

INTRODUCTION TO THE CHINESE MARKET

Databook 2024

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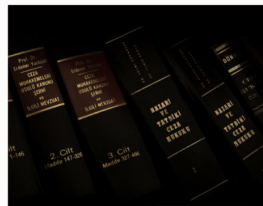
Introduction

Although reputedly difficult to access and with particularly demanding and complex regulations, the Chinese market never ceases to fuel the desire of export candidates. Immense and full of development opportunities, it cannot be conquered without a studied approach and mastery of its subtleties. This dossier is designed as a tool to help you take your first steps. It recalls the essentials of the new regulations, market trends, and consumer preferences and expectations. 祝你中国之行愉快 (Bon voyage to China)!

Regulation

Its acronym has the name of a Roman emperor, even if it is in China. The CSAR, which stands for Cosmetic Supervision and Administration Regulation, came into force on 1 January 2021. At least its founding text, since many others have followed to clarify, specify and detail it.

It is the first barrier to cross before embarking on a trip to the Land of the Rising Sun. And it is best not to overlook its importance, as the Chinese authorities are very careful to ensure that its requirements are respected...



CHINA: THE CSAR IS BORN, LONG LIVE THE CSAR!

China officially announced the release of the final version of the Cosmetic Supervision and Administration Regulation (CSAR). The new regulation will take effect on January 1, 2021. Under the new CSAR, the biggest overhaul lies in the regulations pertaining to cosmetic classification, ingredient management, efficacy claim, etc. ChemLinked experts detail the changes and new features of this new text.

On June 29, China finalised the long-awaited Cosmetic Supervision and Administration Regulation (CSAR). The new fundamental cosmetic legislation, initiated in 2014, was officially published by the Chinese State Council to replace the existing Cosmetics Hygiene Supervision Regulations (CHSR), which was firstly released in 1989. The new regulation is scheduled to be effective on January 1, 2021.

Encompassing 6 chapters with 80 articles, the new CSAR is designed to overhaul the outdated regulatory framework and address issues revolving around cosmetic pre-market and post-market management in new situations, such as cosmetic classification, new ingredient management, efficacy evaluation, safety assessment, online cosmetic supervision, accountability system, and punitive measures.

The cosmetic product definition

The CHSR defined cosmetic products as referring to *“chemical products for the daily use intended to be applied on any external part of the human body (such as skin, hair, nails, lips, etc.) by spreading, spraying or other similar ways to keep the body clean, eliminate unpleasant odor, protect the skin, and improve appearance and beauty.”*

For CSAR, cosmetic products refer to *“chemical products intended to be applied to the external part of the human body, such as skin, hair, nails, lips, etc. by spreading, spraying, or other similar ways for the purpose of cleansing, protecting, beautifying and modifying.”*

Note that the new definition excludes the function of eliminating unpleasant odours. Hence the question: will deodorants still be considered cosmetic products? The answer is not yet clear.

There are also two new exceptions to the general principles:

- Toothpastes, which are not yet defined as cosmetics, will nevertheless be governed by the CSAR, and may claim anti-caries, anti-plaque, anti-sensitivity of the gums, etc.
- Soaps are also outside the scope of CSAR, except for those that claim the efficacy of a “special cosmetic”, for example with a whitening action

The classification of products

Previously, cosmetic products were divided into two categories:

- “Special use cosmetics”, which included hair growth products, hair dyes, hair perming products, depilatories, breast beauty products, slimming products, deodorants, whitening (anti-stain) products and sun protection products
- “Non-special use cosmetics”, which included skin care products, hair care, nail care, make-up and fragrance products

CSAR is evolving these categories:

- The “Special use cosmetics”, which have to be registered, now only include hair dyes, hair perming products, whitening products, sunscreen and anti-hair loss products, to which are added products with a new efficacy

- The “Non special use cosmetics” become the “General cosmetics” and are defined as all other cosmetics excluded from the category of “Special use cosmetics”, which also means that their marketing is subject only to a simple notification.

A phase of transition

A five-year grace period was granted for already registered hair growth, hair removal, breast beauty, slimming, and deodorant cosmetics from the date of implementation of this regulation to ensure a smooth transition. The production, import, and sale of these products are prohibited after the transition period and the products will have to go through the whole registration process again.

Dossiers for registration and notification

The RBSC now specifically lists the information that must be in the dossier:

- Name, address and contact information of registration applicant or filer
- Name, address and contact information of manufacturer
- Name, address and contact information of domestic responsible person
- Product name
- Product formula or a full list of ingredients
- The standards adopted
- Sample manuscript of the label
- Testing report
- Safety assessment dossiers
- COFS (Certificate of Free Sale), intended to prove that the cosmetics imported into China have already been put on sale in the country where they were produced and that they comply with the regulations applicable in that country; for products manufactured specifically for export to China, and which therefore cannot produce a COFS, safety data must be submitted and tests carried out in Chinese laboratories
- GMP (Good Manufacturing Practice) certification
- Any other useful documentation

Efficacy claims

Another novelty introduced by the CSAR is that the claimed efficacy must be proven and based on “sufficient scientific evidence”, which may be relevant literature, research data or efficacy evaluation documents. A summary of this data must be published on a dedicated website of the NMPA (National Medicinal Products Administration) for the general public.

The definition of a new ingredient

The CHSR provides that the manufacture of cosmetics using new ingredients must be approved by the health administrative department under the State Council. In practice, the situation quickly came to a standstill: from 2009 to 2014, only 10 new ingredients were approved. There have been none since.

As a reminder, the “new ingredients” are understood as natural or artificial raw ingredients used for cosmetics for the first time in the territory of the People’s Republic of China.

The CSAR states that the new ingredients are of two types:

- Ingredients with high risk (preservatives, sunscreens, colorants, hair dyes, whitening agents), which must go through a complete registration process to be approved by the NMPA,
- Ingredients with low risk (all others), which can be placed on the market after a simpler and faster