A Glance at Chinese Regulations on Cosmetic Ingredients

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Outline

1. Introduction to State Food and Drug Administration (SFDA)
2. Evolution of Chinese cosmetic regulation
3. New cosmetic ingredient registration
4. Inventory of Existing Chemical Substances (IECS)
SFDA was established in 1998

Functions:

> a regulatory agency directly under the State Council,
> supervises food, health care products, cosmetics safety management and competent drug.
> responsible for the administrative and technical supervision of the research, production, circulation and the use of pharmaceutical product;
> responsible for the supervision and coordination, and organizations of food, health care products, cosmetics safety management and for investigation of the major accidents in accordance with the law
> responsible for the approval of the health care products
Ministry of Health to SFDA

Ministry of Health (MOH) regulated cosmetic prior to FDA:

- **9/26/1989**
  - issued Cosmetics Hygiene Supervision Ordinance
- **3/27/1991**
  - issued Cosmetics Hygiene Supervision Ordinance Implementation Rules
- **5/20/2005**
  - issues amended rules
  - issued Hygienic Standard for Cosmetics
- **2008**
  - passed the authority to SFDA
Cosmetics Hygiene Supervision Ordinance

Promulgated by: Ministry of Health
Date of enactment: November 13, 1989
Implementation date: January 1, 1990
Document No.: Ministry of Health Order No. 3

Chapter I Overview
Chapter II Supervision of cosmetics production hygiene
Chapter III Hygiene supervision of cosmetics business
Chapter VI Cosmetic hygiene supervision agencies and their responsibilities
Chapter V Penalty
Chapter VI Supplementary

Cosmetics Hygiene Supervision Regulations Implementing Rules

Document No.: Ministry of Health Order No. 13
Implementation date: March 27, 1991
Chapter II, Article 9

Production of cosmetics, new cosmetic raw materials must be approved by the State Council administrative department of health.

New cosmetic raw materials is the natural or synthetic materials used in the manufacture of cosmetics for the first time in China.
Chapter V  Penalty

1. Having their good and illegal earnings confiscated
2. A fine 3 to 5 times their illegal profits
3. Giving a warning or even publicizing the violation through media

Enforcement has been poor:

- MOH - cosmetic business is a new area in 1990s.
- FDA - local SFDA offices were asked to supervise since 2004, but had no executive power until recent years
Hygienic Standards for Cosmetics

- Issued by: Ministry of Health
- Date of enactment: January 2007

- General Principle
- Methods of Toxicological Test
- Methods of Hygienic Chemical Test
- Methods of Microbiological Test
- Methods of Safety and Efficacy Evaluation in Human
List of In-use Cosmetic Ingredients

4/27/2003 Minister of Heath issued a “List of In-use Cosmetic Ingredient” based on all approved formulas in China by 2000.

* This has become the only official list of approved ingredients up to now.

The list contains:

- General ingredients - 2156
- Generally restricted ingredients
  - Preservatives - 152
  - Sunscreen actives - 24
  - Colorants - 151
- Natural ingredients - 563
Ingredients with restricted use were updated

- Table 2 (1) - prohibited synthetic ingredients - 1028
- Table 2 (2) - prohibited natural ingredient - 78 and their extract
- Table 3 - Restricted cosmetic ingredients 73 (like Triclosan, ZPT)
- Table 4 - Restricted preservatives in cosmetic ingredients - 56
- Table 5 - Restricted sunscreen actives - 28
- Table 6 - Restricted colorants - 156
- Table 7 - temporarily allowed hair dyes - 93
Directory of Standard Chinese Names of International Cosmetic Ingredients

国际化妆品原料标准中文名称目录

1st Directory
- Published In 2007 by Ministry of Health

2nd Directory
- Published in 2010 by SFDA

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Notice on the Issuance of the Directory

3. Directory is not based on the safety evaluation of the listed ingredient. Cosmetic manufacturers should strictly follow the relevant laws and regulation, the relevant provisions of the standard when using the raw materials, and be responsible for the safety of the raw material.

4. New cosmetic ingredient, regardless if it is listed in the directory, should be used only after approval in accordance with the "Cosmetics Health Supervision Ordinance" and related regulations.
New List of Cosmetic Ingredients in Use

- **1st Set** - SFDA Health Food/Cosmetic Doc [2012] No.198
  - Published 12/6/11 and revised on 4/27/12
  - 1210 ingredients

- **2nd Set** - SFDA Health Food/Cosmetic Doc [2012] No.298
  - Published 6/28/12
  - 637 ingredients

- **3rd Set** - SFDA Health Food/Cosmetic Doc [2012] No.298
  - Published 6/28/12
  - 1356 ingredients

For ingredients with use level limits, the limits are set the same as in Hygienic Standard for Cosmetics issued in 2007
New Cosmetic Ingredient Registration
New Cosmetic Ingredient Registration

New Cosmetic Ingredient Registration Application and Review Guideline

-SFDA Health Food/Cosmetic Doc [2011] No.207
Issued: 5/12/11 Effective: 7/1/11

- Definition of New Cosmetic Ingredients

-- defined as a natural or artificial ingredient used in the manufacture of cosmetics in China for the first time.
How to define a new ingredient?

- On 2003 list of In-use Ingredients (excluding banned ingredient)
- Ingredient approved for use in special purpose cosmetic products
- Parts of a plant that has been used in cosmetic as a whole piece

* With the development of scientific research, SFDA may re-exam a previously approved ingredient
How to define a new ingredient?

- Ingredient listed in INCI dictionary
- Ingredient approved for use in non-special purpose cosmetic products
- Ingredient with safe use history in food products

New ingredient
Needs safety evaluation
Requirement of Application Dossier

1. Administrative Permit Application Form for new ingredient

2. R&D Report
   - Name, source, relative molecular mass, molecular formula, chemical structure, physical and chemical properties
   - Research background, process and related technological info
   - General info about the application in foreign countries
   - Intended application, application scope, use limits and restriction

3. Manufacturing process and flow chart

4. Quality and safety control requirements
   -- Specification, test method and supporting documents
5. Toxicological evaluation data

6. The applicant shall submit
   - the copy of authorization letter to a business unit in China
   - a copy of business license of the party in China responsible for registration with the official seal.

7. Other information that may contribute to the administrative licensing
Toxicology Test Requirement

1. The acute oral and acute dermal toxicity
2. Skin and acute eye irritation / corrosion
3. Skin allergy
4. Skin phototoxicity and light sensitivity (for those having UV absorption)
5. Mutagenicity (at least one gene mutation test and a chromosomal aberration test)
6. Subchronic oral and dermal toxicity
7. Teratogenicity
8. Chronic toxicity / carcinogenicity binding assays
9. Toxicokinetics and dynamic tests
10. Other test may be required according to the characteristics and uses of the raw material. If the new raw material has the similar chemical structure and characteristics as an approved ingredient, some tests can be waived.
Use of Alternatives to Animal Testing

- SFDA traditionally required animal toxicology test reports
- Started to consider alternative method due to pressure from EU and USA

2/10/12

-SFDA Health Food/Cosmetic Doc [2012] No.45;

Opinion Letter to solicit comments on Draft of In Vitro 3T3 Neutral Red Uptake phototoxicity test method “

关于征求《化妆品用化学原料体外3T3中性红摄取光毒性试验方法（征求意见稿）》意见的函
Common Problems in Application

1. No original documents. Documents in Chinese only.
2. Test report from a foreign lab is not the original (copy even with company stamp is not good)
3. Test report in foreign language is incomplete or not detailed enough (for example an abstract).
4. Use code instead of product name. No certification by the testing lab to prove the tested article is the ingredient
5. Test items are incomplete (use in-vitro as a replacement)
6. Only data was reported but not as a detailed formal report.
7. No observed adverse effect level (NOAEL) is obtained through calculation rather from actual testing
Special Notes for Applying

No. 1
Prepare the registration documents and follow the procedure EXACTLY according to the regulation

No. 2
Pay close attention to the R&D report and make sure that is complete

No. 3
If you do not have full confidence, hire an experienced Chinese consulting firm
Designated Testing Laboratory

关于印发《国家食品药品监督管理局保健食品化妆品指定实验室管理办法》的通知

Health food/Cosmetics Designated Laboratory Management

- SFDA Health Food/Cosmetic Doc [2012] No.149; Issued: 6/11/12

Designated Laboratory of X X, State Food and Drug Administration

- Carry out research in key areas of health food and cosmetic inspection technology, safety efficacy evaluation, and risk control
- To solve the basic, critical and forward-looking technology issues
- To train technical personnel and develop talent

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## Cosmetics Review Experts

### Administration of cosmetics review experts

《化妆品审评专家管理办法》

-SFDA Health Food/Cosmetic Doc [2010] No.301; **Issued: 7/29/10**

### Committee members:

Experts in the field of cosmetic raw materials, formulations, health, microbiology, toxicology, skin science and oversight management.

### General Review Meeting

**12 + members**

- new application
- renewal of approval
- application for a review

### Auxiliary Review Meeting

**3 + members**

- supplementary information
- changes to the approved product

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## Procedure for Launching Cosmetics in China

<table>
<thead>
<tr>
<th></th>
<th>Product registration</th>
<th>Labeling Record</th>
<th>New ingredient registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (approx.)</td>
<td>4 - 11 M</td>
<td>1 - 1.5 M</td>
<td>12 - 18 M</td>
</tr>
<tr>
<td>Sample quantity(pcs)</td>
<td>14 - 56</td>
<td>6 - 8</td>
<td>1 or more</td>
</tr>
<tr>
<td>Validity</td>
<td>48 M</td>
<td>Life time of record</td>
<td>Infinite</td>
</tr>
<tr>
<td>Agency</td>
<td>SFDA</td>
<td>Inspection and Quarantine Bureau</td>
<td>SFDA</td>
</tr>
</tbody>
</table>

- Only 8 ingredients have been approved since 2004

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**Chemical Inspection and Regulation Service Limited**
Inventory of Existing Chemical Substances (IECS)
Inventory of Existing Chemical Substances (IESCS)

Chemical Registration Center (CRC)
State Environmental Protection Administration (SEPA)

Issued on: 11/14/2004
Implementation: 12/30/2004

Amended
12/30/09

Issued on: 1/19/2010
Implementation: 10/15/2010

Cosmetic Ingredient (except natural ingredients)
- domestically made or imported is regulated

Finished cosmetic products,
- Exempted as they are regulated by MOH (SFDA)

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Inventory of Existing Chemical Substances (IECS)

http://www.crc-mep.org.cn/iecsweb/IECSC.aspx?La=1
Gaps in Regulations

- TRIOCTYLDODECYL CITRATE
- 三(辛基十二烷醇)柠檬酸酯
- CAS No. 126121-35-5

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFDA</td>
<td></td>
</tr>
<tr>
<td>2003 List of In-use Ingredients</td>
<td>Y</td>
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<tr>
<td>2004 CTFA Dictionary</td>
<td>Y</td>
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<tr>
<td>2010 List of In-use Ingredients (Draft)</td>
<td>Y</td>
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<tr>
<td>EPA</td>
<td></td>
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<tr>
<td>2009 Inventory of Existing Chemical Substances</td>
<td>N</td>
</tr>
</tbody>
</table>

How to deal with the gap in regulations in China is an art.
Commercial Finished Products

Examples from Baidu.com search

Revlon (露华浓) Super Lustrous Lipstick 成分 | CosDNA
> 化妆品... Trioctyldodecyl citrate 三个辛基十二烷醇柠檬酸酯, ... 柔首页 单一成分分析 化妆品搜寻 原料成分买卖 论坛 CosDNA润剂 Ozokerite...
www.cosdna.com/chs/cosmetic_492e759... 2012-11-15 - 百度快照

LelanVital水漾盈润唇膏让您的双唇丰润娇嫩性感诱人 上海
物品类型:化妆品 产品标签:化妆品 物品形态:二手 物品所属:个人 ..
三个辛基十二烷醇柠檬酸酯,辛基-对-甲氧基肉桂酸酯,月桂酸三酯
shanghai.jinti.com/huazhuangpin/4201... 2012-11-7 - 百度快照

EsteeLauder/雅诗兰黛 弹性紧实活颜柔肤晚霜
化妆品 服装 鞋子 包包 配饰 家居 兴趣 福利汇 品牌
三个辛基十二烷醇柠檬酸酯,肌酸,维他命C磷酸氨盐,野生
pin.abang.com/product/mianshuang/lau... 2012-11-4
1. Cosmetic products are currently regulated by SFDA. Under its governance, regulatory research and policy making have been more active, and regulations have become more comprehensive.

2. All regulations are available to the public on the internet. However, clarity in the interpretation of regulations is still lacking.

3. There are gray areas in regulations, which demand regulatory experiences in China and understanding of Chinese government culture.
1st US-China Cosmetic Regulatory Symposium

May 16, 2012

SFDA officials
Experts from Chinese Academia and Institute
Chinese regulatory consultants
Global regulatory Experts

Organized by:
NYSCC
Chinese-American Cosmetic Professional Association

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