

international business relations

TIME TO ENTER CHINESE COSMETICS MARKET WITHOUT ANIMAL TESTING



TABLE OF CONTENT

Background	3
The tremendous growth of the Chinese cosmetics market	
The fast recovery from COVID-19	
Cosmetic Supervision and Administration Regulations (CSAR)	4
Introduction of the Chinese cosmetics market	4
What you should know before entering the Chinese market	6
How are cosmetics products classified in China?	6
What are the dossiers necessary for cosmetic registration/recordation?	8
What are the requirements of cosmetics labeling?	9
How to avoid animal testing?	9
Option 1: Cross-border e-commerce	9
Option 2: Do the filling in China	10
Option 3: Animal testing exemptions	10
Conclusion	12
Relevant regulations/guidelines overview	13
CSAR and New Regulatory Framework	13
Brief introduction on several regulations	13
About the author	15

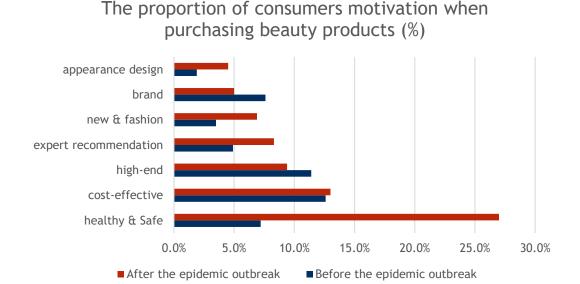
BACKGROUND

With a population of 1.4 billion, continuously impressive GDP growth and speedy recovery from COVID-19, China has a unique position in that it is a key global consumption market that is also growing domestically. The Chinese market is now opening up to foreign cruelty-free beauty brands, many of which have been in high demand with local consumers.

The tremendous growth of the Chinese cosmetics market

The cosmetics sector in Mainland China has been growing at a tremendously fast pace with the rapid development of the Chinese economy. In 2019, the Chinese market for cosmetics had a market capacity of 477.72 billion RMB. The growth rate of the cosmetics market is expected to rise to 11.6% in 2020 (final figures still to be published).

According to Euromonitor statistics, China's cosmetics market has a greater import rate than export rate. Customs data show that China's imports of beauty-, cosmetics- and skincare products totaled \$13.495 billion in 2019, up 36.02 percent year-on-year. The development of increased income and the rapid pace of e-commerce, people spend more on daily consumer goods and they are more and more willing to buy safe and natural cosmetic products¹.



The fast recovery from COVID-19

Affected by the epidemic, the retail sales of cosmetics in the first quarter of 2020 reached 63.6 billion yuan, down 13.2 percent compared with the same period in 2019.

¹ https://www.cbndata.com/report/2457/detail?isReading=report&page=13&readway=stand

However, with the effective control of the epidemic in China, the national retail sales of cosmetics began to recover in April 2020, reaching 24.4 billion yuan, with a year-on-year increase of 3.5%. From January to May in 2020, the retail sales of cosmetics nationwide reached 114.6 billion yuan. Consumption is expected to rebound in 2021 due to a significant reduction in COVID-19 outbreaks.

Cosmetic Supervision and Administration Regulations (CSAR)

In the past few months, China has been updating its cosmetics regulations. The guiding updated legislation is the *Cosmetic Supervision and Administration Regulation (CSAR)*, which has gone into effect on Jan 1, 2021. It is a general instructional regulation including some new provisions about the requirements:

- how the safety assessment to be carried out before registration;
- efficacy claims need to be backed by sufficient scientific evidence;
- Good Manufacturing Practices (GMP) certificates required for imported cosmetics. On Feb 26, 2021, the Instructions for Cosmetic Registration and Recordation

(Notification) Dossier was published, which details animal testing exemptions for imported general use cosmetics. Due to this update, it is now possible to bring imported cosmetics to the Chinese market without having the products tested on animals.

For more detailed information about the requirements and procedures for importing cruelty-free cosmetics, please see below.

INTRODUCTION OF THE CHINESE COSMETICS MARKET

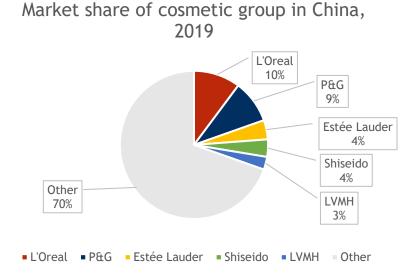
The consumption scale of cosmetics in China increased from RMB 204.9 billion to 340 billion from 2015 to 2020, with a compound growth rate of around 8.81%. According to data from the National Bureau of Statistics, China's cosmetics sector had a total sales volume of RMB 340 billion in 2020, with a 9.5% year-on-year growth. The total cosmetics market volume is expected to reach RMB 364.4 billion³.

² https://www.gianzhan.com/analyst/detail/220/210210-a0fe84c4.html

³ https://www.cbndata.com/report/2617/detail?isReading=report&page=5



The world's main consumer countries of cosmetics are Japan, South Korea, the United States, France, the United Kingdom and China. According to Euromonitor data, in 2019, among the main consumption countries (including Japan, South Korea, The USA, German, France and The UK) the annual consumption of cosmetics per capita was \$37.5 and the per capita consumption of skin care was \$73.2. While we compare this to the numbers in China, we can see that the average is much lower. The annual consumption of cosmetics per capita and skin care was \$5.7 and \$25.4 in 2019. Laying this next to the growth trends in the China market mentioned above, it is clear there is still a huge market space to explore in cosmetics in the coming years.



Foreign brands are sharing the biggest part of the cake in the Chinese cosmetics market. The top 5 players are L'Oreal, P&G, Estée Lauder, Shiseido and LVMH⁴. This is further supported by the general market trend where online consumers shift away from general e-commerce platforms and move their purchases to vertical platforms. Younger generations tend to prefer platforms which target their consumers according to product category and/or lifestyle⁵. This gives an advantage to foreign brands, which are leading in the Chinese market in terms of multichannel branding and marketing and new trends like live commerce.

Up until now, China has posed very strict requirements on imported cosmetics brands and products. For example, all imported cosmetics products need to provide animal testing reports to the authorities to register their products in the Chinese cosmetics system. Things have not changed with the promulgation of the Administrative Provisions of Cosmetics Registration and its series of implementing regulations. Doing registration/recordation in China for general imported cosmetics products is now a possible option. Keep reading for more details.

WHAT YOU SHOULD KNOW BEFORE ENTERING THE CHINESE MARKET

How are cosmetics products classified in China?



Cosmetic products are classified into two categories by the National Medical Products Administration (NMPA): Non-special use cosmetics and special use cosmetics.

⁴ https://bg.qianzhan.com/report/detail/300/210303-42d80bb1.html

⁵ https://www.iresearch.com.cn/Detail/report?id=3748&isfree=0

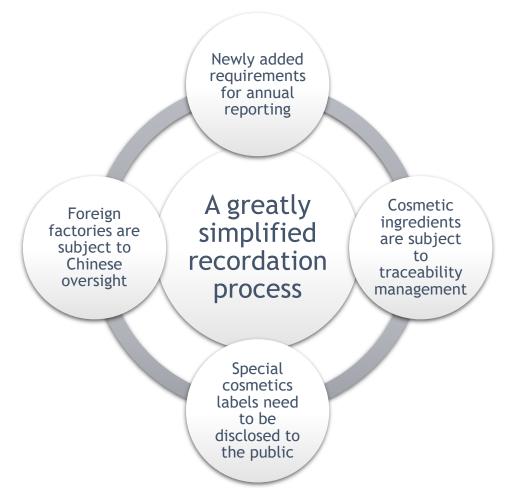


What are the dossiers necessary for cosmetic

registration/recordation?

Documents needed	"Cosmetic Registration and Recordation Information Form" and relevant documents
	Naming basis of the product name
	Product formula
	Product executive standard
	Product label sample manuscripts
	Product testing report
	Product safety assessment documents

On Dec 31, 2020, the draft Administrative Measures on Cosmetic Registration officially passed the State Administration for Market Regulation (SAMR) and was renamed as Administrative Measures on Cosmetics Registration and Recordation(AMCRR). The new measures went into effect on May 1, 2021. The main changes brought about by this regulation are:



What are the requirements of cosmetics labeling?

The new regulations also clarify that the following items shall be marked on the cosmetic label:

- 1. Product name and registration license number (for special cosmetics);
- 2. Name and address of the registrant/notifier (require name and address of the domestic representative person for imported cosmetics and toothpaste);
- 3. Name and address of the manufacturer (require production license number for domestic cosmetics);
- 4. Product executive standard number;
- 5. List of ingredients;
- 6. Net content;
- 7. Durability;
- 8. Application method;
- 9. Safety warnings; and
- 10. Other content prescribed by laws, administrative regulations and mandatory national standards.

Imported cosmetics can directly use or affix Chinese labels. In cases where the Chinese labels are affixed, the content related to product safety and efficacy claims on Chinese stickers are required to be consistent with the contents on the original labels.

It is required to label all ingredients with content more than 0.1%(w/w) rather than the 1% currently stipulated. For ingredients with the content less than 0.1%(w/w), they shall be labeled separately with "Other trace ingredients" as the guiding word. If a compound is contained, the content of each ingredient in the compound shall be used to judge whether it is a trace ingredient.

For product efficacy claims that have been evaluated and validated by approved human trials of a qualified testing institution, the product can claim "the efficacy has been evaluated and validated" on the product label.

How to avoid animal testing?

Option 1: Cross-border e-commerce

Before the implementation of the new regulations, this was the main method for many brands to export their cruelty-free cosmetics to China. Customers buy the products through a cross-border e-commerce platform like Tmall International, JD International etc. for personal use only. The goods will be sent from the warehouse to customers directly and no animal tests are required during the process.

The cross-border e-commerce market in China is quite well-structured at present and it will be a good gateway for brands to give a try in the Chinese market.

There are two forms of cross-border e-commerce in Chinese market:

Direct CBEC(B2C)

Products will be sent from another country to Chinese customers directly. The delivery may take weeks.

Bonded CBEC(B2B2C)

Products will be saved in the bonded area in China and will be sent to customers from Chinese bonded area. The delivery normally takes less than one week.

Option 2: Do the filling in China

Importing finished goods to China always required animal testing and human testing (for some function categories), even for non-special use products, imported or domestic special use products. However, goods that are domestic non-special use can avoid animal testing. Goods will be considered as domestic if the final production is done in China - which for cosmetics companies often is the filling and packaging stage of the production process.

This option was also possible before the implementation of the new regulations in China, but it was not very popular as brands feared to lose control over their production process. Moreover, brands worried that they would lose their appeal to certain consumers as they would then be classified as 'domestic' rather than 'foreign'.

To avoid animal testing and human testing, companies can do their filling and packaging process in China and register these products as domestic non-special cosmetics products.

Option 3: Animal testing exemptions

On 26 February 2021, the China National Medical Product Administration ("NMPA") officially promulgated the provisions which exempted imported ordinary cosmetics from animal testing as of May 1, 2021. Special cosmetics are not exempt. In order to avoid animal testing these ordinary cosmetics need to meet the below pre-requisites and avoid the exceptions:

Pre-requisites

Ordinary cosmetics manufacturers need to obtain a certification of the manufacturing quality management system (QMS - similar to GMP) that is issued by the government anthorities or certification organizations of its country.

A product safety assessment that can fully confirm the safety of the products needs to be provided. The assessment results will be reviewed by NMPA based on the risk of management materials submitted by the applications.

Exceptions Products claims to be used for children or infants.

Products which contain any new cosmetics raw materials or new ingredients that are still under the safety monitoring period in China.

Any of the brand applicants, its Chinese responsible agent or manufacturer have been listed as being subject to supervision.



Good Manufacturing Practice regulations

Ordinary cosmetics manufactures need to obtain Good Manufacturing Practice (GMP) certifications that have been issued by their local government authorities or official national certification organization. GMP regulations require that manufacturers take proactive steps to ensure that their products are safe, pure, and effective.

GMP regulations address issues such as record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides some flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

It should be noted that the recognition of the GMP is on a bilateral basis between China and the relevant manufacturing country. Not all countries have established such

recognition yet, but many countries are currently in the process of doing so like France.

Safety assessment report

Non-special cosmetics manufactures should provide a product safety assessment that can fully confirm the safety of the products. The assessment results will be reviewed by NMPA based on the risk management materials submitted by the applicants. At the same time, the safety assessment report needs to be obtained by qualified assessors.

CONCLUSION

Chinese younger generations are becoming the main consumption force in recent years. Products with impressive design on both the package and the formula are becoming a hit among the younger generation in China, especially those niche brands who are expertise in certain sectors.

The well-structured ecommerce & logistics system makes cross-border ecommerce easy for both brands and consumers. At the same time, with the newly published CSAR regulation system, the registration/recordation process is greatly simplified for imported cosmetics if the brands would like to enter the Chinese market through general trades. The investment environment for foreign entities is being optimized and more pilot cities and free trade zones are being set by the Chinese government which brings great opportunities for foreign brands who have been blocked by previous complicated regulations.

RELEVANT REGULATIONS/GUIDELINES OVERVIEW

CSAR and New Regulatory Framework

Туре	Regulations	Date
Classification	Cosmetic Classification Rules and	Went into effect
	Catalog	since May 1 st , 2021
Registration and	Administrative Measures on Cosmetic	Went into effect
Recordation	Regulation and Recordation	since May 1 st , 2021
Standards	Instructions for Cosmetic Registration	Went into effect
	and Recordation Dossiers	since May 1 st , 2021
	<u>Instructions for New Cosmetic Ingredient</u>	Went into effect
	Registration and Recordation Dossiers	since May 1 st , 2021
Labeling	Administrative Measures on Cosmetics	Will go into effect
	Labeling	since May 1 st , 2022
Safety	<u>Technical Guidelines for Cosmetic Safety</u>	Went into effect
Assessment	Assessment	since May 1 st , 2021
Efficacy Claim	Standards for Cosmetic Efficacy Claim	Went into effect
	<u>Evaluation</u>	since May 1 st , 2021
Enterprise	Supervision and Administration Measures	Draft
Obligations	on Cosmetics Manufacture and Operation	
	Good Manufacturing Practices for	Draft
	Cosmetics	
	Measures for the Management of	
	Cosmetics Adverse Reaction Monitoring	
	Standards for the Management of	Draft
	Cosmetic Sampling Inspection	
	Measures for the Management of	Went into effect
	<u>Cosmetic</u> <u>Supplementary</u> <u>Testing</u>	since May 1 st , 2021
	Methods	
Toothpaste	Administrative Measures on Toothpaste	Draft
Management		

Brief introduction on several regulations

Cosmetic Supervision and Administration Regulation (CSAR)

(went into effect on Jan 1, 2021)

It's a general instructional regulation, at the same time, it's one of the most anticipated regulations released by NMPA in 2020. Following the release of the CSAR, NMPA has issued a number of published/drafted measures and guidelines to implement the new law.

The Administrative Measures of Cosmetics Registration

(went into effect on May 1, 2021)

The scope of the drafted "The Administrative Measures of Cosmetics Registration" not only includes product filing and registration, but also a focus on the new raw material application process and raw material quality & safety. It clarifies basic requirements and each party's responsibilities for registration and filing management. The scope of the draft addresses both cosmetic products and new cosmetic raw materials. New concepts such as raw material safety supervision, quality management system, new coding filing format are also introduced. Patent protection for new ingredients and ingredient traceability were two great additions.

The Technical Guidelines of Safety Assessment of Cosmetics

(went into effect on May 1, 2021)

The purpose of issuing the draft "The Technical Guidelines for Safety Assessment of Cosmetics" is to further ensure the safety of cosmetics, and to provide with the relevant guidance regarding technical requirements for safety assessment of cosmetics. The scope of the new technical guidelines not only includes finished cosmetic products, but also focus on the cosmetic raw material safety. It details basic requirements for cosmetic raw materials and finished products safety assessment, requirements for cosmetic safety assessment personnel in charge, guidelines for safety assessment report and toxicology studies.

The Classification Rules and Catalogue of Cosmetics

(went into effect on May 1, 2021)

The other important draft "The Classification Rules and Catalogue of Cosmetics" intends to strengthen supervision and management of cosmetic products, and to clarify the cosmetic classification determination. This includes cosmetic efficacy claims category coding catalog, classification and coding catalogue of cosmetic application parts, classification and coding catalogue of cosmetic target group, classification and coding catalogue of cosmetic product dosage forms, classification and coding catalogue of cosmetic use methods. The authorities introduced a new codification system that adopts hierarchical code. The code is divided into five levels: efficacy claims, usage application, product dosage form, target group and usage method.

Measures for Supervision and Management of Cosmetics Product and Operation

(Draft)

Draft "Measures for Supervision and Management of Cosmetics Production and Operation" has been issued to implement the newly introduced CSAR guidelines, to further stipulate the requirements, and to clarify the legal responsibilities for the production and operation supervision of cosmetics. This includes refining manufacturing, license and production quality management, improving operation management and supply chain supervision. The important legal basis of post market supervision is to guide the behaviors of cosmetics manufacturers and operators, standardize the law enforcement of regulatory departments

at all levels within the cosmetic production industry and ultimately support consumer safety.

Instructions for Cosmetic Registration and Notification Dossier

(went into effect on May 1, 2021)

A draft published by NIFDC. To further implement the newly introduced CSAR guidelines with scientific supervision. To clarify constructional needs of new registration & recordation system with the combination of current industrial development needs.

ABOUT THE AUTHOR



Tiffany Zhang
Junior Advisor at Dr2 Consultants Shanghai
t.zhang@dr2consultants.eu
+86 180 160 22974
Linkedin



About Dr2 Consultants Shanghai

For 20 years Dr2 Consultants (NL: Dröge & Van Drimmelen) has been trusted by many governments, associations, companies and NGOs. Our expertise lies in managing complex multi-stakeholder processes, thereby leveraging our broad network and research capabilities. From our offices in Shanghai, Brussels and The Hague, we serve clients like the Port of Rotterdam, Ecommerce Europe, Google, Microsoft, Tesla, Brambles, Allego, Koopman, the City of Amsterdam, the Consulate-General of the Netherlands, and many others.

Dear reader,

Thank you for reading our whitepaper!

Due to the limited information we can share in a whitepaper and the newly implemented regulations, we are glad to offer a free consultation for your business. At the same time, we welcome any corrections!

Please do not hesitate to contact us through shang@dr2consultants.eu or contact the author at t.zhang@dr2consultants.eu for more details. It is our pleasure to introduce ourselves to you!

Dr2 Consultants Shanghai Tiffany Zhang