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What is New

18 April 2012, Free Webinar: Updates of SFDA Registration of Cosmetics and Cosmetic Ingredient in China

21 Feb 2012, China SFDA publishes draft guidelines for the registration and evaluation regarding cosmetics for children

25 Feb 2012, China SFDA consults on re-classification of cosmetics and adjustment of registration requirements.

6 Sept 2011, CIRS to Host 2011 Shanghai Summit Meeting on Chemical Regulations in China, Korea and Japan.

18 Aug 2011, CIRS to Build China Chemical Toxicology and Risk Assessment Centre (CCTRAC) with China Entry & Exit Inspection and Quarantine Bureau(CIQ) Ningbo

SFDA Registration of Imported Cosmetics in China - Hygiene License, Record-keeping Certificate and CIQ labels

In China, cosmetics and cosmetic ingredients are regulated by the following laws:

Regulations concerning the hygiene supervision over cosmetics (1990);
 Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics(2005);
 Hygienic Standard for Cosmetics(2007)
 The Measures for the Administration of Hygiene License for Cosmetics (revised in 2010);
 Guideline for Risk Evaluation of Substances with Possibility of Safety Risk in Cosmetics(2010);
 Standard Chinese Names of International Cosmetics Ingredients Inventory (2010);
 Cosmetics Technical Requirement Standard(2011);
 Guideline of Cosmetic Ingredients Application and Review(2011);
 AQSIQ Order No. 143 of 2011 - The Administrative Measures on the Inspection, Quarantine and Supervision of Chinese Imported & Exported Cosmetics (2011)

For finished cosmetics, companies who plan to place cosmetics on Chinese market must apply for and obtain **hygiene license** or **record-keeping certificate** from Health Administrative Department of the State Council - State Food and Drug Administration (**SFDA**). Foreign companies shall appoint a Chinese responsible agent to deal with registration and obtain such certificate.

Please contact [April Guo](#) if you would like to get a full list of cosmetics regulations in China and national standards related to cosmetics. You can also download April's latest presentation about cosmetics registration [here](#).

What is New?

14 March 2012, China Exit-Entry Inspection and Quarantine Bureau(CIQ) has issued a public notice to stop issuing CIQ labels for imported cosmetics that have passed CIQ's inspections. For more info, please click [here](#).

Definition of Cosmetics and Classification

Cosmetics are defined as daily used industrial chemicals which can be spread on the outer surface of human body (e.g. skin, hairs, nails, lips etc) for the purpose of cleaning, deodorizing, providing skin care, beauty and make – up, by way of smearing, spraying or other similar means.

Imported cosmetics are divided into two classes: ordinary cosmetics and special use cosmetics. Each class requires different type of license from SFDA.

Type of Product	Required SFDA License	Who Shall Apply?
Ordinary cosmetics hair care, nail care, skin care, perfumes and make-up	Record-keeping Certificate	A Chinese responsible agent appointed by a foreign manufacturer
Special use cosmetics products for hair growth, hair dye, hair perm, hair removal, breast shaping, fitness, deodorizing, spots removal and sun block	Hygiene License (More expensive and time-consuming)	
New Cosmetic Ingredient	Hygiene License	

What is New?

On **17 February 2012**, the Chinese State Food and Drug Administration (SFDA) has issued a notice No. 57-2012 inviting public comments on the latest draft administrative measures for non-special use cosmetics. The draft measures have changed how cosmetics shall be categorized in China dramatically and adjusted registration requirements for different types of cosmetics.

The biggest noticeable change is that some of non-special use cosmetics



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[Presentation: Application of SFDA license and CIQ label for imported cosmetics in China by Ms April Guo](#)

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[China New Substance Notification\(IECSC\)](#)

[EU Cosmetics Registration](#)

under the current law will be moved to **type II special use cosmetics** and be subject to stricter requirements. The change will have a great impact on companies who plan to register or who have registered ordinary cosmetics in China.

For more info, please click [here](#).

Requirements of Ingredients in Cosmetics

The Hygienic Standard for Cosmetics published by the Ministry of Health in 2007 has banned over 1200 chemicals in cosmetics and restricted the use of 73 chemicals, 56 preservatives, 156 colorants, 28 sun block agents and 93 dyes in cosmetics. Before companies apply for hygiene license or record-keeping certificate, companies shall make sure their formula meets this hygienic standard.

Companies shall also check if there is any new ingredient in their product. A new ingredient that is not currently listed on the Inventory of Existing Cosmetic Ingredients in China (IECIC) also requires registration with SFDA. However, a new ingredient might not require registration if there is proof that the ingredient has been used in approved cosmetics in China before. It is very difficult and expensive to register a new ingredient. Please contact us to review your formula and cosmetic ingredients to determine if your ingredient is approved to be used in China.

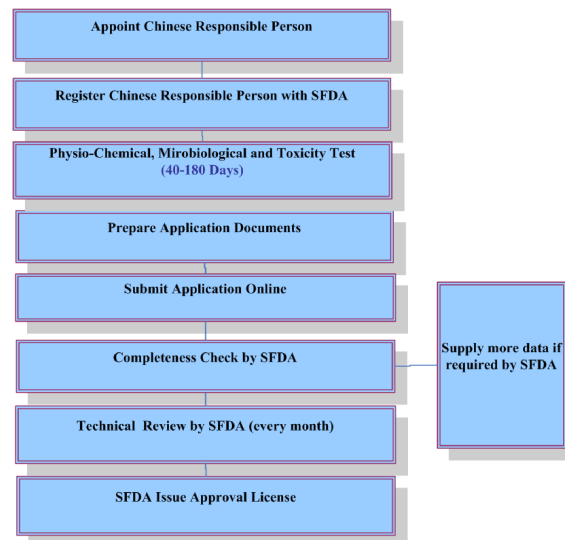
In addition, a new cosmetic ingredient might be subject to the requirements of new chemical notification in China.

Please contact [April Guo](#) if you would like to know whether all ingredients in your cosmetic product are approved to be used in China.

Application of Hygiene License or Record-keeping Certificate

The following documents are required for application of hygiene license or record keeping certificate:

- Application form for license;
- Product ingredients;
- Effective components, evidence of use and inspection methods;
- Manufacturing technique and diagram;
- Product quality standard;
- Testing report from a cosmetics testing institution approved by the SFDA and related materials;
- Product package (sales package & product label);
- Certified document for production and sales in the manufacturing country (region);
- The statement on related problems of 'Mad Cow Disease';(new)
- Power of attorney, if responsible person has been appointed;
- Some other documents that may be helpful for inspection;



Note: Technical review is not required for ordinary cosmetics. It takes **4-6** months to obtain record-keeping certificate for ordinary cosmetics and **8-15** months to acquire hygiene license for imported specific use cosmetics.

Testing Requirements

According to the official implementation of the national standard: Procedures and methods of safety evaluation for cosmetics (**GB 7919-87**), all testing items below are required for new cosmetics ingredients. For finished cosmetics, only some of the testing items below are required.

- Physiochemical and microbiological testing;
- Acute oral toxicity and acute dermal toxicity;
- Acute dermal irritation and acute eye irritation;
- Dermal sensitization;
- Dermal photo-toxicity test & dermal photosensitivity;

Sub-chronic oral toxicity and dermal toxicity;
 Teratogenicity test;
 Mutagenicity test;
 Chronic toxicity and carcinogenicity test;
 Safety evaluation of using tests of cosmetics on human body;

For finished cosmetics, only some of testing items above are required depending on the type of cosmetics. Please consult [April Guo](#) to find out which tests need to be carried out for your products.

Labeling Requirements

According to the official implementation of the national standard: Instruction for use of consumer products— general labeling for cosmetics (**GB5296.3-2008**), the following information, in Chinese, needs to appear on a label for cosmetics:

Product name;
 Name and address of the manufacturer;
 Net content;
 Product ingredients;
 Shelf life;
 The code of manufacture license and product standard;
 The code of hygiene license or record-keeping certificate;
 Safety statement and guidance on uses;

In case of imported cosmetics, country of origin and the name and address of the distributor in China shall also be given on the label. Besides, a **CIQ** label needs to be acquired from AQSIQ. An imported cosmetic with a CIQ label means it has already passed the examination of China Entry-Exit Inspection and Quarantine Bureau and is allowed to be sold in China. Consumers will check the CIQ label before purchasing imported cosmetics.

CIQ Inspection of Imported Cosmetics

Even though CIQ labels will no longer be required for imported cosmetics from 1 Feb 2012, CIQ's inspection is mandatory. For **cosmetics imported to China for the first time**, Chinese importer needs to provide the following documents when applying for an inspection from CIQ:

A self-declaration letter stating that the imported cosmetic product complies with relevant Chinese laws and the normal use of the product will not cause any harm to human health;
 Product formula;
 Hygiene license or record-keeping certificate;
 For cosmetics exempted from hygiene license or record-keeping requirement, the following documents are required:

Safety evaluation report issued by the qualified institutions for substances of potential safety risks; and
 Documentation that permits the production and distribution of the imported cosmetics in the country of production or a Certificate of Country of Origin;

Sample labels in Chinese, product labels in the original language and the translated text in Chinese;

Information on the product name, volume/weight, specifications, country of origin, batch number, expiry date (production date and shelf life), target market, and information about packaging company;
 Other documentation required by AQSIQ.

Please note that non-trade cosmetics (for example, product samples, R&D samples) are exempt from CIQ's inspection.

How Much Does Application Cost Per Product?

The total costs of application consist of three parts: Testing fee, risk evaluation fee charged by approved inspection authorities and consulting fee. The total costs vary among different service providers, quoted prices in various inspection authorities, and test items for the distinct usages of cosmetics.

Generally speaking, the total application cost of record-keeping certificate for imported ordinary cosmetics is between 10,000 and 30,000 RMB per product.

The total application cost of hygiene license for imported specific use cosmetics is between 20,000 and 60,000 RMB per product.

The total application cost of hygiene license for new cosmetic ingredient is between 80,000 and 100,000 RMB per ingredient.

Please note the above cost estimation does not include risk evaluation fee and human body test.

Our Services

Previously set up by China Inspection and Quarantine Bureau (CIQ), CIRS has strong presence in China and close links with regulatory authorities in China, especially CIQ. CIRS China can act as the Chinese responsible agent, coordinate testing, prepare application materials and obtain hygiene license or record-keeping certificate and CIQ labels for your cosmetics products.

If you wish to avail of our integrated compliance solutions for the entry of cosmetic products or cosmetic ingredient into China, please don't hesitate to

consult us.

Contact Us

Ms April Guo, CIRS China

Specialized field: application for hygiene License, record-keeping certificate for imported cosmetics, safety evaluation of cosmetics and cosmetic ingredients, standard labelling for cosmetics, SFDA registration, CIQ label, etc.

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