

More Make-Up Applied to China's Management of Cosmetics: Here's How It Looks

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On June 29, 2020, the Chinese State Council released the long-awaited Cosmetic Supervision and Administration Regulation (hereinafter "Regulation")^[i], which will enter into force on January 1, 2021. This extensive Regulation contains six chapters detailing issues surrounding the supervision and management of cosmetic products and ingredients, production, import and operations, and legal liability. This Regulation, once adopted, will replace the current Cosmetics Hygiene Administration Regulation^[ii] (hereinafter "Hygiene Regulation") which has been governing the regulation of cosmetics for over 30 years in China.

Following the adoption of the Regulation, on July 21, the National Medical Products Administration (NMPA) published two important draft documents to detail the implementation of the Regulation for public consultation, including but not limited to the Administrative Measures for Cosmetic Registration (Draft for Comment) ("Registration Measures")^[iii], and on July 29, NMPA released the Cosmetic Classification Rules and Catalog (Draft for Comment) ("Classification Rules")^[iv].

Once the above draft documents are adopted, there will no doubt be a significant impact on domestic and overseas cosmetic producers and distributors in the China marketplace. Below we provide an overview of key changes in the newly published documents.

1. Adjusted Definition and Classification of Cosmetics

Compared with the current Hygiene Regulation, the Regulation now defines "cosmetic" as "daily used industrial chemicals which can be used on the outer surface of human body, including skin, hairs, nails, lips, etc., for the purpose of cleaning, protecting, beautifying and making up, by way of smearing, spraying or other similar means". Of particular note is that products for deodorizing have been removed from the scope of cosmetics, whereas functions of "skincare" and "facial beautifying" are revised to "protecting" and "beautifying", respectively; terms which have broader meanings.

In addition, the Regulation classifies cosmetic products into two categories per their inherent risk

levels, i.e., special cosmetics vs. general cosmetics, which are formerly known, respectively, as "cosmetics for special uses" and "cosmetics for non-special uses". Special cosmetics are subject to pre-market registration while general cosmetics are subject to notification to the local administrative agencies.

Specifically, "special cosmetics" refer to cosmetic for hair dyeing or perming, anti-spot and whitening, sun-screening and anti-hair loss, as well as cosmetics with new function claims. Under this scope, cosmetics with functions such as "depilatories" and "deodorants" will no longer be automatically subject to pre-market registration. A five-year transition period has been granted to special cosmetics that are not in compliance with applicable rules. According to the draft Classification Rules, product categorization and catalogues of cosmetics will be established per cosmetic's function, use area, dosage, the intended user group, and the use method. These rules and catalogues list 28 cosmetic functions, including moisturizing, soothing, refreshing, anti-wrinkle, etc. Notably, cosmetics with functions other than those listed will be regulated as special cosmetics and are subject to product registration. Functions such as hair growing, breast enhancement, and body slimming are not among the listed functions, meaning cosmetics having those functions will be subject to pre-market registration. In the meantime, the draft Classification Rules explicitly define the age range of "infants and young children" as well as "children" and carve out both user groups from the scope of "general population". Cosmetics that have functions other than those cleared for infants and children under the draft Classification Rules will be regulated as special cosmetics.

Regarding the notification of general cosmetics, the government aims to ease the burden on notifiers by streamlining the procedures and clarifying the timeline. However, it is still too early to tell whether the local authorities, in practice, will ease the review of general cosmetics and make the notification process less burdensome than registration.

2. Catalogue Management of Cosmetic Ingredients

The Regulation categorizes cosmetic ingredients into existing ingredients and new ingredients. A new ingredient, per its risk level, is required to be registered^[v] or notified to the Chinese government before it can be used in cosmetics for the first time in China. Following this requirement, some cosmetic ingredients that are widely used overseas must nonetheless be evaluated by the Chinese government if they are used in cosmetics that will be sold in China for the first time. Of particular note is that, under the draft Registration Measures, clearance of a new cosmetic ingredient will be proprietary, meaning that a cosmetic ingredient made by different manufacturers will be subject to separate approvals. If a cosmetic manufacturer wishes to use that new ingredient in its cosmetic product to be sold in China, it must obtain approval from the ingredient registrant/notifier. Otherwise, the cosmetic manufacturer shall petition to clear the intended use of the new ingredient.

In particular, the draft Technical Guideline for Cosmetics Safety Risk Assessment (Draft for Comment)^[vi] further sets forth detailed requirements for the safety risk assessment of new cosmetic ingredients. Specifically, ingredients sourcing from minerals, animals, plants, and biotechnologies are subject to specific documentation requirements for product safety evaluation.

Catalogues of cosmetic ingredients will be published detailing prohibited ingredients, ingredients subject to use restrictions, and special ingredients permitted for use as well as general existing ingredients. According to the Registration Measures, for cosmetic ingredients that have been registered for three years without safety issues, NMPA will include those substances into the Catalogue. In addition, permitted ingredients intended for use with new purpose or limitation are subject to new registration/notification.

3. Cosmetic Registrants and Notifiers Subject to More Stringent Supervision

One of the focal points of the Regulation is to strengthen the management of cosmetic product safety and quality by shifting more of the burden to registrants and notifiers. For this purpose, the Regulation introduces a set of new requirements that apply to the registrant/notifier. For instance, according to the draft Registration Measures, the scientific basis for function claims of the product shall be included with the registration or notification petition. In addition, newly added Article 22 of the Regulation requires the registrant and notifier to publish their reference materials in support of the product's function claims on designated government websites. Failure to fulfill this obligation will result in penalties from fines to business suspension. Additionally, registrants and notifiers of new cosmetic ingredients must file annual reports for three years on the ingredient's safety and usage to the local authority.

Furthermore, for imported cosmetics, the Regulation confirms that the overseas registrants/notifiers are the primary responsible persons in product safety, quality, and claim substantiation. Article 66 of the draft Registration Measures further allows the authority to initiate on-site inspections with cause on overseas manufacturers who submit false materials or conceal actual conditions in their applications.

The Regulation mandates a responsibility sharing scheme between the foreign registrant/notifier and its agent, i.e. the domestic legal entity is designated only to assist with product registration/notification, adverse reactions monitoring and reporting, as well as performing product recalls, when necessary. Under the current practice, the domestic responsible agent, which commonly is the product importer, shoulders more responsibilities in this regard. There is a wide range of penalties if an overseas registrant or notifier violates the Regulations, and failure to fulfill an imposed penalty can result in a company being barred from cosmetic importation for 10 years.

4. Other Highlights

- Toothpaste

In the draft cosmetic regulation that was published in 2015 for consultation,[vii] "cosmetics" is defined in a way that covers oral care products in general. Under the finalized Regulation, however, toothpaste no longer clearly fits the definition of cosmetics. For the first time, the Regulation directs reference to general cosmetics in terms of toothpaste management, meaning, toothpaste will likely be subject in the future to a notification mechanism. The Regulation also states that detailed management measures of toothpaste will be drafted by relevant authorities [viii].

- Labeling

For imported cosmetics bearing Chinese stickers, the Regulation requires consistency between information on the sticker and information on the original label [ix]. It is not yet clear what level of consistency will be required in practice.

Online trading of cosmetics has been booming in China in the last few years. Regulation of this emerging trading platform is scattered across various legal documents. The Regulation, for the first time, prescribes legal obligations of online traders and trading platforms in the area of cosmetics.

None of the newly released cosmetic documents touches upon exemptions for the use of toxicological tests in animals, which attracted much attention after draft measures on the notification of non-special purpose cosmetics was published for consultation in 2019 [x]. The industry is looking forward to having more clarity on this issue in the near future.

The Regulation will take effect on January 1, 2021. This Regulation is an important step taken by the Chinese government towards a more risk-based management approach to the regulation of cosmetic products. As the fundamental cosmetic regulation in China, the Regulation sets forth the legal framework for cosmetic supervision and management in China, but like most other umbrella laws and regulations, is sparse on details regarding implementation guidance. We anticipate that its accompanying rules and measures will become available in the coming months. Please stay tuned for more updates on the development and management of China's regulation of cosmetics.

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