and</td>
<td></td>
</tr>
<tr>
<td>change room</td>
<td></td>
</tr>
<tr>
<td>The surface of tables in filling area</td>
<td>Total APC ≤ 500 (CFU/m³)</td>
</tr>
<tr>
<td>The hands of workers</td>
<td>Total APC ≤ 500 (CFU/hand)</td>
</tr>
<tr>
<td>And the objectionable organism should be</td>
<td>Negative by test</td>
</tr>
<tr>
<td>negative by test</td>
<td></td>
</tr>
</tbody>
</table>

- Location of lab and instruments, and equipment in lab shall meet with the regulatory requirements.
- Staffs working on hygiene testing shall have a basic knowledge of microbiology and be trained well.
- Additionally, it is required that facilities, equipments, and process layout shall minimize cross-contamination.
In the *Requirements on Testing for Cosmetic Hygiene Permission*, there are detailed testing requirements of microbiological quality of cosmetic products. The condition for not requiring microbiological test is also prescribed:

- For cosmetics used to remove nail color, microbiological test can be omitted.
- For cosmetics whose ethanol content is $\geq 75\% \ (w/w)$, microbiological test can be omitted.
- If micro test result is out of spec, it is not allowed to repeat the test during.

**Preservative and Microbiology**

**Outlines**

1. Regulatory framework in China
2. Preservatives and microbiology
3. Regulatory Issues
Regulatory Issues

Key Issues

瘦身 Impact from negative reports

There has been great concern with safety issues associated with cosmetics. After experiencing several public incidents, like dioxane, and asbestos in cosmetics, the government authorities have been put a big pressure from the consumers and the media. To lower potential risks, the government authorities have to take more strict way to administrate products and manufacturers. As a result, China is going to be a higher regulator oversight market.

瘦身 Overlapped regulations

There are multi-regulatory bodies, like the National People's Congress, State Council, SFDA, AQSIQ, MOH, and SAIC. The regulations are overlapped, and some even are conflicted. For example, definition of cosmetic in MOH regulations is different from that in AQSIQ regulations. And the definitions are also different in different AQSIQ regulations. In market surveillance, the industry has to repeat burdensome explanation. Labeling is another area where duplicate and overlap requirements add complexity for cosmetics companies. Likewise, MOH and AQSIQ enforce duplicative licensing requirements for manufacturing facilities in China, adding costs and burdens to manufacturers.

瘦身 Ingredients new to China

There has been no clear base for determination of a new ingredient. And the requirements on safety substantiation of a new ingredient are also not clear. new ingredients must be registered before the final products are registered. Registration of special use cosmetics and imported cosmetics has been suspended if the expert panel of SFDA suspected that there were new ingredients in the registered formulae.

瘦身 Safety assessment on potentially hazardous substances

This new requirement of safety assessment on hazardous substances is under the new registration regulation on cosmetics, which has been implemented since April 1 this year. So far there has been no new special use cosmetic and imported cosmetic passed the review and approval of SFDA since April. It is because there has been no clear direction about the format and contents of the assessment report. China SFDA has formally issued the Guidelines for Risk Assessment on Hazardous Substances in Cosmetics. Although the guidelines could not completely address the issue, it could help us better understand what SFDA wants.

Any questions?
Thanks for your attention