EU-Like Registration of New Cosmetic Ingredients (NCIs) in China

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The Main Purpose of this Presentation

To interpret the Chinese new cosmetic registration policy from the EU’s perspective
Outlines

• 1. NCIs Registration Scheme in EU
• 2. NCIs Registration Scheme in China
• 3. Comparison between EU and China
• 4. Regulatory challenges of NCIs in China
• 5. Compliance advices
Outlines

• 1. NCIs Registration Scheme in EU
• 2. NCIs Registration Scheme in China
• 3. Comparison between EU and China
• 4. Regulatory challenges of NCIs in China
• 5. Compliance advices
1. NCIs Registration in EU

Regulatory Provisions

- Here is no specific definition of ‘new cosmetic ingredient’ in 76/768/EEC, and its recast, 1223/2009/EC

- New entries into Annexes will be possible in accordance with Art 8(2) and Art 10 of 76/768/EEC, and Art 32(2) and Art 32(3) of 1223/2009/EC, through the method of ‘Adapting Annexes to Technical Progress (ATP)’

- Outcomes of ATP:
  1. Negative: prohibited or stricter condition of use for existing entries in Annex III to VII
  2. Positive: new inclusion into ‘positive list’, such as preservative or UV filters

- Positive ATP = ‘New Cosmetic Ingredients’ registration in EU
1. NCIs Registration in EU

**Basic Registration Procedure**

1. **Toxicological Dossier Submission**
2. **DG SANCO/European Commission**
   - Opinion
3. **Standing Committee on Cosmetic Products (Member States)**
   - Opinion
4. **Commission Directive on ATP**
5. **New Ingredients listed in Annexes**

**Scientific Committee on Consumer Safety (SCCS, scientific panel)**

- Request
- Opinion
Outlines

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• 5. Compliance advices
2. NCIs Registration in China

Regulatory Provisions

- Here is the clear definition on ‘New Cosmetic Ingredient’ in the umbrella law, Cosmetic Hygiene Management Regulation (CHMR).

- Art 9 of CHMR stated that ‘any new cosmetic ingredients should be subject to the pre-market review, prior to being used in cosmetic application’

- CFDA defines the new ingredient as the raw material, synthesized or occurring in nature, which is firstly applied in cosmetic products in China.

- Inventory of Existing Cosmetic Ingredients in China (IECIC) is the primary determinant for check the status of cosmetic ingredients as ‘New’ or ‘Existing’.
2. NCIs Registration in China

Basic Registration Procedure

Pre-Market Application Dossier Submission

CFDA Administrative Review Center (completeness check)

CFDA Cosmetic Evaluation Center (compliance check)

CFDA Administrative Review

Public Consultation

Pre-Market Approval

Request

Opinion

CFDA Expert Panel Review
Outlines

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3. Comparison between EU and China

#1 Similarity

No clear provision on the required data-set in the legal text, both 1223/2009/EC and CHMR Guidance is the our ‘pointing-guard’

- SCCS Guidance for the testing of cosmetic substances and their safety evaluation (8th version)
- CFDA Guidance on registration and administrative review on new cosmetic ingredients (12-May-2011)
3. Comparison between EU and China

#2 Similarity
The required data-set is quite the same

## Physicochemical Properties

<table>
<thead>
<tr>
<th>Endpoints</th>
<th>SCCS Guidance</th>
<th>CFDA Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Chemical identity</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>2) Physical form</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3) Molecular weight</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4) Purity/impurity</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5) Water solubility</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>6) Partition coefficient</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>7) UV-VIS-Absorption spectrum</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>8) Function and use</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>9) Additional PC data</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
3. Comparison between EU and China

<table>
<thead>
<tr>
<th>Toxicological Profile</th>
<th>SCCS Guidance</th>
<th>CFDA Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endpoints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) Acute toxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>2) Skin/eye corrosivity and irritation</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>3) Skin sensitization</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>4) Dermal absorption</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>5) Repeated dose toxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>6) Reproductive toxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>7) Mutagenicity/genotoxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>8) Carcinogenicity/chronic toxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>9) Toxicokinetics</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>10) Photo-induced toxicity</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>11) Human data</td>
<td>√</td>
<td>X</td>
</tr>
</tbody>
</table>
3. Comparison between EU and China

#3 Similarity

The safety assessment methodology is quite the same

SCCS Guidance

(1) Hazard Identification

(2) Dose-Response Assessment

(3) Exposure Assessment

(4) Risk Characterization

CFDA Guidance

(1) 危害识别

(2) 剂量反应关系评估(危害特征描述)

(3) 暴露评估

(4) 风险特征描述
3. Comparison between EU and China

#1 Difference
Regulatory acceptance of alternative methods

SCCS Panel Review
(1) Fully accept the in vitro data on skin irritation/corrosion and photo-irritation for safety assessment
(2) May accept the un-validated alternative results for safety assessment, on a case-by-case basis

CFDA Panel Review
(1) Be hard to accept the safety assessment results mainly based on alternative methods, especially in silico methods (QSAR)
(2) Be still ‘conservative’ in the alternative method results for safety assessment
3. Comparison between EU and China

#2 Difference
Reference data for exposure assessment

**SCCS Guidance**
1. Clear calculations method for the Systemic Exposure Dosage (SED) of a cosmetic substance
2. Amount of reference data on exposure assessment (such as exposed skin surface area or estimated daily exposure level)

**CFDA Guidance**
1. No clear statement on the SED calculation method
2. No clear reference data for exposure assessment
3. Comparison between EU and China

#3 Difference
Submission Body/Applicant

Applicant for Annex ATP under 1223/2009/EC
1. No clear regulatory provision on the qualification of the applicant to submit the toxicological dossier for new ingredient with inclusion of Annex III to VII
2. The applicant can be the industry association, EU legal entity, or Non-EU company

Applicant for NCIs registration in China
1. CFDA clearly define the qualification on the applicants
2. The applicants can be the ingredient manufacture or the related formulator, in China or aboard
3. Comparison between EU and China

#4 Difference
Scope of NCIs subject to pre-market application

NCIs under 1223/2009/EC
Annex III ~ VI
New colorant, preservative or UV filter

NCIs under CHMR
All types of new ingredients, besides colorants, preservative or UV filter
Milestones of NCIs Registration in EU and China

1976
Introduction of the Directive 76/768/EEC, the 1st EU level legislation

1989
China firstly introduce the umbrella law on cosmetics (CHMR)

1990
SCCNFP firstly issue the Guidance on safety assessment

1993
Firstly specify the provision on Annex amendments due to ATP (93/35/EEC)

2000
SCCNFP (former of SCCS) firstly issued the data-set requirement of toxicological dossier of new Annex entry

2003
China Ministry of Health firstly compiled the IECIC (only for internal use)

2004
China MoH firstly approved the NCIs registration

2008
China MoH delivered the authority to CFDA

2011
CFDA firstly published the Guidance on registration and review of NCIs

2012
Over 600+ opinions have been prepared by SCCNFP/SCCP/SCCS in the past 15 years

2014
CFDA intend to revise the management on NCIs registration

Key Item | EU | China | Time Behind
--- | --- | --- | ---
NCIs registration Data set | 2000 | 2011 | 10+ years
Safety Assessment Guidance | 1990 | 2011 | 20+ years
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4. Regulatory challenges in China

The position of CFDA could be that, the regulatory scheme on NCIs registration will not be changed, but the focus will be around to how to smooth the panel review procedures and limit the impacts on innovation.

To this end, here are three priorities of CFDA in 2014

(1) Revision on the Inventory of Existing Cosmetic Ingredients in China (around 8,000+ entries)

China Drafts a Consolidated List of 8641 Existing Cosmetic Ingredients (IECIC 2014)

By Echo Cao on Thursday, 23 January 2014 in Cosmetic News

(2) Revision on the administrative management of NCIs registration (such as 4-year proprietary protection), and updated the CFDA Guidance

China Makes Significant Amendment to New Cosmetic Ingredients Registration

By Echo Cao on Sunday, 26 January 2014 in Cosmetic News
4. Regulatory challenges in China

The position of CFDA could be that, the regulatory scheme on NCIs registration will not be changed, but the focus will be around to how to smooth the panel review procedures and limit the impacts on innovation.

To this end, here are three priorities of CFDA in 2014

(3) Establish the centralized notification system on domestically produced ordinary cosmetics, and strengthen the investigation on non-approved New Ingredients.
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Compliance Advices

✓ Oversea supplier should assign one local responsible agent for pre-marketing application;
✓ New cosmetic ingredient should be registered prior to being used in final product by CFDA;
✓ Recommend to evaluate the safety of ingredients by Chinese local assessors with well understanding of international principles;
✓ Be proactive to commission any animal testing for Chinese new cosmetic ingredient application;
✓ New ingredients regarded as the new chemicals under China chemical regulation, should be registered and approved by MEP before manufacturing or importing.
Company background

-Locations

Vancouver, Canada
Dublin, Ireland
Under establishment, US
Hangzhou, China

We call us as ‘REACH24H’ due to the fact that
(1) born in REACH services
(2) 3*8 hours services
Our services

- Industry chemicals
- Agrichemicals
- Pesticides and biocides
- Food and food contact materials
- Cosmetic and health products
- Information and news
- Registration and compliance
- Database and software
- Knowledge and training
Our Services

• 1. Pre-Market Application Service (for finished product and new ingredient)
• 2. Responsible Agent Service
• 3. In-depth Consultancy (from label/ingredient review to full market access)
• 4. Client-dependent Training (for oversea companies and your China supplier/distributor)
• 5. Chinese Trademark Registration (for clients with interests in Chinese brand name)
Thanks you for your attention!

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