
Regulations on the Supervision and Administration of Cosmetics

Corporate Legal Flash

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Summary

On June 16, 2020, the State Council promulgated the Regulations on the Supervision and Administration of Cosmetics, which will come into effect on January 1, 2021.

When they do, the current Regulations on the Hygiene and Supervision of Cosmetics, which have been in force for over 30 years, will be simultaneously abolished.



Regulations on the Supervision and Administration of Cosmetics

On June 16, 2020, the State Council promulgated the Regulations on the Supervision and Administration of Cosmetics (the “New Regulations”), which will come into effect on January 1, 2021, at which time the Regulations on the Hygiene and Supervision of Cosmetics will be abolished.

The New Regulations will play a fundamental role in regulating the cosmetic industry, with 80 articles covering (i) the administration of cosmetic raw materials and products; (ii) production and operation requirements; and (iii) supervision and management. They will also regulate the legal consequences of breaching these regulations, some of which differ from those established in current regulations, rules and announcements.

This legal flash summarizes the New Regulations, as well as the significant changes to the provisions of the current Regulations on the Hygiene and Supervision of Cosmetics and related regulations, rules and announcements applicable to the cosmetic industry (collectively, the “Previous Regulations”).

Cosmetic raw materials and cosmetics

The New Regulations confirm that cosmetic raw materials and cosmetics are subject to classified administration systems based on their risks. Different administration and supervision methods will be applied according to the corresponding risk level of the cosmetic raw materials and cosmetics.

Cosmetic raw materials

In line with the Previous Regulations, cosmetic raw materials are divided into new and used raw materials in the New Regulations. New raw materials are natural or artificial raw materials that are used in cosmetics for the first time in China, while used raw materials refer to those that have already been listed in the catalog of used cosmetic raw materials issued by a competent authority.

Unlike the registration administration system that applies to all new raw materials, under the New Regulations, new raw materials are subject to a classified administration system based on risk levels. New raw materials with relatively high risks (i.e., those with antiseptic, sunscreen, coloring, hair dyeing, freckle removal, and whitening functions) must be registered with the competent authority before being used; while other new raw materials are subject to the record-filing procedure.



Under the New Regulations, new cosmetic raw materials must be monitored for three years from the date they are placed in the market. Within this three-year period, the registrant or the record-filing applicant of the material must annually report on the usage and safety to the competent authority. Provided no safety issues are identified, the new raw material will be added to the catalog of used cosmetic raw materials.

Cosmetics

Under the New Regulations, cosmetics are divided into special and ordinary cosmetics, which are different from the special use cosmetics and non-special use cosmetics category under the Previous Regulations. Under the New Regulations, special cosmetics are those used for hair dyeing, hair perming, freckle removal, whitening, sunscreen, anti-hair loss and those that allegedly have new effects. All others are defined as ordinary cosmetics. Besides, toothpaste will be regulated by referring to articles related to ordinary cosmetics under the New Regulations.

Comparing the special cosmetics category under the New Regulations to the special use cosmetics under the Previous Regulations, cosmetics used for hair growth, hair removal, breast building, and deodorizer are removed from the special cosmetics category. The New Regulations also establish a five-year transition period for the production and sale of these cosmetics based on their existing registrations.

Similar to the new cosmetic raw materials administration system, cosmetics are subject to a classified administration system based on risk levels. Under the New Regulations, special cosmetics must be registered with the competent authority, while ordinary cosmetics are subject to the record-filing procedure. The New Regulations also highlight the responsibilities of registrants and record-filing applicants of cosmetics, stating that they are accountable for the cosmetics' quality, safety, and alleged functions.

Imported cosmetics are also subject to the above classified administration system, which is in line with the current regime of regulating the importation of special use cosmetics and non-special use cosmetics under the Previous Regulations.

The New Regulations also require overseas registrants and record-filing applicants of cosmetics to designate domestic legal persons in China to handle the registration and record-filing procedures, assist with monitoring adverse reactions to cosmetics and implement product recalls. Compared to the current administration system applicable to imported cosmetics, it seems that the new provisions aim to reconcile the roles of (i) the unit responsible for application in China for registration of imported special use cosmetics and (ii) the domestic responsible person for the record-filing, import, operation, and quality and safety liabilities of imported non-special use cosmetics. The New Regulations do not state whether the responsible unit for application in China and the domestic responsible person will be replaced by the designated domestic legal persons in China once the New Regulations



come into effect. However, after consultation by phone with the competent authorities on a no-name basis, they verbally confirmed that this will be the case.

Also, on July 21, 2020, the National Medical Products Administration published the Administrative Measures for the Registration of Cosmetics (Draft for Comment). This draft details the requirements and procedures for the registration and record-filing respectively applicable to new cosmetic raw materials and cosmetics, as well as the obligations of the domestic legal persons in China designated by overseas registrants and record-filing applicants of cosmetics. However, provisions for this type of documentation are for reference purposes only. We expect that formal regulations and rules will be issued to clarify these matters.

Production and operation

Regarding the production of cosmetics, the New Regulations explicitly allow the registrants and record-filing applicants of cosmetics to manufacture them on their own or to authorize a qualified third party to manufacture them. The New Regulations also list the general obligations of registrants, record-filing applicants and authorized manufacturers of cosmetics, which include:

- establishing a cosmetics production quality management system and other management systems;
- complying with the technical requirements under the corresponding cosmetics registration or record-filing application materials;
- managing raw materials, packaging and labels; and
- appointing the person in charge of the quality, safety and health management of staff working on cosmetics production.

The New Regulations do not clarify whether the overseas registrants, record-filing applicants and authorized manufacturers of cosmetics are subject to the obligations established in them if the cosmetics are imported into China. However, after consultation by phone with the competent authorities on a no-name basis, they verbally confirmed that these obligations will apply in this case.

Under the New Regulations, cosmetic business operators are obliged to establish and implement a system for checking purchase records. They also establish the obligations for operators that sell or supply cosmetics to consumers via certain special channels such as centralized trading markets and trade fairs, e-commerce platforms, salons and hotels. Particularly, importers are required to review (i) whether the cosmetics that they intend to import into China have been registered or record-filed in China, and (ii) whether they comply



with the New Regulations, mandatory national standards and technical specifications. They must also keep records of imported cosmetics.

Also, on July 21, 2020, the National Medical Products Administration published the Administrative Measures for the Supervision of Production and Operation of Cosmetics (Draft for Comment). This draft establishes more detailed obligations for cosmetics registrants, record-filing applicants, authorized manufacturers and operators. However, again, this type of document is for reference purposes only, and we expect that formal regulations and rules will be issued to clarify these matters.

Supervision and administration

The New Regulations list measures that the competent authorities may take to supervise and inspect the production and operation of cosmetics in China, including:

- carrying out onsite inspections;
- carrying out sampling inspections;
- reviewing and copying related documents;
- sealing or seizing cosmetics, raw materials, packaging materials, and tools and equipment;
- seizing premises for production or operation activities;
- taking emergency control measures such as ordering the suspension of production or operation, issuing safety warnings or suspending the import of certain cosmetics;
- interviewing the legal representative or person in charge of manufacturers or operators of cosmetics; and
- establishing credit files for manufacturers and operators of cosmetics.

To strengthen the supervision and administration of cosmetics after they enter the market, the New Regulations establish a monitoring system for adverse reactions, the cosmetics recall system, and the safety re-assessment system of cosmetics and raw materials. Registrants and record-filing applicants of cosmetics must set up and carry out these systems according to the New Regulations, and the competent authorities are also entitled to request the registrants and record-filing applicants of cosmetics to carry out the recall or the re-assessment.



Legal consequences

The New Regulations are generally considered stricter than the Previous Regulations, as the main change relates to the legal consequences of not complying with the obligations they establish.

Administrative penalties established in the Previous Regulations, i.e., warnings, fines, confiscation, ordering the suspension of production or operation, and revoking licenses, can still be applied, but with much higher fines and more detailed application conditions.

The New Regulations also add new administrative penalties, including the following:

- Penalties against individuals: if a company violates applicable laws and regulations, penalties can be imposed on the legal representative, the person directly in charge, or other persons directly responsible. These penalties include fines, as well as being prohibited from producing or operating in the cosmetic industry for a certain period, ranging from five years to permanently.
- Prohibition from being involved in the cosmetics business: just like individuals, companies may also be subject to certain prohibitions, including having their applications for registration or record-filing of cosmetics rejected or being prohibited from importing cosmetics into China. The period can be up to ten years.

Conclusion

To further regulate the cosmetic industry, the New Regulations confirm certain concepts, categories, production and operation requirements, while establishing the legal consequences of breaching those requirements. They also provide guidance for companies from a compliance perspective and add certainty for competent authorities to exercise their power. We expect detailed regulations or rules will be issued to clarify certain ambiguities, such as the exact obligations applicable to overseas registrants, record-filing applicants and authorized manufacturers of cosmetics, and the scope of liabilities of the designated domestic legal persons in China.



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