

Exporting Cosmetics to China (Regulations Update 2022)



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Executive summary

Over the past few years, China's cosmetics sector has grown enormously, and has even intensified during the COVID-19 pandemic. In 2021, China imported a total of RMB 161.3 billion (€22.34 billion) worth of cosmetic products – a 23% increase compared to the previous year.¹ Although the market is led by Japan and S. Korea, followed by France and the United States, most EU countries are actively exporting various categories of cosmetics to China.

At the same time, China's cosmetic sector is undergoing profound regulatory developments, which are changing the way cosmetic products can be imported into China. The *Cosmetic Supervision and Administration Regulation (CSAR)* came into effect on 1 January 2021, representing the new, overarching cosmetic regulatory framework in China – covering the areas of cosmetic classification, product notification and registration, new ingredient management, efficacy evaluation, safety assessment, online cosmetic supervision, accountability systems, and punitive measures. Simultaneously, since 1 May 2021 a new, long-awaited milestone came into force: the possibility for imported general cosmetics to be exempted from mandatory animal testing in China, and thus opening up the Chinese market to several European cruelty-free brands which previously could only export limited quantities through cross-border e-commerce, or were not exporting at all. Other regulations on many other specific regulatory aspects, such as labelling, efficacy claims and safety assessment, have also been updated and issued, or are currently being formulated.

This report provides an up-to-date overview of the new regulatory requirements that European manufacturers of cosmetics must comply with to be able to export to China. The first section provides a summary of the recent regulatory updates, for both general trade and cross-border e-commerce, with a section focusing in particular on the exemption of mandatory animal testing for imported general cosmetics. The second section will provide detailed guidelines on the different steps required for exporting cosmetics to China, starting from the classification of the cosmetic as general cosmetic vs special cosmetic, navigating through the various steps of the product notification or registration process, and highlighting the requirements for packaging, labelling, customs clearance, and the documentation for animal testing exemption.

At the end of the report, a list of which EU Member States and corresponding government agencies actively issuing GMP certificates to be used for animal testing exemption in China is provided – based on information collected through desk research and direct feedback received by EU Member States representations in China.

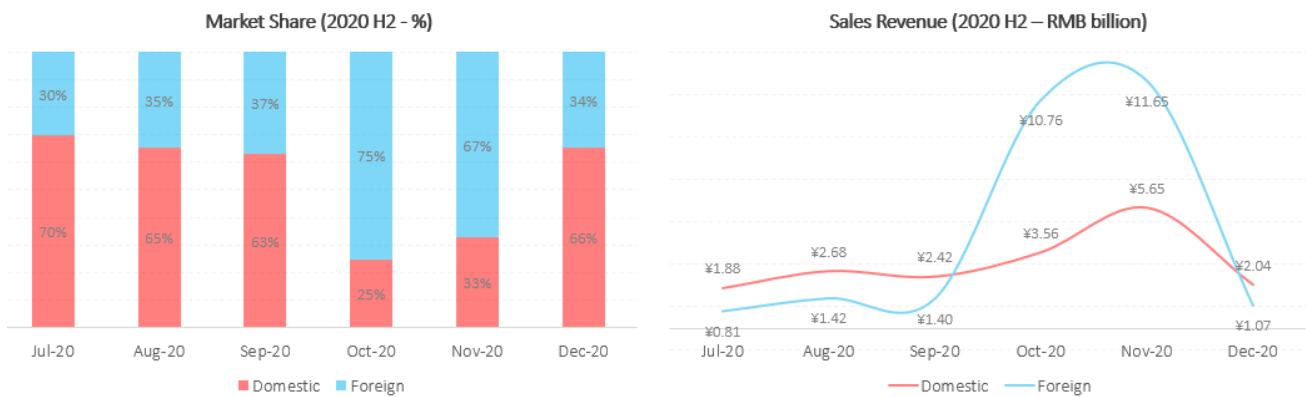
¹ <http://www.customs.gov.cn/customs/302249/zfxgk/2799825/302274/302275/4122074/index.html> (accessed: 24 Jan 2022)

1. Overview of China’s cosmetics regulations

Just as the Chinese economy has grown in the past decades, the Chinese cosmetic sector has also been growing rapidly.² In particular, the Chinese market fulfilled a huge appetite for sales revenue during the COVID-19 pandemic. According to China’s National Bureau of Statistics, retail sales of cosmetic products in 2021 reached RMB 402 billion, a year-on-year increase of 14%.³

These sales revenue during the COVID-19 pandemic was achieved mainly through online platforms. While physical stores were affected – at least initially – by the higher number of people preferring to stay home or avoiding crowded areas, Chinese consumers turned to China’s e-commerce and social platforms to find recommendations and conclude their purchases. Chinese millennials are the key driving force of the beauty market – and the majority of them relies on bloggers and user reviews when buying beauty products.⁴ Foreign cosmetics are in general seen more favourably compared to local brands when it comes to safety and quality, and it is not a coincidence that sales of foreign cosmetics in China surges during shopping festivals (especially before and during Singles Day in October and November) – when numerous deals are made available resulting in more affordable prices.⁵ Still, outside shopping festivals, domestic cosmetics brands seem to have a more stable resonance with Chinese consumers. Finally, although still limited, the awareness of ‘organic’ and ‘natural’ cosmetics is trending upward, particularly in first-tier cities.

Performance of domestic vs foreign cosmetics



Source: webinar “Cosmetics Policy Updates, Landscape & Non-compliance Case Study in China” (May 2021): <https://www.eusmecentre.org.cn/event/2021-06-03/cosmetics-policy-updates-landscape-non-compliance-case-study-china>.

This trend is expected to intensify further in the coming years, making China’s cosmetic market a key target for European brands, also given other key developments currently being rolled out – such as the Hainan Free Trade Port which since 2020 allows visitors from the Chinese mainland to purchase cosmetics duty-free, for up to RMB 100,000 (€13,850) per year.

However, benefitting from China’s opportunities is a challenging and arduous task, and requires meticulous planning, resources, patience and resilience, as well as close monitoring of the rapidly changing regulatory environment governing every aspect of selling cosmetics in the country. In fact, 2021 has been a key year for China’s cosmetics sector, with long-awaited key developments finally coming into force: this chapter will provide an overview of the state of affairs.

² <https://www.statista.com/statistics/298177/china-cosmetics-retail-value/> (accessed: 17 Jan 2022).

³ http://www.stats.gov.cn/tjsj/zxfb/202201/t20220117_1826402.html (accessed: 17 Jan 2022).

⁴ <https://daxueconsulting.com/industries/china-beauty-industry/> (accessed: 17 Jan 2022).

⁵ For an overview of China’s shopping festival, recent figures, trends and case studies of brand strategies, see a dedicated EU SME Centre report on China’s e-commerce: <https://www.eusmecentre.org.cn/report/e-commerce-ecosystem-china-checklist-european-smes-2021-update>.

1.1. Key regulations and governance framework

Competent Authorities

Before the large-scale administration reform adopted in 2018, the China Food and Drug Administration (CFDA) was the main administrative and supervisory body for cosmetics in China, overseeing all the processes relating to the registration, marketing, sales, and distribution of cosmetics in China. The reform led to a series of regulatory and administrative overhauls, such as the merging or the creation of state-level ministries and departments, with the objective of reducing red tape and streamlining administration. For the cosmetic industry, three major competent authorities are playing the leading role for market regulation.

State Administration for Market Regulation (SAMR)

Under the new centralised structure, SAMR merged the functions of the former CFDA, as well as those of the former State Administration for Industry and Commerce (SAIC) and some others of the former Administration of Quality Supervision, Inspection and Quarantine (AQSIQ). Thus, SAMR is a single body covering the areas of food, cosmetics, pharmaceuticals, and medical devices, mainly responsible for market regulation and supervision, the issuance of business permits, licenses regulating anti-monopoly behaviour, and management of intellectual property; additional functions include drug safety supervision, quality inspection, certification and accreditation.

National Medical Product Administration (NMPA)

The NMPA, under SAMR, is the agency in charge of regulating drugs and medical devices in China, and at the same time the lead agency responsible for cosmetics. Its mandate covers the drafting of regulations and rules for cosmetics, drugs and medical devices, as well as product supervision (including filing/registration), quality standards and risk management.

General Administration of Customs, P.R. China (GACC)

Lastly, GACC is a ministry-level authority directly under the State Council and is the key border agency in China. As such, it is responsible for both customs clearance and inspection of imported cosmetics.

Policies and regulations

Previously, companies exporting cosmetics to China had to deal with an outdated regulatory framework when addressing market management issues. The situation changed in June 2020, when the *Cosmetic Supervision and Administration Regulation (CSAR)* was promulgated by the Chinese Prime Minister,⁶ coming into effect on 1 January 2021, and thus replacing the three-decade-old *Cosmetics Hygiene Supervision Regulations*.

CSAR constitutes the overarching cosmetic regulatory framework in China, overhauling the outdated regulatory standards and addressing issues revolving around cosmetic pre- and post-market management for different circumstances. With 6 chapters and 80 articles, covering the areas of cosmetic classification, new ingredient management, efficacy evaluation, safety assessment, online cosmetic supervision, accountability systems, and punitive measures. Art. 3 defines cosmetics as “daily chemical products applied on human skin, hair, nails, lips, mouth, etc., by spreading, spraying or other similar ways for cleansing, protecting, beautifying, or grooming purposes”. More details on specific aspects CSAR and its requirements for imported cosmetic products will be provided in chapter 2 of this report. All cosmetic products and new ingredients sold in China after 1 January 2021 must fully comply with CSAR – although a five-year transition period was introduced for products already registered or notified before the implementation date.

⁶ 化妆品监督管理条例: http://www.gov.cn/zhengce/content/2020-06/29/content_5522593.htm (accessed: 17 Jan 2022).

Based on the CSAR, additional implementation rules have been or will be issued to regulate detailed aspect of cosmetics, such as the *Administrative Measures for Cosmetics Regulation and Notification*,⁷ the *Technical Guidelines for Cosmetic Safety Assessment*,⁸ the *Administrative Measures on Cosmetics Labelling*,⁹ the *Good Manufacturing Practices for Cosmetics*,¹⁰ etc.¹¹

1.2. General trade vs Cross-Border E-Commerce

Products can be exported to China through two main pathways: general trade, and Cross-Border E-Commerce (CBEC). General trade refers to the traditional way of exporting products through importers and distributors, and selling them in physical stores in China. Whereas CBEC involves the sale of e-commerce products across borders; over the years, it has become one of the cornerstones of the Chinese government's strategy to increase the volume and quality of imports and exports.¹² Through CBEC, after a Chinese customer makes an order, the product is shipped individually in one of the following ways:

- **Direct import pattern:** goods are shipped from overseas warehouses to Chinese consumers after an order is made on an e-commerce platform;
- **Bonded warehouse import pattern:** goods are shipped anytime by overseas companies and stored in a bonded warehouse in mainland China; after an order is made on an e-commerce platform, goods go through customs clearance and are shipped from the bonded warehouse to the final consumer in China.¹³

The biggest advantage of CBEC is that products are classified as personal goods, therefore enabling foreign merchants to sell directly to customers in China without having to go through the lengthy and costly product notification or registration procedures required for general trade. This results in less strict requirements in terms of labelling and packaging (such as for natural and organic cosmetics, more details in section 2.3 of this report). However, only commodities specifically included in an ad hoc Catalogue can be exported to China through CBEC – and cosmetics are.¹⁴

At the same time, Chinese authorities must approve transactions made on CBEC platforms, and afterwards transmit further information such as transaction data, payment data and logistic data to the official platform of the Chinese customs. Generally, this is processed by a domestic agent authorised by the foreign company selling through CBEC; in practice, however, CBEC platforms are the ones responsible for notifying and communicating with the Chinese customs on behalf of the companies that sell through them.

⁷ 化妆品注册备案管理办法: https://gkml.samr.gov.cn/nsjg/fgs/202101/t20210112_325127.html (accessed: 17 Jan 2022).

⁸ 化妆品安全评估技术导则: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210419163037171.html?type=pc&m=> (accessed: 17 Jan 2022).

⁹ 化妆品标签管理办法: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210603171933181.html> (accessed: 17 Jan 2022).

¹⁰ 化妆品生产质量管理规范: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20220107101645162.html> (accessed: 17 Jan 2022).

¹¹ A detailed list of all enforced regulations in the field of cosmetics, is available on the website of specialised consulting firm ChemLinked: <https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation> (accessed: 17 Jan 2022). A webinar was also organised by the EU SME Centre in June 2021: <https://www.eusmecentre.org.cn/event/2021-06-03/cosmetics-policy-updates-landscape-non-compliance-case-study-china>.

¹² According to a Report issued by China's MOFCOM, in 2020, the value of CBEC exports and imports amounted to RMB 1.69 trillion (€234 billion), a 31% increase on the previous year, around two-thirds of which being exports and one-third being imports. <https://dzswgf.mofcom.gov.cn/news/5/2021/9/1631698018580.html> (accessed: 7 Jan 2022). Developed countries and regions are still the preferred source of imports among Chinese consumers, with Japan, the United States, and South Korea the top three countries by sales value through CBEC channels. It should be noted that the business-to-business (B2B), including the B2B2C model, as explained previously, still plays a dominant role in CBEC, compared to business-to-consumer (B2C).

¹³ The direct import pattern is more attractive for merchandise of smaller volume and more occasional demand from a foreign country; delivery times however may be extremely long which might impact the decisions of Chinese consumers to purchase the product. The bonded warehouse pattern, on the other hand, is more suitable for merchandise with large, stable and constant demand; however, the seller must store a certain volume of merchandise in the bonded warehouse at its own cost before receiving online sale orders.

¹⁴ The Catalogue is available, in Chinese, at: <http://cws.mofcom.gov.cn/article/swcjc/202001/20200102929369.shtml> (accessed: 7 Jan 2022). For an unofficial translation in English, please reach out to the EU SME Centre through our website: <https://www.eusmecentre.org.cn/expert>.

Finally, products sold via CBEC also enjoy a preferential tax policy compared to general trade, based on a ‘comprehensive tax’ combining import duties, VAT and consumption tax.

This report will focus primarily on cosmetic products exported to China through general trade. More details on CBEC, requirements, tax policy, CBEC platforms and costs, shopping festivals, etc., can be found on two dedicated EU SME Centre reports.¹⁵

1.3. Exemption of animal testing for general cosmetics

China has long been associated with strict animal testing requirements for cosmetics, aimed at ensuring the quality and security of cosmetic products produced in and exported to China. As such, it was not an appealing market for cruelty-free brands. However, this has gradually been changing in the past few years, opening up – at least partly – the Chinese market for the many ethically-produced cosmetic products that Europe is well-known for.

The first steps were taken in June 2014, when the *Requirements for Filing of Domestic Non-special Use Cosmetic Products* allowed non-special use cosmetics produced within mainland China, to be exempted from animal testing if instead reliable safety assessment reports were provided. With the emergence of Cross-Border E-Commerce (CEC), animal testing requirements were exempted for imported cosmetics products exported to China exclusively via third-party CEC platforms – and not directed by the seller; in practice, this was the only existing method possible for cruelty-free cosmetics brands to export their products to China. The situation changed substantially in May 2021, when the NMPA-released *Provisions for Management of Cosmetic Registration and Notification Dossiers* came into force.¹⁶ The Provisions allow all general use cosmetics to be exempted from mandatory animal testing requirements during the notification process with NMPA, taking into account that:

- The product does not claim to be used by infants and children;¹⁷
- The product does not contain new cosmetic ingredients;
- The product’s notifier/intermediary/manufacturer is not listed as a key supervision target according to the results of the quantitative rating system established by NMPA.

However, it must be noted that the animal testing exemption is not an automatic process. It is granted only when the manufacturer submits, as part of the notification process with NMPA: (i) a good manufacturing practice (GMP) certificate issued by an official government agency where the manufacturer is located; (ii) a safety assessment report fully confirming the safety of the product.

Finally, it must also be noted that the above applies only to general use cosmetics, and not to special cosmetics. More details on the classification, as well as the content of the safety assessment report, will be provided in section 2 of this report.

¹⁵ See “The E-Commerce Ecosystem in China - A Checklist for European SMEs”: <https://www.eusmecentre.org.cn/report/e-commerce-ecosystem-china-checklist-european-smes-2021-update>.

¹⁶ 化妆品注册备案资料管理规定: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210304140747119.html>

¹⁷ Since 1 January 2022, cosmetics for infants and children are regulated by the Supervision and Administration Provisions on Children Cosmetics (儿童化妆品监督管理规定) <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20211008171226187.html> (accessed: 18 Jan 2022).

2. Step-by-step export guidelines

Before exporting cosmetic products to China through general trade, it is vital to fully understand the most recent regulations and market access rules that European SMEs need to comply with, thus avoiding unnecessary delays and financial costs during product registration or customs clearance procedures. The first step is to understand the classification of the cosmetic product, followed by a formal notification or registration process with NMPA or local-level counterparts, which also aims to ensure that the packaging and labelling of the product are compliant before final approval is obtained and products are ready for customs inspection.

2.1. Definition and classification

The first step is to ensure that a product effectively falls within the official definition of ‘cosmetics’, as indicated by CSAR. Then, the entire process for exporting cosmetics will depend on one fundamental aspect: whether they are classified as ‘general cosmetics’ or ‘special cosmetics’.

Definition

Under the CSAR regulation, cosmetic products must have particular usages and functions in order to be effectively considered as cosmetic products in China. According to CSAR (Art. 3), cosmetic products are daily chemical products that are intended to be applied to external human body parts, such as skin, hair, nails, and lips. Thus, by definition, the focus lies on the external human body parts – excluding teeth and oral mucosa. The methods on how to apply the product to the human body parts are limited to spreading, spraying or similar (e.g. rubbing) – thus excluding oral intake as well as an injection of products. Lastly, the purpose of a cosmetic product is defined to clean and protect the human body parts, eliminate unpleasant odour as well as improve the appearance for beautifying and grooming purposes. Other purposes such as preventing and/or treating diseases are explicitly excluded from the cosmetic product definition and are therefore not affected by the new regulation.

Considering the definition of cosmetics, it emerges how certain products that in the EU are fully considered as cosmetics, in China may not be considered as such. These include, for instance, soaps that are solely for the purpose of cleaning and not serving a special cosmetic purpose such as whitening; and products in contact with teeth and mucous membranes of the oral cavity, such as toothpaste,¹⁸ mouthwash and nasal care products.

Classification

With the new CSAR regulations, the classification of cosmetic products also has been updated. These classifications determine the specific requirements, processes, and paperwork for cosmetic products to obtain a license for export to China.

CSAR’s Art. 4 and Art. 16 divide cosmetics products into two categories, based on risk management principles:

- **Special cosmetics** (特殊化妆品): including six categories of cosmetic products: (i) hair dyes; (ii) hair perming products; (iii) freckle-removing (whitening) products; (iv) sunscreens; (v) anti-hair loss products; and (vi) cosmetics with new efficacy.
- **General cosmetics** (普通化妆品): all other cosmetics products not falling within the scope of ‘special cosmetics’. Before CSAR, general cosmetics were previously called ‘non-special use cosmetics’

¹⁸ According to Art. 77 of CSAR, even if not effectively considered as a cosmetic, toothpaste products will need to follow the same registration procedures of CSAR for ‘general cosmetics’, but will have its own administration measures in the future. At the end of November 2020, NMPA published a call for public comments on a draft version of the Administrative Measures on Toothpaste, but it is not clear when the final document will be released, see: <https://www.nmpa.gov.cn/directory/web/nmpa/zhuanti/hzhpjdgj/hzhptlzqyj/20201113094757150.html> (accessed: 18 Jan 2022).

For the sixth category of special cosmetics, i.e., cosmetics with new efficacy, an efficacy claim evaluation proving the new efficacy will be required before an import of the product is permitted (Art 22 of CSAR). A more detailed description of the efficacy claim report will be provided in section 2.2. At the same time, while cosmetics for infants and children (<12 years' old) follow the same registration, claims and packaging procedures as cosmetics for adults, but they are subject to stricter standards and regulations for safety assessment, manufacture, labelling, etc.: for instance, as illustrated in section 1.2 of this report, animal testing will still be mandatory for such products, even if they are general cosmetics.¹⁹ At the same time, since 1 January 2022 cosmetics for infants and children are regulated by the *Supervision and Administration Provisions on Children Cosmetics*.²⁰

It is noteworthy that, in the past, certain cosmetics such as products for breast beauty, depilating, slimming, and deodorising, were considered as 'special cosmetics', but were reclassified as 'general use cosmetics' by CSAR, thus requiring different import management requirements (but a five-year transition period is given by CSAR – Art. 78 – if such products were registered in China before 1 January 2021).

In addition to the two cosmetics categories, cosmetic products can be further subdivided into domestic and imported products: the main distinguishing criterion is the area where the last process of contacting cosmetic content is completed. This last process is usually identified as the filling process of the product.

Once the classification is completed, the notification or registration process can get started (see next section).

New Ingredients

Finally, CSAR also applies to cosmetic ingredients. Art. 4 and Art 11 of CSAR divide them into:

- **New ingredients** (新原料): natural or artificial ingredients used for cosmetics and entering the Chinese market for the first time. Based on their level of risk, these are further divided into (i) high-risk new ingredients: those with functions of preservative, sun protection, colouring, hair dyeing, freckle removal, and whitening; (ii) Low-risk new ingredients: those not falling within the scope of high-risk new ingredients. Similar to finished products, new ingredients must be notified or registered with NMPA before they can be sold in the Chinese market, depending on if they are low-risk new ingredients (notification) or high-risk new ingredients (registration).
- **Already used ingredients** (已使用原料): all ingredients already used in cosmetics, specifically 8,972 ingredients listed in an ad hoc *Inventory of Existing Cosmetic Ingredients in China*.²¹

At the same time, NMPA has issued ad hoc catalogues of prohibited substances in cosmetics, including 1,284 substances (e.g. cannabidiol, methenamine) and 109 plant and animal substances that cannot be intentionally used in the production of cosmetics.²² Therefore, any new cosmetic ingredients must not be on these catalogues.

The following sections will focus on the requirements and processes for imported cosmetic products in China, rather than the new ingredients – although there are many similarities. At the same time, the procedures and requirements described below apply to products imported through general trade, not the CBEC model.

¹⁹ For further information, see: *Cosmetic Classification Rules and Catalogue* (化妆品分类规则和分类目录): <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210409160151122.html?type=pc&m=> (accessed: 18 Jan 2022).

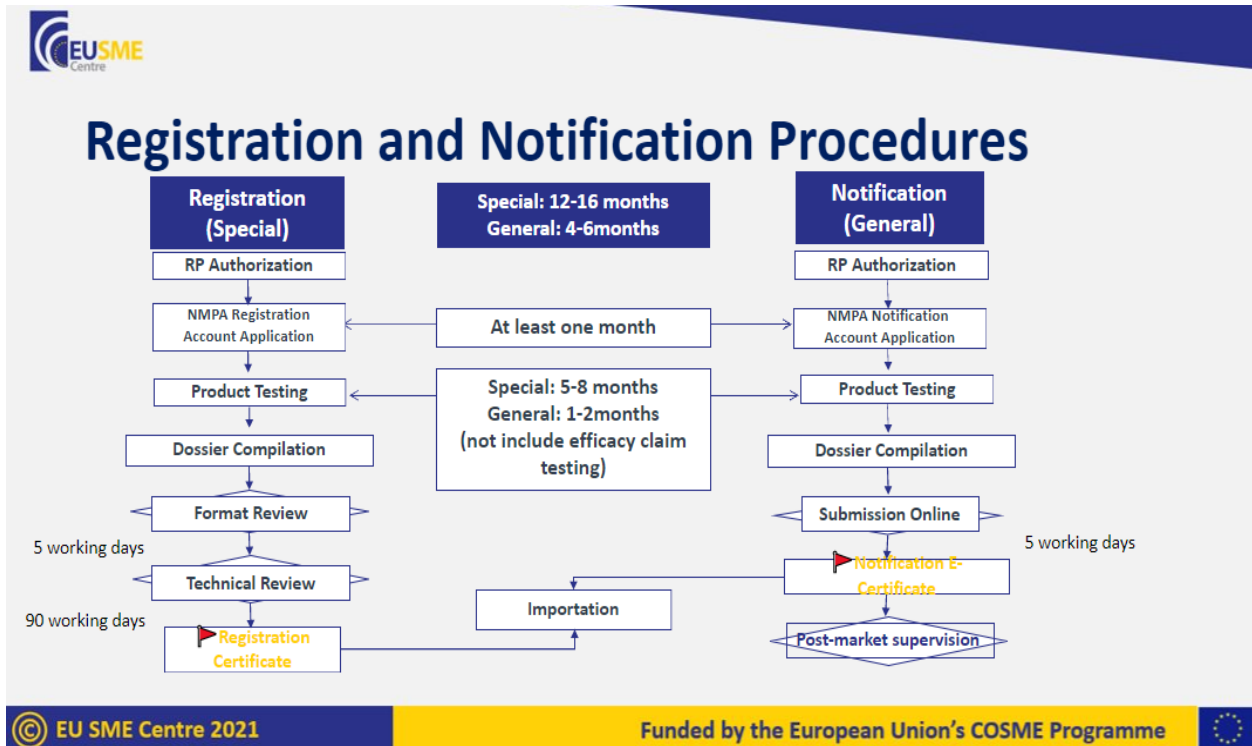
²⁰ 儿童化妆品监督管理规定: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20211008171226187.html> (accessed: 18 Jan 2022).

²¹ The Inventory was last revised by NMPA in 2021. Compared to its previous version, the Inventory now specifies the 'highest historical use concentration', thus providing a useful reference for the safety assessment of cosmetic products. See: *已使用化妆品原料目录* (2021年版): <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210430162707173.html?type=pc&m=> (accessed: 18 Jan 2022).

²² 化妆品禁用原料目录: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210528174051160.html> (accessed: 18 Jan 2022).

2.2. Notification and registration

The notification or registration of cosmetics is a mandatory step stipulated by CSAR to obtain the relevant certificates to export and sell the product in China. The process is based on the cosmetic classification: general cosmetics will follow a notification process, whereas special cosmetics will follow a registration process with NMPA. In general, the registration process is much longer and stricter than the notification one and may take around 12 to 16 months (compared to 4 to 6 months for notification).



Source: EU SME Centre webinar “The Organic and Natural Cosmetics Sector in China” (November 2021): <https://www.eusmecentre.org.cn/event/2021-11-11/organic-natural-cosmetics-sector-china>

Regardless of whether notification or registration is required, the steps are roughly the same, with the main differences relating to the different testing requirements, paperwork to be submitted, review and approval procedure. A visual overview of the ideal notification and registration procedure is provided below.

Overview of the procedures for general cosmetics (notification) and special cosmetics (registration)

Step 1: Find a Domestic Responsible Agent for authorisation

Independently of the cosmetic classification, the first step required for any overseas cosmetic product is to appoint a Domestic Responsible Agent (DRA, sometimes called RP, ‘responsible person’) – i.e. a legal entity within the territory of mainland China to handle and assist with the notification/registration process, on behalf of the overseas product’s manufacturer.

According to relevant regulations (CSAR, Art. 23; *Administrative Measures for Cosmetics Regulation and Notification*, Art. 8, etc.), the DRA is responsible for communicating and coordinating with NMPA and other regulatory authorities, launching the product, assisting in carrying out adverse reaction monitoring and product recalls, and compiling annual product compliance reports. Therefore, the DRA’s role is mostly limited to acting as a liaison point between the overseas cosmetic manufacturer and the Chinese authorities, instead of

guaranteeing the quality and safety of the product or its efficacy claims. Still, DRAs are subject to serious liability in case the information provided to the authorities is deliberately inaccurate, non-scientific, or false.

At the same time, DRAs must possess a business license for the sales, import and export of cosmetics. Therefore, DRAs cannot be individuals, but only entities with legal personality – often the Chinese distributor of a foreign product (not recommended), or subsidiaries of the manufacturer in China (either WFOE or JV). An authorisation letter must be signed.

Step 2: NMPA account application and creation

Once the DRA is determined, the second step will be to apply for an official account on the specific notification/registration platform designated by NMPA.²³ According to Art. 10 of the *Provisions for Management of Cosmetic Registration and Notification Dossiers*,²⁴ the following documents must be uploaded during the account application process:

- Registrant or Notifier Information Form;
- The Information of Domestic Legal Entity (Intermediary) in China;
- Authorisation Letter of Domestic Intermediary and Notarial Certificate;
- Resume of the Person in Charge of Product Safety and Quality;
- The Form of Quality Management System Overview;
- The Form of Adverse Reaction Monitoring and Evaluation System Overview;
- Certificate of Compliance to the Good Manufacturing Practices (GMP).

If no mistakes occurred, the account application process usually takes around one month.

Step 3: Testing, assessment, evaluation

Product testing and assessment

As part of the notification/registration process, all cosmetics to be imported into China are required to be tested at a NMPA-designated testing institution – even if they have already been tested overseas.²⁵ This is a mandatory requirement, aimed at obtaining testing reports providing adequate data to guarantee the quality, safety, and efficacy of cosmetic products sold in the Chinese market.

The test requirements are different for general cosmetics and special cosmetics. For general cosmetics, hygiene safety tests including physiochemical, microbiological, and toxicological tests are required; whereas for special cosmetics, additional human safety tests are compulsory. If a cosmetic product contains substances that are believed to present risks to human health, additional tests are required for these ingredients. Therefore, the testing process may take 1 to 2 months for general cosmetics, and between 5 to 8 months for special cosmetics or those with high-risk substances.

The mandatory animal testing for safety and quality assurance may be exempted for general cosmetics only in certain conditions, see section 2.5 of this report.

At the end of the testing process, a detailed assessment report will be released by the testing institution, which must then be submitted by the applicant to NMPA, together with a Safety Assessment Report and an Efficacy Claim Evaluation.

²³ 国家药监局网上办事大厅: <https://zwfw.nmpa.gov.cn/web/index> (accessed: 18 Jan 2022).

²⁴ 化妆品注册备案资料管理规定: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210304140747119.html> (accessed: 18 Jan 2022).

²⁵ There are a total of 304 NMPA-designated institutions, the full list is accessible from the database of NMPA's website (网站首页>> 数据查询>> 化妆品注册和备案检验检测机构).

Safety Assessment

Starting from 1 January 2022, China implements the *Technical Guidelines for Cosmetic Safety Assessment*, specifying the procedures and requirements to conduct safety assessments on cosmetic products and ingredients, as well as the formal specifications on reports and safety assessors.²⁶ The main goal of the safety assessment is to ensure the safety of cosmetics, identifying potential risks arising from chemical reactions of the ingredients that form the cosmetic product.

The safety assessment can be done independently or can be done through third-party professional institutions. A final Safety Assessment Report of the cosmetic product or ingredient must be produced, based on specific requirements, toxicology research methods and risk assessment procedures outlined by the *Technical Guidelines for Cosmetic Safety Assessment*, and usually reflecting a standard structure indicated in Annex 2 of the Technical Guidelines, namely:

- Abstract;
- Product Brief Introduction;
- Product Formula;
- Formula Design Principles (only for children cosmetics);
- Safety Assessment of each Ingredient in the Formula;
- Assessment of Possible Risk Substances;
- Risk Control Measures or Suggestions;
- Safety Assessment Conclusions;
- Signatures and Resumes of Safety Assessors;
- References and Appendices.

The Safety Assessment Report constitutes one of the required documents to be submitted as part of the notification/registration application dossier – together with the Product Test Report (see previous section), and the Efficacy Claim Evaluation. For companies that have successfully notified or registered their products before 1 January 2022, a transition period until May 2024 is granted: instead of a full safety assessment report, a simplified version must be submitted and claiming the safety of each ingredient.

Efficacy Claim Evaluation

In addition to the product testing and safety assessment requirements, from 1 January 2022 overseas manufacturers must complete an efficacy evaluation for their products and submit the results during the notification/registration process. NMPA issued the *Specifications for the Evaluation of Efficacy Claims of Cosmetics* in order to standardise the evaluation process and obtain reasonable, feasible and scientific results.²⁷

The new standard provides instructions on the methodologies supporting the evaluation of efficacy claims for general and special cosmetics, i.e. through literature review, research data analysis, and efficacy tests – which in turn can consist of human trials, consumer use testing and laboratory tests. For a total of 20 different efficacy claims an evaluation is necessary; the method to be used depends on the given efficacy claim. For instance, Art. 10, Art. 15 and Art. 18 stipulate that for products with claims of whitening, sunscreen, acne-removing, anti-hair loss, nourishing and repairing, additional human trials must be conducted by an NMPA-accredited lab in China; while the other product efficacy claim categories can be evaluated by international institutions but must provide a Chinese translation. A comprehensive overview of the testing requirements for selected efficacy claims can be found in Table 1.

²⁶ 化妆品安全评估技术导则: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210409160436155.html?type=pc&m=> (accessed: 18 Jan 2022).

²⁷ 化妆品功效宣称评价规范: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210409160321110.html?type=pc&m=> (accessed: 18 Jan 2022).

According to Art. 7 of the Specification, an exemption of the evaluation may be possible for some efficacy claims, for instance, those that can be directly recognised by smell, vision, or other senses, such as cleansing, make-up removal, beautifying and grooming, perfuming, body refreshing, deodorising, shaving, hair dying, perming, and colouring. Additionally, exemptions may be possible for efficacy claims that function through physical covering, maintaining, friction, etc., and that clearly indicate on the label to only have physical effects, such as freckle-removing by physical covering, physical exfoliation, physical removal of blackheads.

Table 1: Overview of the testing requirements for selected efficacy claims

Efficacy Claim	Human Trial	Consumer Use Test	Laboratory Test	Literature Docs/ Research Data
Freckle-removing and whitening	X			
Sunscreen	X			
Anti-hair loss	X			
Acne-removing	X			
Nourishing	X			
Repairing	X			
Anti-wrinkle	*	*	*	+
Tightening	*	*	*	+
Relieving	*	*	*	+
Oil-control	*	*	*	+
Exfoliation	*	*	*	+
Hair breakage prevention	*	*	*	+
Anti-dandruff	*	*	*	+
Moisturising	*	*	*	+
Hair care	*	*	*	*
Specific claims suitable for sensitive skin	*	*	*	*
Specific claims (efficacy of an ingredient)	*	*		
Claim gentle (no stimulation)	*	*	*	*
Claim quantitative index (time, stats, etc.)	*	*	*	+
Claim new efficacy	*	*	*	+

X refers to mandatory methods; * refers to optional methods, but at least one required; + refers to methods that can be combined simultaneously to at least one * optional method.

Source: Annex 1 of the Specifications for the Evaluation of Efficacy Claims of Cosmetics (see footnote no. 27).

The results must be summarised in a full report and abstract, clearly indicating the product information, parameters and testing methods of efficacy claim evaluation, and containing a final conclusion and relevance of the test results. The final report will then be an integral part of the application dossier to be submitted to NMPA.

Step 4: Dossier submission

Once the relevant notification and registration documents are complete, the applicant submits the full dossier to the NMPA. While the notification process (general cosmetics) documents in electronic form are allowed, the registration process (special cosmetics) also requires documents as paper version.

According to Art. 19 of CSAR and Art. 20 of the *Provisions for Management of Cosmetic Registration and Notification Dossiers*, the following documents must be included in the application dossier for both notification and registration processes of imported cosmetics (more details on the label will be provided in section 2.3 of this report):

- Cosmetic Registration and Notification Information Form and Related Documents;
- Information of the Production Enterprise;
- Product Name;
- Product Formula or Full Ingredient List;
- Product Executive Standards;
- Product Label Sample Manuscript;
- Product Testing Report;
- Product Safety Assessment Documents;
- Efficacy Claim Evaluation Report (if necessary).

Step 5: Review, approval, and certificate issuance

Once the application dossier has been submitted, NMPA will start the review process. The process varies significantly depending on whether it is a notification (general cosmetics) or registration (special cosmetics).

Specifically, for general cosmetics, the notification process is completed after submission of the application dossier on NMPA's online platform and receiving the final approval from the provincial-level competent authority where the applicant is located. The review process takes around 5 working days, after which an electronic certificate of the notification is granted: at this point, the cosmetic product may be officially imported and sold in China.

Special cosmetics, on the other hand, must go through two different reviewing processes before the registration certificate will be granted. After submission of the electronic and paper version to NMPA, a first formal review is conducted, lasting for around 5 working days, followed by a technical review from a technical institute, lasting around 90 working days.

- If the technical review is successful, the results are submitted to NMPA, which in turn needs additional 20 working days to issue an administrative decision, and additional 10 working days to issue the registration certificate: at this point, the cosmetic product may be officially imported and sold in China.
- If the technical review is unsuccessful, the applicant has a maximum of 20 working days to file objections and to submit supplementary documentation; additional 30 working days will be needed for a re-examination from the institute in charge of the technical review.

Step 6: Post-market supervision

Once the approval certificate is obtained, the cosmetic product can be imported and sold into China. However, the duration of the certificate usage differentiates for general cosmetics and special cosmetics:

- General cosmetics: no expiration date. However, a technical review will need to be done by the responsible authority within 3 months after the issuance of the e-certificate: if any issues appear (e.g. missing or incorrect documents), supplementary documentation must be submitted; if the issues are not solved, the cosmetic approval certificate will be suspended. In addition, ad hoc reports with relevant information and product compliance status will have to be submitted every year.
- Special cosmetics: the certificate is valid for 5 years. An application for renewal can be submitted 30 working days before the expiration; NMPA would then approval the renewal within 30 working days –

unless in the meantime the relevant national and technical standards have been revised and the cosmetic product is not anymore compliant (Art. 24 of CSAR).

2.3. Packaging and labelling

Currently, the mandatory national standard for the labelling of cosmetic products is GB 5296.3-2008 *Instruction for use of consumer products - General labelling for cosmetics*.²⁸

However, as part of the implementation of the CSAR, in the coming years, new standards will set principles on cosmetic labelling. For instance, in 2021 NMPA released the *Administrative Measures on Cosmetic Labelling*, which will start to be implemented from 1 May 2022.²⁹ The content of the label must be legal, true, complete, accurate and consistent with the information provided during the notification or registration process of the cosmetic product.

Two options for the label are available: (i) create a label and sales packaging specific for the Chinese market; (ii) create a Chinese label to be attached to the original packaging of the product. Regardless of the option chosen, the label must follow very detailed rules in terms of language, information provided and design. For instance, all the information on the label must be in Chinese characters, with the exception of the name and address of the manufacturer, as well as conventional terms – which can be displayed in Latin words but with a size equal to or smaller than the Chinese character, and with the same colour. The specific information to be included in the label is specified in Art. 7 and Art. 14 of the *Administrative Measures on Cosmetic Labelling*, namely:

- Product name (generally consisting of a brand name, a generic name, and an attribute name);
- The number of the notification/registration approval certificate;
- Name and address of product registrant / notifier;
- Name and address of the manufacturer, and its production license;
- The number of the standard executed by the product;
- List of ingredients – which have to be written according to their Chinese INCI names, in descending order of concentration, at least for ingredients with a concentration above 1%;
- Net content – if the net content of the product is less than 15g/15ml, then only a reduced number of information must appear on the packaging of the product sold;³⁰
- Durability – in one of the following formats (i) production date and shelf life; (ii) production batch number and expiration date; or (iii) production date and the period of use;
- Methods of use;
- Safety marks and precautions for use and storage conditions, e.g. for children or other special groups;
- Efficacy claim evaluation;
- Country of origin of the imported product;
- Other content prescribed by laws, administrative regulations, and mandatory national standards.

According to Art. 19 of the *Administrative Measures on Cosmetic Labelling*, there are several restrictions for using – either explicitly or implicitly – certain content on the label, for instance, if it includes medical functions or terms, therapeutic claims, exaggerated or misleading descriptions. Specifically, the following is prohibited:

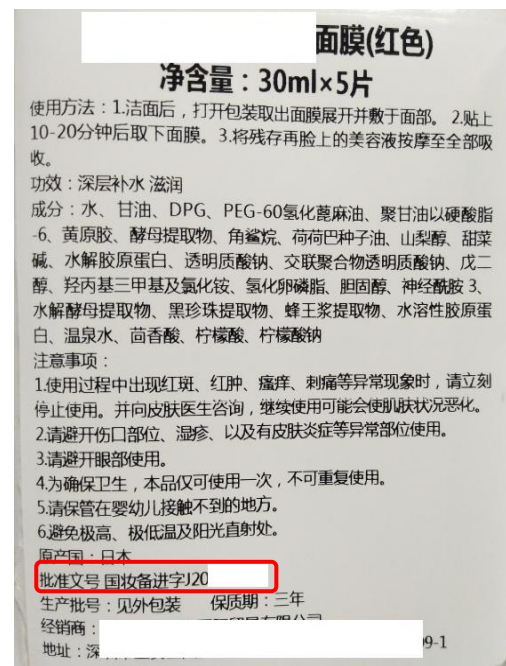
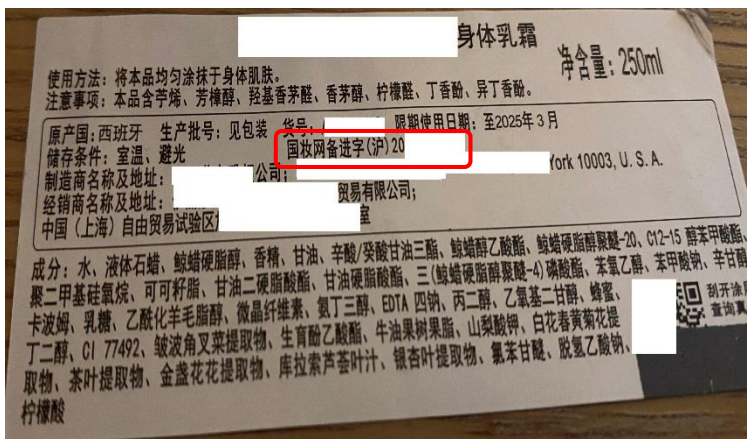
²⁸ GB 5296.3-2008 消费品使用说明—化妆品通用标签: <http://std.samr.gov.cn/gb/search/gbDetailed?id=71F772D7F656D3A7E05397BE0A0AB82A> (accessed: 19 Jan 2022). For a detailed overview of China's standardisation system, see the recording of a dedicated webinar organised by the EU SME Centre in January 2021: <https://www.eusmecentre.org.cn/event/2021-01-28/chinese-standards-compliance-european-exporters-online-workshop>.

²⁹ 化妆品标签管理办法: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/gtg/qtggtg/20210603171933181.html> (accessed: 19 Jan 2022). A transition period until May 2023 is granted to products which have completed the notification or registration process before the implementation date.

³⁰ Specifically, product Chinese name, number of the notification/registration approval certificate, Name and address of product registrant / notifier, net content, durability; all the other information must be included in the package leaflet.

- Medical terminology, names of medical celebrities, words describing the role and effects of medical treatment, or names of approved drugs, expressing or implying that the product has a medical effect;
- False or misleading descriptions using false, exaggerated or absolute terms;
- Trademarks, designs, font colour size, colour differences, harmonics or suggestive words, letters, pinyin, numbers, symbols, etc., used in a way implying medical effects or make false claims;
- Fabricating concepts using terms or mechanisms that are not widely accepted by the scientific community, and thus misleading consumers;
- Fabricating false information, disparaging other legitimate products, and thus misleading consumers;
- Misleading consumers by using fictitious and unverifiable scientific research results, statistics, survey results, abstracts, quotations and other information;
- Efficacy claims of new raw materials that the product does not actually have, or is not allowed to claim;
- The use of logos, awards and other cosmetic safety and efficacy-related claims and terms not confirmed by the relevant industry authorities;
- The use of state agencies, medical and public welfare institutions or their staff, as well as the name and image of experts appointed to certify or recommend the product;

Examples of labels, stuck on the original packaging (cosmetic registration approval numbers circled)



- Assertions or guarantees of efficacy or safety;
- Marking vulgarity, feudal superstition or other content that violates public order and morality.

Finally, it is noteworthy that in China, relevant laws and regulations explicitly forbid cosmetic brands to use the words ‘organic’ and ‘natural’ on both the packaging and label – either in Chinese or in English. However, it seems that such words are allowed to be used in foreign languages (not in Chinese), only if the product is sold through the Cross-Border E-Commerce model. Still, there are some workarounds that many brands are using to advertise their organic and natural products, for instance by engaging Chinese KOLs or creating a social buzz on these words.³¹

³¹ For more information on the regulations, market and tactics to sell organic and natural cosmetics in China, see the EU SME Centre webinar “The Organic and Natural Cosmetics Sector in China”: <https://www.eusmecentre.org.cn/event/2021-11-11/organic-natural-cosmetics-sector-china>.

2.4. Customs inspection

Based on the *Administrative Measures on Supervision of Inspection and Quarantine of Imported and Exported Cosmetic Products*,³² all imported cosmetics require a customs inspection to ensure that import procedures take place in accordance with laws, administrative regulations, and relevant standards in order to guarantee the safety of cosmetics as well as social and public accountability.

Specifically, once NMPA approves the notification/registration of a cosmetic product, the importer of the cosmetic product will need to apply for customs inspection, submitting various documents such as the notification or registration license, product formula, as well as the original label and its translation. According to Art. 11-14 of the Administrative Measures, Customs inspection may be done through:

- On-site inspection: to check the conformity of goods and corresponding certificates, product packaging, and sanitary conditions of transportation, containers, or storage places
- Label inspection: to check the label's compliance with relevant laws, administrative regulations, and mandatory technical standards (see section 2.3 of this report)
- Sampling and laboratory test: the customs may take samples of determined testing items and send them to a qualified testing institution.

If the customs inspection is completed successfully, the cosmetic product will be cleared and allowed to leave the port to reach the final destination.

For a brief overview of the main steps of a general trade mode custom clearance procedure see the table below:

Overview of customs clearance for general trade

Steps	Remarks
Contract set-up	Choose incoterms carefully
Import license application	Understand related import rules for cosmetics in advance, and secure import license and registration/notification for cosmetics
China customs e-port online pre-declaration	Provide all necessary declaration data and information to importer/agent/broker
Shipment arrival at the Chinese port	Goods will be stored in a warehouse, supervised by customs before clearance
Paper documents and license submission for customs review	Customs will check all declared data and information (HS code, declared price, license etc.). The HS Code for cosmetic products usually starts with the 4 digits 3303, 3304 or 3305 (the 7 th to 10 th digits in China may differ)
Import inspection and quarantine	Customs may do further on-site inspections, label checks, and sample testing through a laboratory
Pay import duty and fees	<ul style="list-style-type: none"> ▪ Customs tariffs: 2% to 15%, country-specific differences may apply ▪ VAT: generally 13% ▪ Consumption tax: 15% for certain products only (luxury, high-end) ▪ Other fees may include port fees and warehouse fees
Customs released	Goods are allowed to leave the port

³² 进出口化妆品检验检疫监督管理办法: http://www.gov.cn/govweb/gongbao/content/2012/content_2106865.htm (accessed: 20 Jan 2022); as well as its 2018 revision: http://www.gov.cn/gongbao/content/2019/content_5368593.htm (accessed: 20 Jan 2022).

Products imported into China via CBEC follow simplified customs clearance procedures, and are usually cleared within 24 hours after the importer applies for inspection, provided that all the required documentation is correct. For more detailed information about the customs clearance for general trade mode or for CBEC, please read the EU SME Centre’s dedicated guidelines.³³

2.5. How to export cruelty-free cosmetics

As the graph below indicates, the starting point is to understand the classification of the cosmetic product: special cosmetic, or general cosmetic (more details in section 2.1 of this report).

For special cosmetics imported in China via normal trade, animal testing is unavoidable. The only option would be to sell such products through CBEC – if they are on the Positive List for CBEC imports (more details in section 1.2 of this report). Currently, relevant products allowed to be sold via CBEC are HS codes 33052000 (Preparations for permanent waving or straightening) and 33059000 (Other hair care products) which may be adapted for certain hair dyes, hair perming and anti-hair loss products.

For general cosmetics, animal testing may be avoided if none of the following exceptions applies to the product:

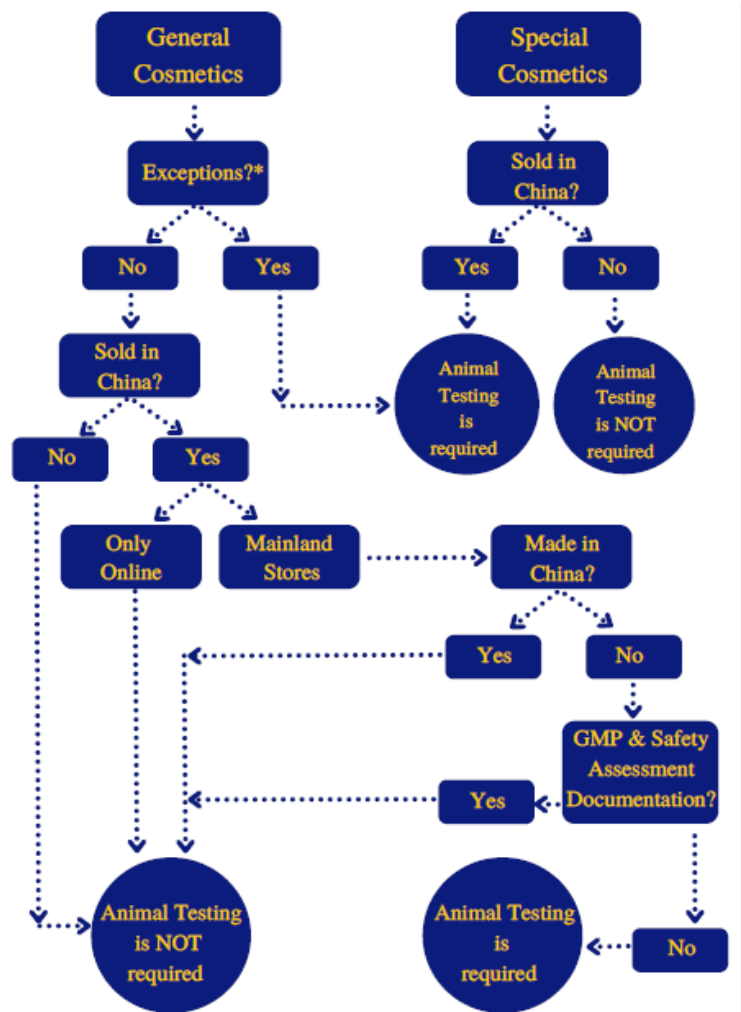
- Used by infants and children;
- Contains new cosmetic ingredients;
- The product’s notifier, intermediary or manufacturer is listed as a key supervision target according to the results of the quantitative rating system established by NMPA.

Then, if the general cosmetic is manufactured domestically in China (by the brand owner or subcontractors), animal testing is not required. The same case applies to the general cosmetic products manufactured overseas and imported in China via the CBEC model.

If the general cosmetic product is manufactured overseas and is imported in China via general trade, then, the mandatory animal testing may be exempted if certain documents are provided, namely:

- Good Manufacturing Practices (GMP) certificate: describing the supervision of the entire manufacturing process and quality control system, thus proving the manufacturer’s compliance. The GMP certificate must be issued by the competent authority of the country of origin or the cosmetic

Figure 5: Navigating through animal testing requirements



* Exceptions include: (i) Cosmetics for infants & Children; (ii) Cosmetics with new ingredients; (iii) Cosmetics whose notifier/intermediary/manufacturer is under focused supervision

³³ Customs Clearance for Imports to China: <https://www.eusmecentre.org.cn/guideline/customs-clearance-imports-china>.

regulatory authority of the local government where the overseas cosmetic manufacturer is based. It must be noted that only GMP certificates issued by government bodies will be accepted by China; GMP certificates issued by international certification organisations or cosmetics associations will not be accepted. A full list of EU Member States that release such GMP certificates is provided in the Annex of this report.

- Safety Assessment Report: to ensure the safety of ingredients and products and to identify risk substances or potential risks arising from chemical reactions of the ingredients by combining them. More details on the Safety Assessment Report are included in section 2.2 “testing, assessment, evaluation” of this report.

Annex: List of countries issuing GMP certificates for cosmetics

As seen in sections 1.3 and 2.5 of this report, the animal testing requirement for imported general cosmetics in China may be lifted under certain conditions – one of which is the submission, during the process of notification with NMPA, of a Good Manufacturing Practice (GMP) certificate issued by an official government agency where the cosmetic manufacturer is located.

However, GMP certificates for cosmetics issued by government agencies are not an EU requirement and are not yet available in all EU Member State; each country manages it differently. In fact, all cosmetics products circulating in the EU have to be produced according to the Cosmetics GMP described by the ISO 22716 standard, but compliance can be demonstrated either by a GMP certificate (issued by a government agency or a certification organisation/cosmetics association), or by a declaration stating compliance of the manufacturing process with ISO 22716.

The following table lists which EU Member States and corresponding government agencies are actively issuing GMP certificates to be used for animal testing exemption in China. The information was collected through desk research, and through direct feedback received by EU Member States embassies in China. For EU Member States not listed in this table, it does not necessarily mean that it is not possible to obtain such GMP certificates, but only that the author of this report did not find relevant information; cosmetic manufacturers from those EU Member States are advised to enquiry directly with the relevant authorities, both at national and provincial level.

Country	Ministry	Comments and links
Austria	Austrian Federal Office for Safety and Health Care / Bundesamt für Sicherheit im Gesundheitswesen (BASG)	https://www.basg.gv.at/en/inspections/gmp/-gdp
Belgium	Federal Public Service of Health, Food Chain Safety and Environment, Inspection Service for Consumption Products, Cosmetics division	The company must conform voluntarily their manufacturing process to the GMP for cosmetic products as detailed in European Standard ISO 22716:2007 Cosmetics - Good Manufacturing Practices (GMP). To receive the certificate, the company must undergo an inspection by the service to verify compliance. Cost: €80 per certificate https://www.health.belgium.be/en
Finland	Finnish Safety and Chemicals Agency (Tukes)	The Finnish Safety and Chemicals Agency (Tukes) acts as the competent authority pursuant to the Act on Cosmetic Products. Tukes is also the supervising authority which, together with Finnish Customs, monitors the cosmetic products on the market. https://tukes.fi/en/chemicals/cosmetics
France	French National Agency for Medicines and Health Product Safety / Agence nationale de sécurité du médicament et des produits de santé (ANSM)	https://ansm.sante.fr/actualites/lansm-delivrer-des-certificats-bpf-aux-fabricants-souhaitant-exporter-des-produits-cosmetiques-vers-des-pays-tiers

Country	Ministry	Comments and links
Greece	Greece's National Organization for Medicines (EOF) / Εθνικός Οργανισμός Φαρμάκων	The requirements for issuing a GMP Certificate is that the manufacturing site is granted a manufacturing authorization and has been inspected. For the issuance of GMP Certificate the manufacturing site must submit an application to the National Organization for Medicines with the following: <ul style="list-style-type: none"> Application of the manufacturing site. Fee of 300 euros for the issuance of a GMP Certificate with the manufactured forms in detail. Each fee is paid increased by 2,4% stamp duty (link to website and legal basis).
Hungary	National Institute of Pharmacy and Nutrition / Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI)	A certificate can be applied for by a Hungarian manufacturing site or an identical Hungarian legal entity, if the subject of the document is a site in Hungary, and less than 3 years have elapsed since the last inspection. The procedural fee: HUF 22,500 per copy https://ogyei.gov.hu/a_gmp_igazolas_igenylese/
Italy	Ministry of Health / Ministero della Salute	An additional declaration to what is requested for CLV (Free Sale Certificate) is needed, sent by certified e-mail or mail, filled with company data, production sites and Declaration of compliance with Italian (art. 9 del Decreto del Ministro della Salute del 27 settembre 2018) and European (art. 8 REG 1223/2009) legal provisions. Each CLV is 190 euro. Stamp duty of 16 euro every 4 pages. <i>Rilascio Certificati di Libera Vendita (CLV) e Good Manufacturing Practice Declaration (GMP) per esportazione in Cina di prodotti cosmetici per uso generale</i> (direct link)
Portugal	National Authority for Medicament and Health Products / Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (Infarmed)	The only Portuguese Government Agency, mandated to issue a Good Manufacturing Practice (GMP) certificate is INFARMED. It must be noted, however, that INFARMED is not obligated by the Portuguese Law, nor by the European Law, to issue such a certificate, for cosmetics, only issuing it normally for medicines. Meaning that is not obvious if this kind of GPM could be issued in Portugal, according to the Chinese requirements. www.infarmed.pt
Slovenia	Health Inspectorate of the Republic of Slovenia (ZIRS)	Under special controlled conditions and to a limited extent, ZIRS issues a free sale statement (FSC) to exporters, for specific shipments or products for which the customs or registration authorities of the importing country require a certificate of the country of origin or a statement that the product is freely sold on the Slovenian market, according to Regulation 1223/2009 / EC. As part of these, a declaration of compliance with GMP can be added to the statement in if there was an addition to the inspection of the production of the cosmetic product performed previously. No costs are charged. https://www.gov.si/en/state-authorities/bodies-within-ministries/health-inspectorate/ .

Country	Ministry	Comments and links
Spain	Spanish Agency of Medicines and Health Products / Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)	<p>There are two types of certificates:</p> <ul style="list-style-type: none"> ▪ <u>Certificados de BPF</u> (Buenas Prácticas de Fabricación) para empresas en territorio nacional que realizan materialmente la actividad y cumplen los requisitos de la norma UNE-EN ISO 22716 ▪ <u>Certificados de productos</u>, que indican la situación legal de los productos en la Unión Europea y de las empresas. Puede ser también de interés ya que tiene una mención específica a la conformidad de los productos cosméticos a exportar con las BPF y puede completarse con anexos que incluyen certificaciones de las empresas fabricantes. <p>Para solicitar un certificado BPF la empresa fabricante debe haber presentado ante la AEMPS de forma previa al inicio de su actividad declaración responsable de actividades de fabricación. Para consultas en relación con todos estos procedimientos, disponemos del buzón institucional cosmetinstal@aemps.es</p>
Sweden	Swedish Medical Products Agency / Läkemedelsverket	<ul style="list-style-type: none"> ▪ Fee for operations: SEK 4,000 ▪ Fee per product in the range: SEK 600 <p>If more than 200 products, no fee is paid for the exceeding part.</p> <p>https://www.lakemedelsverket.se/sv/kosmetika/tillverka-importera-och-salja-kosmetika/anmalan-och-avgifter#hmainbody7</p>

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The EU SME Centre helps European SMEs get ready for China by providing them with a range of information, advice, training and support services.

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To submit your enquiries directly to our experts go to *Ask-the-Expert* www.eusmecentre.org.cn/expert, or contact us at info@eusmecentre.org.cn

Further reading...

The EU SME Centre has nearly 200 reports, guidelines and case studies in its Knowledge Centre, the following may be relevant to you:

- *The e-commerce ecosystem in China: a checklist for European SMEs (2021):*
<https://www.eusmecentre.org.cn/report/e-commerce-ecosystem-china-checklist-european-smes-2021-update>
- *Guidelines on cross-border e-commerce (2019):*
<https://www.eusmecentre.org.cn/guideline/guideline-cross-border-e-commerce-china-2019>
- *How to set up a cross-border Wechat shop (2018):*
<https://www.eusmecentre.org.cn/guideline/how-set-cbec-wechat-shop>

We have also available *recordings of previous webinars* in this field:

- *Organic and natural cosmetics in China (Nov 2021):*
https://www.youtube.com/watch?v=N_jI9cSYqKo
- *The cosmetics sector in China (Jun 2021):*
<https://www.youtube.com/watch?v=WOmzWSReZbA>
- *Selling through livestreaming in China (June 2021):*
https://www.youtube.com/watch?v=d7k_lhcZjWQ
- *How well are you prepared to sell online in China? (Apr 2021):*
<https://www.youtube.com/watch?v=lfJJOIRxi0Q>
- *CBEC – Entering the Chinese market through the power of social networks (Dec 2020):*
https://www.youtube.com/watch?v=IYO28By_8eI

We also have a dedicated set of FAQs on CBEC: <https://www.eusmecentre.org.cn/faq>



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