

# Application of SFDA license and CIQ label for imported cosmetics in China



*Enabling Chemical Compliance  
for A Safer World*

11 August 2011, April Guo, Regulatory Affairs Specialist  
Email: [april.guo@circs-reach.com](mailto:april.guo@circs-reach.com)



# Contents

- Overview of cosmetics regulations in China
- Definition and classification of cosmetics
- Type of SFDA license, application procedure and data requirement
- Cost and duration of application
- Labeling requirement and CIQ label

# Overview of cosmetics regulations in China

Cosmetics Regulations	Implementation Date
<b>REGULATIONS CONCERNING THE HYGIENE SUPERVISION OVER COSMETICS</b>	1-Jan-90
<b>Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics</b>	1-Jun-05
<b>Provision for Naming Cosmetics</b>	5-Feb-10
<b>Guideline of Naming Cosmetics</b>	5-Feb-10
<b>Measures for the Administration of Hygiene License for Cosmetics</b>	11-Feb-10
<b>Guideline for Risk Evaluation of Substances with Possibility of Safety Risk in Cosmetics</b>	23-Aug-10
<b>Main Points of Cosmetics Technical Review</b>	28-Sep-10
<b>Guidelines for the Technical Review of Cosmetics</b>	28-Sep-10
<b>Provision of Application Accepting of Cosmetics Hygiene License</b>	1-Apr-10
<b>Cosmetics Technical Requirement Standard</b>	1-Apr-11
<b>Technical Manual of Testing Method Validation for Forbidden and Restricted Substances in Cosmetics</b>	29-Nov-10
<b>Standard Chinese Name of International Cosmetics Ingredients Inventory (2010)</b>	1-Apr-11
<b>Cosmetics Sanitation Standard (2007)</b>	1-Jan-08
<b>Guideline of Cosmetic Ingredients Application and Review</b>	1-Jul-11
<b>Investigation Essentials of Cosmetics Hygiene License Accepting</b>	2-Nov-10

# Overview of cosmetics regulations in China

All imported cosmetics can only be sold on the Chinese market after they have obtained the document of **hygiene license** or **record-keeping certificate** issued by the SFDA (the State Food and Drugs Administration) and **CIQ labels** issued by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

<b>For companies in China</b>	<b>For foreign companies</b>
<ul style="list-style-type: none"><li>• Apply for hygiene license or record-keeping certificate if needed.</li><li>• Apply for CIQ label when importing cosmetics to China.</li></ul>	<ul style="list-style-type: none"><li>• Apply for hygiene license or record-keeping certificate by appointing a local Chinese responsible agent.</li></ul>

# Definition and classification of cosmetics



# Definition

- ◆ Cosmetics are 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, skin care, beauty and make – up, by the way of smearing, spraying or other similar means.



# Classification



Ordinary cosmetics	Special use cosmetics
Hair care	Hair growth
Nail care	Hair dye
Skin care	Hair perm
Perfumes	Hair removal
Make - up	Fitness
	Breast shaping
	Spots removal
	Deodorizing
	Sun block



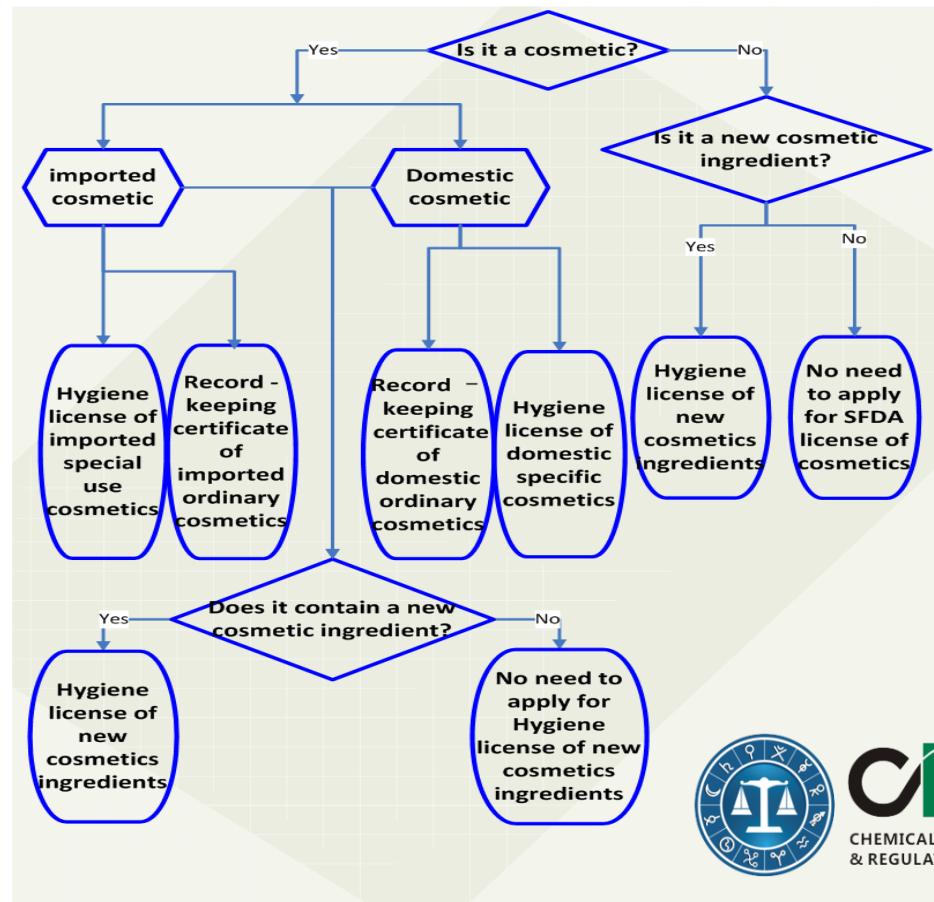
# Type of SFDA license, application procedure and data requirement



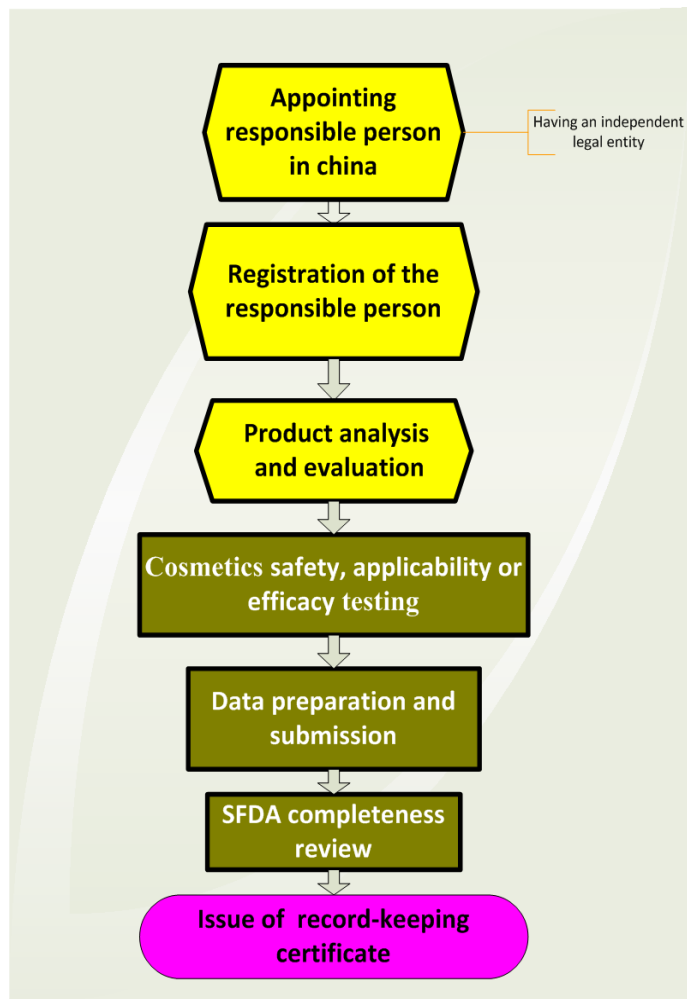


# Type of SFDA license

- Record-keeping certificate for ordinary cosmetics
- Hygiene license for specific use cosmetics and new cosmetics ingredients

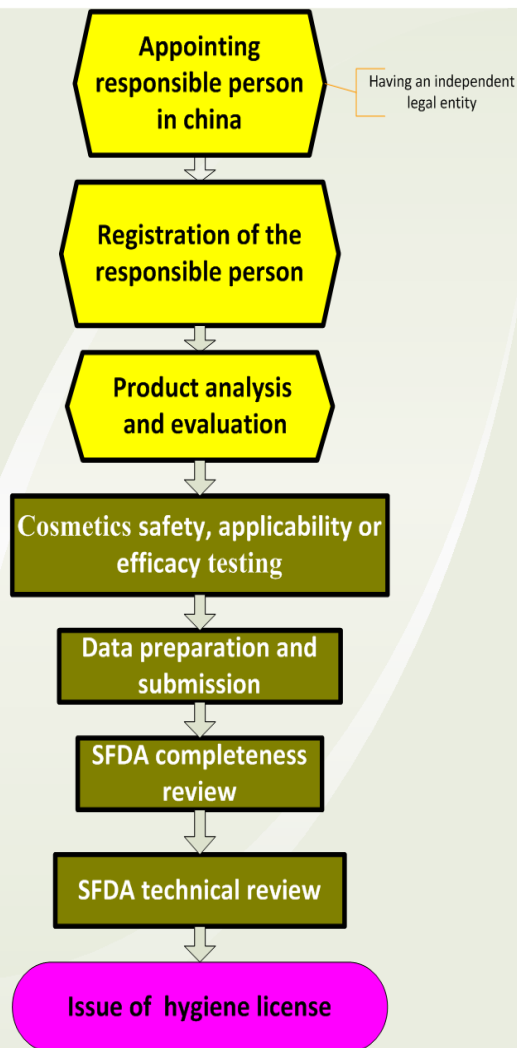


# Record-keeping Certificate for Ordinary Cosmetics



Data Required
(1) Application form
(2) Chinese product name and basis of nomenclature
(3) Product formula
(4) Requirements for product quality and safety control
(5) Original packaging of products (including product label and product information sheet) <i>Note: the applicant will also supply packaging design of products (including product label and product information sheet), if the packaging is designed for Chinese market specially.</i>
(6) Testing report and relevant data from inspection organizations certified by Ministry of Health of China (except for the report of body safety test)
(7) Safety assessment data of substances having a possibility of safety risk in products
(8) Stamped copies of power of attorney and business license of responsible person in China registered
(9) Letter of commitment that the new cosmetic ingredients meet the forbidden or restricted requirements for high-risk substances from the regions with high incidence of mad cow disease
(10) Manufacture and sale license of products in the producing country (area) or source country (area)
(11) Other materials which are helpful for review
(12) Brief description and diagram of production process
(13) Text version information of technical requirements for cosmetic products

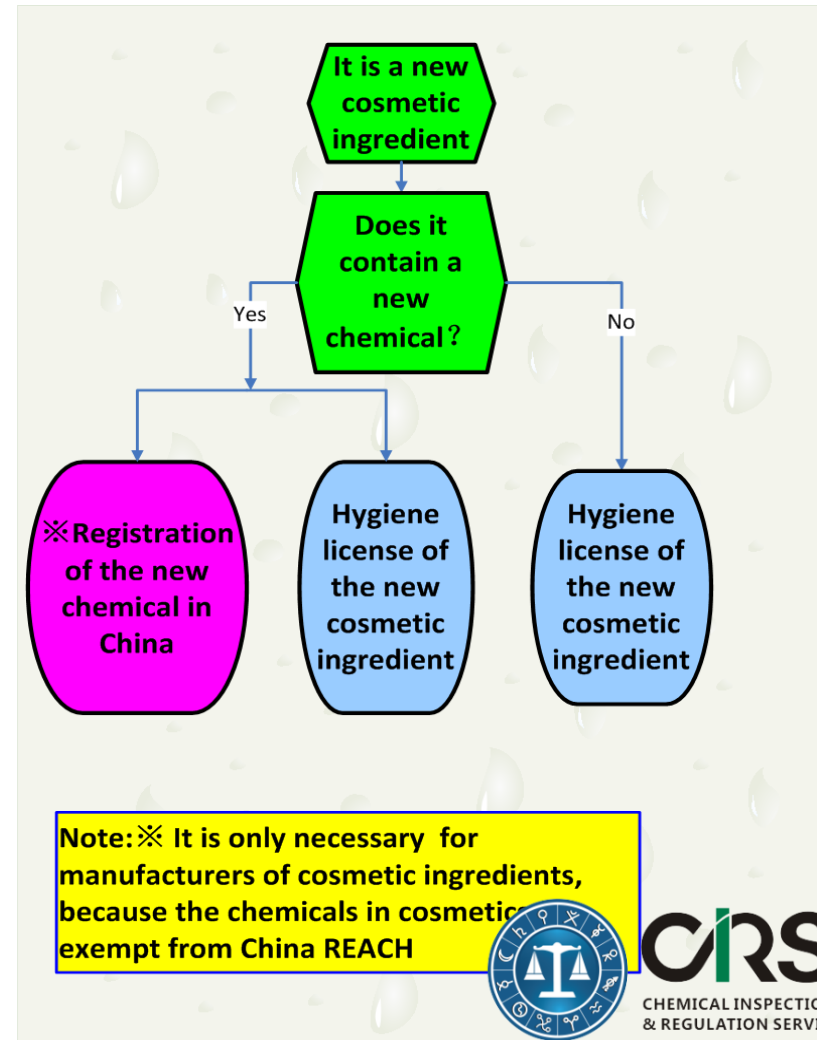
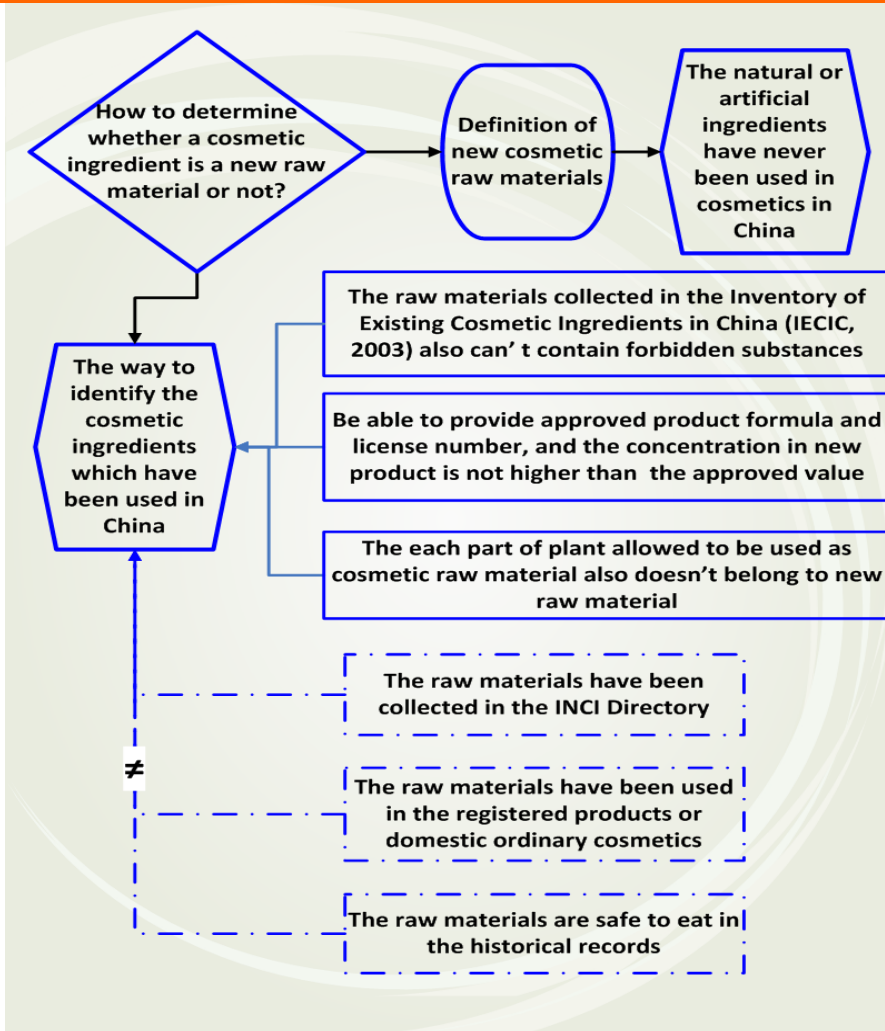
# Hygiene License for Special Use Cosmetics



Data preparation
(1) Application form
(2) Chinese product name and basis of nomenclature
(3) Product formula
(4) Brief description and diagram of production process
(5) Requirements for product quality and safety control
(6)* Original packaging of products (including product label and product information sheet)
(7) Testing report and relevant data
(8) Safety assessment data of substances having the possibility of security risk in products
(9) Submitting efficacy ingredients and relevant basis of cosmetics such as hair growth, fitness and breast shaping
(10) Stamped copies of power of attorney and business license of responsible person in china registered before
(11) Letter of commitment that the cosmetic ingredients meet the forbidden or restricted requirements for high-risk substances from regions with high incidence of mad cow disease
(12) Manufacture and sale license of products in the producing country (area) or source country (area)
(13) Other materials which are helpful to review
(14) Text version information of technical requirements for cosmetic products

\* The manufacturers will supply packaging design of products (including product label and product information sheet), if the packaging is designed for Chinese market specially

# New cosmetic ingredients



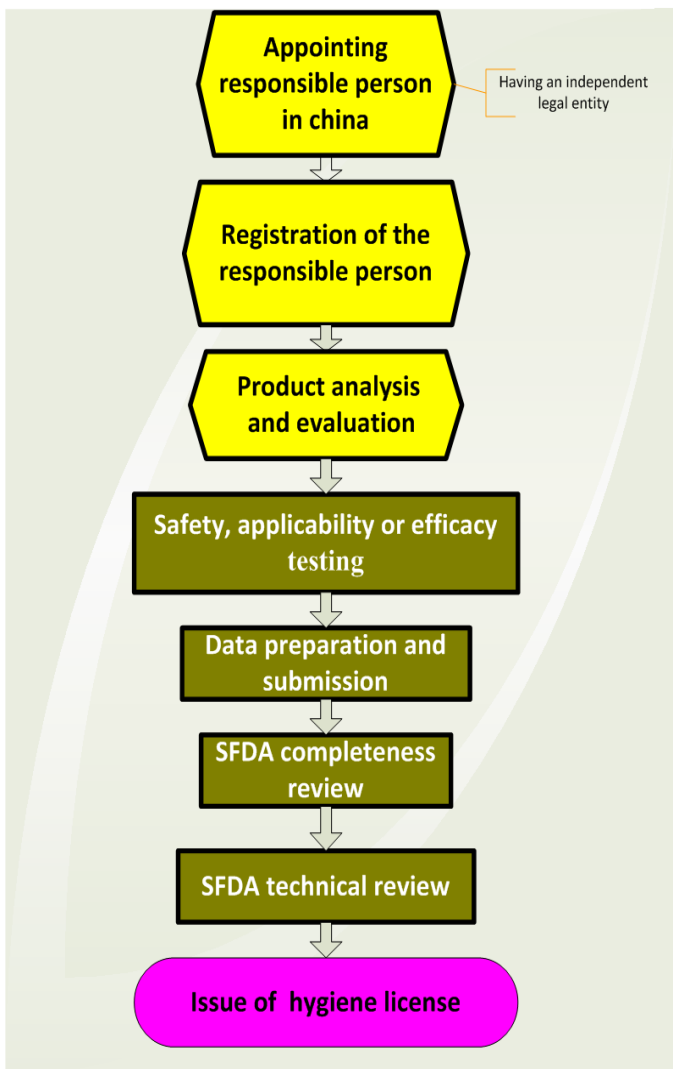
# Regulations on cosmetic ingredients

## ■ Standard Chinese Name of International Cosmetic Ingredients Inventory (2010)

- Total number of cosmetic raw materials: 15649
- Contents: INCI name, Chinese name and CAS
- All of the materials without any safety evaluation are not allowed to be used in China

## ■ Inventory of Existing Cosmetic Ingredients in China (2003; Not in public)

# Hygiene license for new cosmetic ingredients



Data Required
(1) Application form
(2) Research report can be divided into three parts: the first part includes the background and course of raw materials development and relevant technical data. The second part is to clarify the source of raw materials, physical and chemical characteristics, chemical structure, molecular formula and molecular weight. The third part describes some information of raw materials used in cosmetics containing the purpose, basis, scope of use and the limit value for use of raw materials.
(3) Brief description and diagram of production process
(4) Requirements for raw material quality and safety control (including test methods, specifications, etc)
(5) Toxicology safety assessment data
(6) Providing the proof of principle - agent
(7) Other information which are helpful for review

# Application cost and duration of application

# Application cost

Procedure of Registration		Testing Fee (Euros/ per product)	Consulting Fee*(Euros/ per product)	Risk evaluation fee*(Euros/ per product)	
Prepare application	Translation & notarization		N/A	N/A	
	Appoint Chinese responsible person				
	Submit Application				
Safety tests or Physio-Chemical, Microbial and Toxicology Test	specific cosmetics	deodorants	1000-1200	1200-1800	For example,  Dioxane 60-80 Phenol 60-80 Methanol 40-60 Methanal 40-60  pesticides (43parameters) 200-300
		perm products	1000-1200		
		sun block products	2200-2400		
		anti-freckle products	2000-2200		
		hair dye products	1400-2200		
		grow hair products	3200-3600		
	ordinary cosmetics	body building and beautify breast products	2400-2600	800-1200	
		hair products	700-800		
		manicure/pedicure products	500-600		
		skin care products	800-1000		
		perfume products	500-600		
		cosmetics	800-1000		
		New cosmetic ingredient	>3000		5000-6000
SFDA Review and Issue the License	Specific use Cosmetic		For free		
	Ordinary use Cosmetic				
	New cosmetic ingredient				

※ Including the cost of application preparation, Testing coordination, translation & notarization

Note: The laboratory will charge risk evaluation fee only for cosmetics with safety risk substances. For example, if the cosmetic ingredient is natural, the pesticide residue test needs to be carried out.





# Duration of application

Application process		Duration
Duration of testing (qualified inspection organs)	Special use cosmetics	60-80 days※
	Ordinary cosmetics	40-60 days
	New cosmetics raw material	6-12 months
Data preparation and application (responsible person in China)	Translation and notarization	5-10 days
	Authorizing a china responsible agency or representative agency) Data preparation and submission	25-30 days
SFDA review (once every month for technical review/the duration of application will be extended if adding test items or data)	Special use cosmetics	115 days
	Ordinary cosmetics	25 days
	New cosmetics raw material	115 days

※ The duration of test for products like hair growth, fitness and breast shaping is about 150 days. The duration needs to be extended if the test of SPA and PA value is required for sun block products.



# Labeling requirement and CIQ label



# Labeling requirement

Label contents
Product name
Net content
Name of the manufacturer
Address of the manufacturer*
Hygiene license number or record-keeping certificate number*
Country of origin*
Name of the responsible person in China / importer / distributor*
Address of the responsible person in China / importer / distributor*
Ingredient list
Date of manufacture and shelf life / batch code and expiration date
Warning statements*
Instructions for use*

*Note: for sun-block cosmetics, SPF value or UVA shall also be mentioned*

\* for cosmetics with content less than 15g or 15ml, these label contents do not need to be put on the label. However, they shall be mentioned in a leaflet that comes with the cosmetics

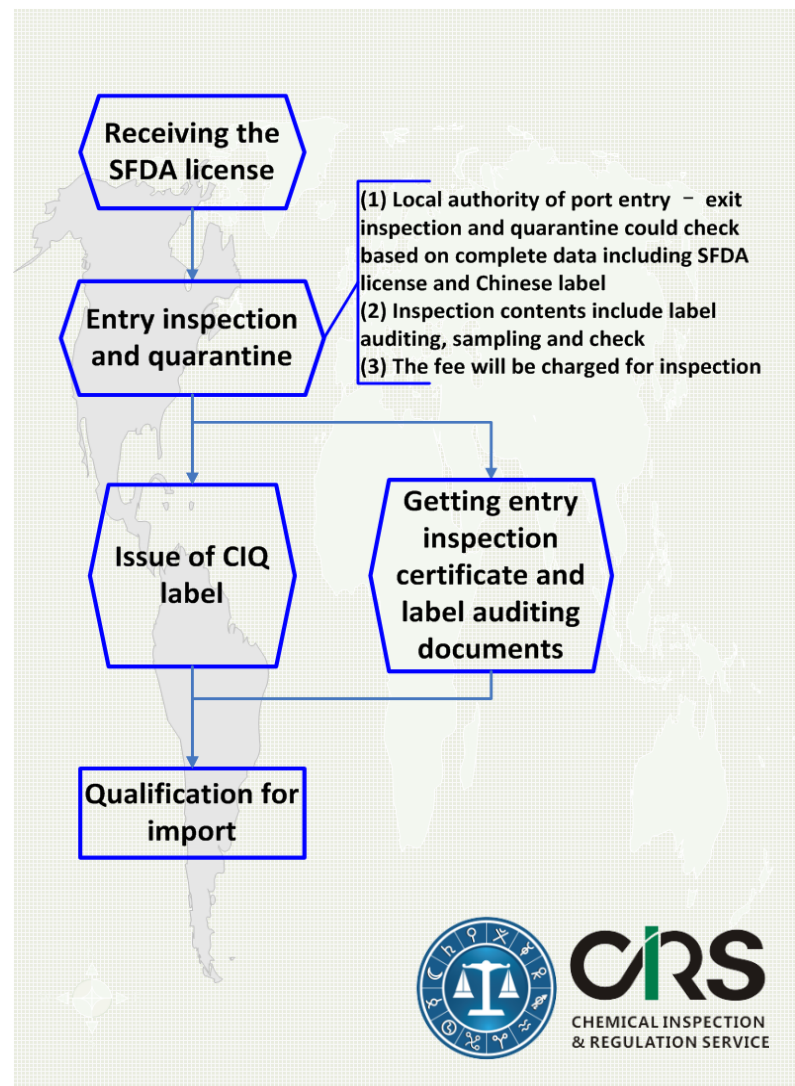
# CIQ label

It is a laser label adhered onto the packages of imported cosmetics which have been approved by China Entry-Exit Inspection and Quarantine Bureau(CIQ) for sale in the Chinese market



## Notes:

- (1) CIQ will charge at least 0.15% of the total value of goods as inspection fee.
- (2) It will take at least 1 month to get CIQ label;
- (3) Chinese importer shall apply for CIQ label with SFDA license provided by foreign companies.





# Thank You!

More info at <http://www.cirs-reach.com>

