

# Registration Process for New Ingredients

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Article 11 of the China's new Cosmetic Supervision and Administration Regulation (“**CSAR**”) (effective since 1 January 2021) states new ingredients are a natural or artificial ingredient not previously used in cosmetics in China. New ingredients must be approved by the National Medical Products Administration (“**NMPA**”) before being included in cosmetics for sale within China.

Additionally, if the new ingredient is a new chemical, then the Ministry of Ecology and Environment (“**MEE**”) must be notified before it is manufactured or imported into China.

New chemical ingredients are classified as being either *high risk* (i.e. preservatives, UV filters, colorants, hair dye; skin whitening – reflect the special use category) or *low risk* (i.e. all others). High risk new ingredients require NMPA registration whereas low risk ones only need to comply with filing (again similar to the difference between how China treats special use and non-special use cosmetics – basically low risk get to market much more quickly).

Both tracks require testing and submission of dossiers but the high-risk new ingredients will undergo a rigorous technical review by the NMPA.



**Learn more**

We frequently publish thought pieces on the Chinese cosmetics industry, regulations and trends. A selection of recent publications are below:

### **Videos:**

- [China: How to Access a Beauty Market Showing 30% Growth](#)
- [Rabbits Rejoice! End of Animal Testing in China... kind of](#)
- [How to protect your brand in China - Registering trademarks and other market entry issues](#)

### **Publications:**

- [China: Beauty Revolution New Regulations Announced for Cosmetics](#)
- [China's Move to Cruelty Free: New Draft Regulation Changes Requirements for Cosmetics Filing](#)
- [China: Beauty Revolution - New Regulations Announced for Cosmetics](#)

## What information needs to be disclosed during the registration process?

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New ingredients are based on innovation and investment by the cosmetics company or their major suppliers.

Understandably, international companies have concerns as to the information that is shared within China in respect of such new ingredients.

**The disclosure is relatively comprehensive including R&D report; research documentation (preparation techniques, quality control etc.), safety assessment and technical requirements.**

This technical requirements are general in nature and include the following general technical summary, new ingredient's name both in Chinese and in English, INCI name, chemical name and trading name; source of ingredients; basic physical and chemical parameters; usage purpose and usage scope; safe usage limit; cautions, warnings, storage conditions, lifespan etc. In addition to the above, it is possible that NMPA may require additional information to be provided by the applicant. Such technical requirements will be attached as an Annex to the approval certificate or filing receipt and will be publicly available.

Although there are concerns voiced by international companies in respect of such disclosures being made to the Chinese authorities, however, we are unaware of any misuse in practice.

### The “Responsible Agent” Risk

A greater risk is that as is the case with imported cosmetic products, the PRC authorities require international companies to authorize a domestic enterprise to act as responsible person to make the application for the new ingredient. The **responsible agent** will apply for an account for applications, arrange for testing and prepare the application dossiers. Crucially, the **responsible agent** will be named in the registration / notification documentation and will often be seen as the “controller” of the registration. This **responsible agent** will have full access to all information and is a far greater risk to the international companies' commercial secrets than the NMPA. Despite this many chemical and cosmetic companies do not take steps to protect such information from the responsible agent. It is crucial to select a reliable partner, have robust contractual protections in place and keep involved in their China business.

## What information needs to be disclosed during the registration process? (cont.)

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In terms of the low-risk new ingredients, according to the current policy, once the applicant finishes application submission the filing has been completed. A preliminary filing code will be issued to the applicant. Generally, the applicant will be able to arrange for production after obtaining the preliminary filing code. However, there will be up to 90 working days' period for the NMPA to review the submitted materials. If during this time the authorities spot any issues then such recording filing will be revoked. . The exact timeline will usually depend on the actual case. Differences may arise from testing reports – raw material will have different testing periods. Companies can often use various testing reports they have on hand to save both time and costs. After submission, the new ingredient can be imported/used in cosmetics in China. If the new ingredient falls within the high-risk category, then a further maximum 128 working days will be required for the NMPA review and issuance of the new ingredient registration certificate.

After successful registration/filing, the registrant or filing party of new cosmetics ingredients is required to establish a safety monitoring system for a 3-year period. The registrant or filing party should, within 30 working days prior to each full year of safety monitoring of new ingredients, summarize and analyse the use and safety conditions of new ingredients, form an annual report and submit it to the NMPA. Such annual report includes:

1. information of the registrant, record- filing party or entrusted manufacturer of cosmetics produced with new ingredients;
2. information on cosmetics produced with new ingredients, including product name, product registration certificate or record-filing certificate number, product production or import or sales quantity, etc.;
3. the supervision and random inspection, investigation and punishment, and recall of cosmetics produced with new ingredients;
4. the adverse effect monitoring system of cosmetics manufacturers for cosmetics produced with new ingredients, the statistical analysis on product adverse effect and the measures to be taken; and
5. the risk monitoring and evaluation management systems, systems and measures to be taken by cosmetics manufacturers for cosmetics produced with new ingredients.

If no safety issues arise during such 3-year monitoring period then the new ingredient will be included into the IECIC as an “ingredient”.

# How are intellectual property rights in new ingredients protected?

The cosmetics sector is particularly affected by widespread counterfeiting. As branded products, the main focus of cosmetics companies typically rests on trademarks.

However, for new ingredients the focus is typically on patents. By way of brief introduction, a patent is when a state grants exclusive rights to an innovator for an invention, design or process for a certain period. The exclusivity is limited to the state (i.e. no global patent regime – you will need to register in each territory where protection is sought).

New ingredients will generally be chemicals or naturally occurring ingredients. Inherently a natural product is not an invention and therefore not patentable. However, companies do patent new ingredients (both naturally occurring as well as those invented in a lab). The approaches generally include registering patents for:

- formulations which include natural ingredients that do not occur in nature and the formulation is a new and not obvious innovation;
- use of a natural ingredient;
- modification of a natural ingredient;
- method by which the ingredient is manufactured or extracted; or
- manufacturing process using such new ingredient.

In addition, it may be that a new ingredient could also be branded as a trademark, such as L'Oreal's Nanoparticles.



## China patent issue

One complexity is that the patent basis may need to be adjusted for China – due to reasons of regulation (i.e. specific ingredients being prohibited or restricted by law in China) or to adapt to the local market. In such cases, it any innovation that was actually created in China must be first patented in China or risk being found invalid in China.

# Can a new ingredient be protected as a business secret in China?

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Chinese law does allow for the protection of trade secrets. Trade secrets are often used by companies that rely on recipes or rely on process know-how. Patents are ill-suited for such innovations as they are essentially a handbook to carry out the innovation.

Unlike patents, trade secrets must remain secret and accessible only to the owner. Accordingly, it is not possible to apply for a patent and also rely on trade secret protection – the two are incompatible.

Article 9 of the PRC Anti-unfair Competition Law requires a company seeking to rely upon trade secrets protection to establish the following:

- the information is confidential in that it is unknown to the public;
- the information is of economic benefit to the owner; and
- protective measures have been taken.

The Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement issued by Supreme People's Court further clarifies the scope of the said technical information<sup>[3]</sup> and business information<sup>[4]</sup>.

Accordingly, the dilemma for many new ingredient innovators will be to disclose the information and rely upon a patent; or seek to throw a protective ring of confidentiality around the secret and keep it as a business secret.

*3. the technical information refers to information as the structures, raw materials, components, formulas, materials, samples, patterns, propagation materials of new plant varieties, techniques, methods or steps, algorithm, data, computer programs and the relevant documents thereof in connection with technologies.*

*4. the information on ideas, management, sales, financial affairs, plans, samples, bidding materials, customer information and data related to the business activities*

# China Dilemmas for International Companies with a New Ingredient

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## Patent or Trade Secret?

As outlined above, the PRC Anti-Unfair Competition law requires maintenance of confidentiality in order to qualify as a trade secret. This collides with the requirement to make disclosures to the NMPA and indeed the public as part of the new ingredient registration/notification process. In respect of new ingredients, the matter will turn on what information the NMPA has disclosed to the public. According to Article 56 of the CSAR, the NMPA is obliged to keep confidential the trade secrets disclosed by the relevant party when publicizing the information related to the NMPA. This provision literally means the NMPA has a duty of confidentiality in their work. To our knowledge the NMPA does take this seriously.

Article 55 of the Administrative Measures for the Registration and Record Filing of Cosmetics further provides that, without the consent of the registrant or record-filing party, the NMPA, professional technical agencies and their staff members and personnel participating in the evaluation shall not disclose the business secrets, undisclosed information or confidential business information submitted by the registrant or record-filing party, except as otherwise provided by law or involving national security or major public interests. However, the PRC laws are silent as to what consequence the NMPA or related entity/persons would face if they fail to do so.

Therefore, trade secrets disclosed to the NMPA may not necessarily lose their secrecy. Provided the information is not included within the NMPA publicly disclosed information, such information will not be freely accessible to the public and therefore remains confidential. The innovator may rely on a mix of patents and trade secrets to protect different elements of the innovation.

## Patents vs China Ingredient Requirements

A further complexity is that China has a body of prohibited ingredients and also has different tolerances than Western markets for certain ingredients. It will be crucial to consider whether such prohibition or restrictions will affect the patent in China. This may mean that the Chinese product may be different from the innovator's patent. The innovator will need to consider this aspect early on to ensure that the innovation is protected in both China and abroad.

# China Dilemmas for International Companies with a New Ingredient (Cont.)

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The fact whether an ingredient is prohibited or restricted from being used in cosmetics in China does not affect the patentability. Even if prohibited/restricted ingredient has been patented in China, the patentee has the exclusive right to prohibit competitors from actually utilizing the ingredient, even if the competitors have obtained necessary approvals or licenses from competent authorities to use the prohibited/restricted ingredient.

## Original Patent in China

As stated above, patents are limited geographically. Accordingly, innovators may decide to patent their innovation in China by way of

1. directly filing a patent application with the Chinese Patent Office (i.e., first filing or convention application filed within 12 months of the first filing date); or
2. application based on an International (PCT) Patent Application (i.e., normally within 30 months from the filing date of the provisional patent application).

## China Innovation to be Patented First in China

One complexity is that the patent basis may need to be adjusted for China – due to reasons of regulation (i.e., specific ingredients being prohibited or restricted by law in China) or to adapt to the local market. In such cases, it should be noted that any innovation that was actually created in China should be first patented in China or risk being found invalid in China. Patenting in China is not a precondition for filing a patent application overseas but according to Article 19 of the PRC Patent Law any innovation created in China must pass a confidentiality review by the China National Intellectual Property Administration (CNIPA) before an application is to be made for a patent overseas. A failure to do so will mean a patent application for the same innovation would not be subsequently granted in China.

The owner of an innovation may apply for confidentiality review through the following three approaches:

1. Filing directly an application for confidentiality review on the innovation with the CNIPA;
2. In case the innovation has been applied for patent in China, filing an application for confidentiality review on the patent application;
3. Filing a PCT application for the innovation through the CNIPA, in which case the application for confidentiality review has been filed at the same time.

# Does the manufacturer who registers the ingredient gain any exclusivity?

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It is very important to note that the manufacturer who registers the new ingredient will obtain the right to import the materials into the market during the 3-year period when the new ingredient is under supervision.

According to Article 20 of the Administrative Measures on Cosmetics Registration and Record Filing, during the safe monitoring period, only the registrant or filing party of the new ingredient can use the new ingredient in cosmetics for production on the Chinese market.

During this safe monitoring period if there are other parties that wish to use this new ingredient to produce cosmetics on the China market then they will need the authorization of the original applicant.

Accordingly, for 3-year safe monitoring supervision period then the innovator of the new ingredient will have a strong market position.



Accordingly, if the applicant is a chemical manufacturer, then it will own the registration and if other parties wish to use the new ingredient (e.g., cosmetics brands) then this will require the applicant's authorization. At present, we understand that when making an application for the cosmetics filing system then it will be necessary to disclose the formula and if the cosmetic product includes a new ingredient, then during such 3-year supervision period the cosmetics manufacturer would need to have its application connected to the new ingredient so as to prove that the use of the new ingredient has been approved.

It is also important to note that if one applicant obtains the registration for a new ingredient then no other applicant can apply for the same ingredient with same function and usage scope/purpose. Such applicant would need to have a different function or usage scope/purpose to allow for a new application. In this way there is a massive first mover advantage in making the application.

After the 3-year period has elapsed then the new ingredient will go into the official list and then there is no need to obtain authorization from the original applicant. Any entity can produce or use this ingredient freely subject to IP rights as outlined above.



# Next steps for international cosmetics companies with new ingredients

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## **Know the registration process**

Cosmetic companies and more importantly their suppliers need to consider how to deal with the introduction of new ingredients into the China market. CSAR is likely to lead to far more new ingredient registrations/notifications in China. As indicated above two applications for new ingredients have already been accepted this year.

## **IP rights are crucial**

Business secrets unlikely to be a full protection. Patent protection is more likely but also need to consider the complexities of how PRC legal system in respect of cosmetics safe monitoring period collides with patent requirements.

## **Protecting the information**

Much time is spent worrying about Chinese authorities – however, in practice unlikely to be a major issue. Of much greater concern should be the domestic responsible person who will have broad access to all information. Also in most cases the domestic responsible person may end up in a position of conflict with the cosmetics company or supplier.

## **First Mover Advantage**

The system by which the NMPA requires a three year safe monitoring period also confers a major first mover advantage upon the first applicant. Any use of the new ingredient during such period will require the authorization of the new ingredient applicant if wishing to use the new ingredient in a cosmetics product for the Chinese market.

We expect that the new regulations coupled with increased competitiveness in the Chinese market will see renewed interest in registered new ingredients in China.

## Awards and recognition

### #1 in Acritas Asia Pacific Law Firm Index

Acritas, 2020

### Strategy and Changing Behaviours

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Financial Times Asia-Pacific Innovative Lawyers Awards 2019

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### North Asia Firm of the Year

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### Hong Kong Firm of the Year

AsiaLaw Awards, 2017

### Innovation in Legal Expertise

Financial Times Asia-Pacific Innovative Lawyers Awards, 2017

### Innovation in the Business of Law

Financial Times Asia-Pacific Innovative Lawyers Awards, 2017/2016

### Best International Firm in China Practice

Euromoney Asia Women in Business Law Awards

### M&A Legal Adviser of the Year

mergermarket, 2017

### Best Law Firm (Revenue over \$200m)

AFR Client Choice Awards, 2017

### Commercial Team of the Year

Lawyers Weekly Australian Law Awards, 2017

### Transaction Team of the Year

Lawyers Weekly Australian Law Awards, 2017

### Most Innovative Firm of the Year

China Law & Practice Awards, 2017

### #1 Asia-Pacific Legal Brand

Acritas, 2016

### Most Innovative Law Firm in China

Financial Times Asia-Pacific Innovative Lawyers Awards, 2016

### China Law Firm of the Year

Who's Who Legal, 2016/2015/2013/2011/2010/2009/2007/2006

### National Firm of the Year – China

IFLR Asia Awards, 2016/2014/2012/2010/2008/2007

### Firm of the Decade (10 Year Anniversary Special)

China Law & Practice Awards, 2016

### China Law Firm of the Year

ALB China Awards, 2016

### Most Innovative Law Firm Asia-Pacific

Financial Times Asia, 2015/2014

### International Law Firm of the Year

Australasian Law Awards, 2015

### Business Excellence Award for Services

AustCham-Westpac Australia China Business Awards, 2015

### #1 for M&A in Asia Pacific (excl Japan) by deal count and deal value

Bloomberg, Thomson Reuters, Mergermarket, 2016

### Structured Finance and Securitisation Team of the Year

IFLR Asia Awards, 2016/2015/2014

### Law Firm of the Year in Asia (Fund Formation)

Private Equity International Annual Awards, 2015

### Law Firm of the Year in Asia – Private Equity

Private Equity International's Infrastructure Awards 2015



## A sample of our experience

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Advised Sephora on potential construction contract dispute

### Charlotte Tilbury

Advised Charlotte Tilbury on contract review, dealing with ecommerce platforms and other daily support

### PAULA'S CHOICE

Advised Paula's Choice on their China market entry and company establishment

### MIKIMOTO COSMETICS

Advised Mikimoto on sales of cosmetics in China

### MARY KAY®

Perennial counsel for Mary Kay



Represented Christian Louboutin on patent infringement litigation

### L'ORÉAL

Advised L'Oréal on product related legal matters

### Johnson & Johnson

Advised Johnson & Johnson on its 100% acquisition of Beijing Dabao Cosmetics Co., Ltd.

### L'OCCITANE EN PROVENCE

Advised L'Occitane on opening its flagship T-Mall store, contract review, and other legal issues



Advised Percy & Reed on distribution contracts

### NU SKIN®

Advised Nu Skin on sales contracts and foreign direct investment and real estate issues



Advised Alain Delon on patent infringement case



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✓ Ranked law firm in  
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Chambers and  
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## A little bit about us



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