

# New Rules for Registering Cosmetics in China



Following the Cosmetics Supervision and Administration Regulation (the "Regulation")<sup>1</sup> coming into effect on 1 January 2021, the Administration for Market Regulation published, on 7 January 2021, the new methods for registering and filing cosmetic products (the "Methods"), which will come into effect on 1 May 2021.

This new Regulation and the Methods clarify and simplify the rules that apply to registering and controlling cosmetic products sold in China.

This article will present the main changes affecting cosmetics manufactured outside of China and imported into China for marketing purposes, bearing in mind that the rules that apply to domestic cosmetics are slightly different to those that apply to imported cosmetics. A cosmetic product is considered to be imported if the last manufacturing stage involving contact with the product itself is carried out outside of China. Inversely, if this final stage is carried out within China, the product is considered to be a domestic product<sup>2</sup>.

## ■ CLASSIFICATION OF COSMETICS

Cosmetics are classified into two main categories:

- The first category is subject to a filing system managed by the local offices of the National Medical Product Administration (the "NMPA"), and concerns "regular use cosmetics" and cosmetics that contain new ingredients that do not pose high risks<sup>3</sup>;
- The second category is subject to a registration system managed at the national level by the NMPA and concerns "special use cosmetics", which essentially refer to hair-dyeing and perming products, anti-freckle treatments and skin whitening products, sunscreen products, anti-hair loss products and cosmetics that claim to have new effects, as well as cosmetics that contain new, relatively high-risk ingredients.

## ■ REGISTRATION/FILING OF COSMETICS

Registration/filing formalities will be carried out online through a dedicated platform<sup>4</sup>.

It is strictly forbidden to market a cosmetic product in China if it is not first registered/filed with the competent NMPA authorities.

The Methods list, for the first time, the conditions that must be met by an applicant (namely the foreign company, for imported cosmetics) before it may apply for registration/filing of its cosmetics. These include the following<sup>5</sup>:

- The applicant must be a legally-incorporated company or organisation;
- The applicant must have a quality control system that is adapted to the cosmetics subject to the registration/filing application;
- The applicant must be able to monitor and assess any negative effects that may be caused by the cosmetics.

Documents proving that the applicant meets the above conditions must be submitted to the competent NMPA when the first registration/filing application is made.

## ■ LOCAL AGENT

For imported cosmetics, the applicant must, given that it is registered outside of China, and as was previously the case, appoint a local agent, whose role and obligations are clarified and extended by the Methods:

<sup>1</sup> Decree no 272 of the State Council, superseding the Regulation on the Supervision of Cosmetics Hygiene

<sup>2</sup> Article 61 of the Methods

<sup>3</sup> Articles 4 and 16 of the Regulation

<sup>4</sup> Currently <http://jyxt.nmpa.gov.cn:8080/jyxt/>. A new platform is being designed by the NMPA that will eventually replace the current platform.

<sup>5</sup> Article 28 of the Methods

	From 1 May 2021	Before 1 May 2021
Role and obligations of the local agent	<p>The local agent<sup>1</sup> must:</p> <p>(1) carry out the registration/filing formalities for cosmetics/new ingredients in the name and on behalf of the foreign applicant;</p> <p>(2) assist the foreign applicant with monitoring any adverse reactions caused by the cosmetics and any quality issues caused by the use of new ingredients, and report these results to the competent authorities;</p> <p>(3) assist the foreign applicant with the defective product recall process;</p> <p>(4) in accordance with the provisions of the agreement entered into with the foreign applicant, be liable for the quality and safety of cosmetics marketed in China;</p> <p>(5) co-operate with the NMPA in the event of controls and inspections.</p> <p>Every year, the local agent must also submit the general use cosmetics import data to the competent NMPA, as well as the confirmation that they comply with legal and regulatory requirements, compulsory standards and technical requirements<sup>2</sup>.</p>	<p>For special use cosmetics, the local agent <sup>3</sup> is only in charge of carrying out the administrative formalities related to filing in China.</p> <p>For general use cosmetics, the local agent is in charge of carrying out registration and exploitation formalities and is also liable for product safety.</p>

Given the very important role played by the local agent and in so far as it is the one who, in practice, manages the registration/filing applications and all of the content submitted on the platform, we recommend that you select your local agent carefully, and that you enter into a detailed contract that clearly specifies its rights and obligations, with a particular focus on the formalities that must be carried out in the event of a termination of contract and change in local agent.

## ■ REGISTRATION/FILING TIMEFRAMES

The registration/filing application timeframes have changed: immediate effect for general use cosmetics but longer timeframes for special use cosmetics:

<sup>1</sup> Article 8 of the Methods  
<sup>2</sup> Article 37 of the Methods  
<sup>3</sup> Article 5 of the Regulations on the Approval of Administrative Licence Declarations for Cosmetics

	From 1 May 2021	Before 1 May 2021
Processing time for filing applications - general use cosmetics	Immediate effect once the application has been submitted on the dedicated NMPA platform The systematic technical examination has therefore been withdrawn, but once products are marketed in China, they obviously remain subject to NMPA controls.	Verification of formal requirements carried out by the competent NMPA within five working days and issuance of a registration certificate; Then followed by a technical examination carried out within three months from the date of registration <sup>1</sup> .
Processing time for registration applications - special use cosmetics	Verification of formal requirements carried out by the NMPA within five working days, then compliant applications are sent to the technical assessment commission <sup>2</sup> ; Technical assessment carried out within 90 working days; NMPA confirms the content of the technical assessment within 20 working days of receipt Filing certificate is issued within 10 working days, Certificates are valid for five years and renewable upon request made between 30 and 90 days before the date of expiry.	Verification of formal requirements carried out by the NMPA within five working days, then compliant applications are sent to the technical assessment commission <sup>3</sup> ; Technical assessment carried out within 60 working days; Filing certificate issued.

## ■ PREPARING THE REGISTRATION/FILING APPLICATION

In accordance with the provisions of article 19 of the Regulation, the documents/information that must be submitted to the NMPA are from now on the same for a filing application (general use cosmetics) as for a registration application (special use cosmetics), namely:

- (1) The applicant's name, address and contact details;
- (2) The manufacturer's name, address and contact details;
- (3) The name of the product;
- (4) The formula or complete list of ingredients;
- (5) The norms and standards used;
- (6) A label sample;
- (7) An inspection report;
- (8) Documents related to product safety assessments;
- (9) The product's marketing permit for the country of manufacture or, in the case of a product specifically manufactured for sale in China, research documents and tests carried out specifically for Chinese consumers;
- (10) Documents showing that the product manufacturer meets cosmetic product manufacture and quality standards.

The Chinese authorities have greatly simplified the list of documents to be submitted compared to the current requirements, most notably by removing the following documents/information from the list:

<sup>1</sup> Article 16 and 21 of the Regulation on the acceptance of declarations in respect of administrative licences for cosmetics  
<sup>2</sup> Article 13 to 16 of the Methods  
<sup>3</sup> Article 16 and 21 of the Regulation on the acceptance of declarations in respect of administrative licences for cosmetics

- the product quality control and safety requirements;
- the pictures of the product's packaging, including the label and the instructions for use;
- the description of the manufacturing process;
- the technical specifications that apply to the product;
- the product safety assessment reports for products that contain ingredients that pose a safety risk;
- for sunscreens, the inspection report confirming the protection factor (SPF, FPA or PA);
- for some special use cosmetics, the active ingredients used and the corresponding scientific literature related to their uses;

It is however still possible that when the system and new platform are actually implemented, they will still require the submission of additional documents.

Once a special use cosmetic product has been filed, but before it is marketed, the local agent must submit a photo online of its label in order to inform the public<sup>1</sup>.

## ■ REGISTRATION/FILING OF CHANGES

The Methods also provide further clarifications on the need for registering/filing any potential changes made to cosmetics that have already been registered/filed.

For general use cosmetics:

- The name may not be changed unless a justification is provided.
- The composition may not be changed unless it is a minor change, such as, for example, one related to an ingredient's supply source.
- A new registration is required if a change in the address of the local agent results in a change of the competent NMPA office<sup>2</sup>.

For special use cosmetics, the formalities to be carried out depend on the type of change<sup>3</sup>:

- if the change has no impact on safety or the uses of the product, then a simple filing application is required;
- if the change has an impact on safety, or is related to a substantial change in the manufacturing process, or the uses of the product, an application for a change of the registration must be submitted;
- in the event of a change in the name of a product of its ingredients that results in a creation of a new cosmetic product, a new registration must be carried out.

In the months to come, further regulations, memorandums and application decrees will certainly be published in relation to the practical aspects of implementing the Methods and Regulations. These will provide further clarifications on, most notably, the practical ways to carry out registration and filing formalities for cosmetic products.

<sup>1</sup> Article 48 of the Methods  
<sup>2</sup> Article 36 of the Methods  
<sup>3</sup> Article 41 of the Methods



For any additional information  
please contact:

Sylvie SAVOIE  
HEAD of Beijing office  
[savoie@dsavocats.com](mailto:savoie@dsavocats.com)

Chen Xiaoyun  
Legal Advisor - Beijing Office  
[chenxiaoyun@dsavocats.com](mailto:chenxiaoyun@dsavocats.com)

Pour vous désinscrire cliquer [ici](#)