

Summary and Comment on the Features of Regulations on Cosmetics Supervision and Administration

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Abstract

This article summarizes the characteristics of China's newly promulgated "Regulations on the Supervision and Administration of Cosmetics", and at the same time reviews and analyzes the contents of the clauses in accordance with chapters, in order to provide reference and suggestions for the smooth implementation of the regulations.

Keywords

Cosmetics supervision and management regulations; Features; Overview; Cosmetics.

1. Introduction

Recently, Chinese government signed the state council order and promulgated the "Regulations on the Supervision and Administration of Cosmetics" (hereinafter referred to as the "Regulations"). The "Regulations" will come into force on January 1, 2021.

The new "Regulations" has six chapters and 80 articles (see Table. 1). The full text is based on the principles of risk management, full-process governance, responsible governance, and social co-governance. It aims to optimize the business environment, promote industrial innovation, ensure cosmetics quality and safety, and improve supervision. Measures and legal liabilities have been improved.

Table 1. Framework of the regulations

Chapter	Tab. of Contents	Section
Chapter One	General	Article 1 to Article 10
Chapter two	Raw materials and products	Article 11 to Article 25
Chapter three	Production and operation	Article 26 to Article 45
Chapter Four	Supervision and management	Article 46 to Article 58
Chapter Five	legal liability	Article 59 to Article 76
Chapter Six	Bylaws	Article 77 to Article 80

Cosmetics are daily chemicals used for cleaning, maintenance, modification and beautification, which directly act on the surface of the human body, and their quality is closely related to the health of the people. With the continuous development of the global economy and people's continuous pursuit of a better life, the development of the global cosmetics industry has also shown vigorous vitality. According to Euromonitor statistics, the global cosmetics market has maintained a sustained growth momentum in recent years, and its market size has exceeded US\$500 billion in 2019.

At the same time, with the wave of reform and opening up, Chinese cosmetics industry has also ushered in a huge room for development. From only 70 cosmetics manufacturers in the 1980s to more than 5000 cosmetics manufacturers in China today, not only cosmetics The number of manufacturers has undergone earth-shaking changes, and according to Euromonitor statistics, as of the end of 2019, Chinese cosmetics market share has accounted for 12.8% of the global

cosmetics market, becoming the world's second largest cosmetics market after the United States.

Although China has become the second largest cosmetics market in the world, the current Chinese cosmetics industry still has a series of insufficient technological innovation capabilities, low development quality and efficiency, low international brand recognition, illegal additions, counterfeit and inferior products, and false claims. problem. These problems not only severely restricted the healthy development of the cosmetics industry, but also failed to fully and effectively protect the rights and interests of consumers.

The “Regulations on Cosmetic Hygiene Supervision” originally promulgated in 1989 has been implemented for more than 30 years. Although it has played an active role in promoting the healthy and rapid development of Chinese cosmetics industry, the original “Regulations” have obviously not been able to adapt to the development and development of the cosmetics industry at this stage. The need for supervision, therefore, the comprehensive and systematic revision of the original “Regulations” has always been the common expectation of the industry and all sectors of society.

2. Features Overview

The new “Regulations” take the registrant and the recorder as a link throughout the entire life cycle of cosmetics, firmly establish the main responsibility of corporate quality and safety, follow the concept of full-process management and risk management, and use information technology to give full play to the principle of co-governance from all sectors of society Improvements have been made in the following aspects:

2.1. Classified Management and Define Clearer

The “Regulations” first reclassified cosmetics and new cosmetic raw materials according to the degree of risk, and implemented registration and filing management respectively (see Table. 2). At the same time, special cosmetics and general cosmetics were reclassified and defined (see Table. 3). In addition, the “Regulations” also stipulate that toothpaste shall be managed with reference to the category of ordinary cosmetics, and ordinary soaps are also not included in the category of cosmetics for management, but special soaps that claim to have similar related effects to special cosmetics are subject to this “Regulations”.

Table.2 Overview of classification management of cosmetics and new cosmetic raw materials

product category Management classification	cosmetics	new cosmetic raw materials
Registration Management	Special cosmetics	New raw materials with higher risk
Record management	Ordinary cosmetics	Other new raw materials

Table. 3 Classification and definition Tab. of cosmetics

Classification	definition
Special cosmetics	Cosmetics for hair coloring, perming, freckle whitening, sun protection, anti-hair loss and cosmetics that claim new effects
Ordinary cosmetics	Cosmetics other than special cosmetics
Other	Toothpaste refers to ordinary cosmetics Soap that claims to have special cosmetic effects

2.2. Online Management and Optimize Services

The “Regulations” require the cosmetics supervision and management department to implement online processing in accordance with requirements and procedures for administrative licensing, registration and filing related to cosmetics, and to publish relevant information in a timely manner to accept social supervision. The registration and filing of cosmetics refer to the registration and filing process of new cosmetic raw materials (see Figure. 1).

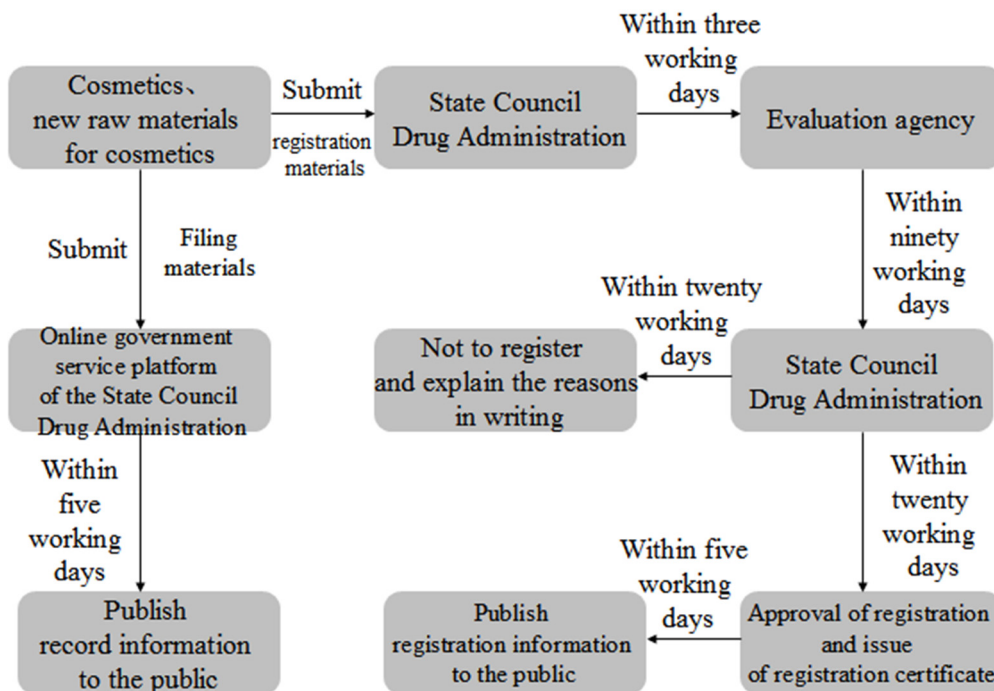


Figure. 1 The registration and filing process of cosmetics and new cosmetic raw materials

2.3. Targeted Management and Clear Responsibilities

The “Regulations” clarify the relevant responsible entities involved in the production and operation of cosmetics from the entire process of cosmetics production and operation, and ensure the quality and safety of cosmetics through the respective duties of the relevant responsible entities (see Figure. 2).



Figure. 2 Relevant entities responsible for cosmetics quality and safety

2.4. Risk Management and Make Quality Safer

The “Regulations” combine the cosmetics adverse reaction monitoring and management system and the risk information exchange mechanism to form a safety risk monitoring and evaluation system. The purpose of ensuring the quality and safety of cosmetics is achieved through risk monitoring, risk analysis, risk assessment and risk control (see Figure. 3).

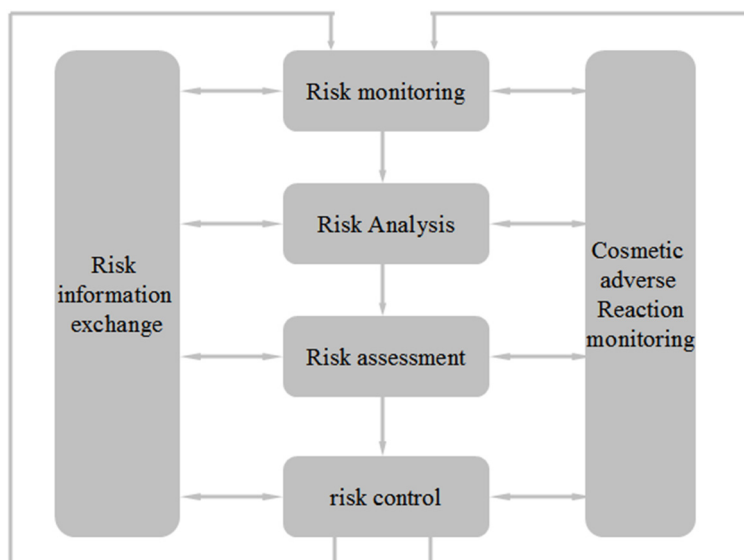


Figure. 3 Cosmetic risk monitoring model

2.5. Implement Legal Management and More Scientific Supervision

The “Regulations” stipulate the legal liability of the entities responsible for the illegal production and operation of cosmetics in accordance with the severity of the illegal circumstances (see Table. 4). At the same time, for cosmetics registrants and recorders, centralized market and exhibition organizers, e-commerce platforms, Cosmetic inspection agencies, technical review agencies, adverse reaction monitoring agencies, safety risk monitoring agencies, and staff in charge of drug regulatory agencies have also made legal liability regulations.

3. Content Analysis

3.1. On the General Provisions of Chapter 1

The general provisions of Chapter one have ten articles in total, which mainly summarize the purpose, scope of application, compilation principles, and attribution of responsibilities of the Regulations.

The second article mentioned that the first is related to the production and operation of cosmetics, and the second is related to the supervision and management of cosmetics. They must abide by the “Regulations”, but in addition to the above two subjects, the “Regulations” It also involves inspection agencies, review agencies, industry associations, consumer associations and other related organizations, but these organizations are not clearly expressed in Article 2.

In addition, Article 5 clearly states that the general responsibility for cosmetics supervision is the drug supervision and administration department. It is necessary to clarify the supervision department. However, if the supervision department changes during the implementation of the Regulations, it needs to be dealt with separately; The article also mentions “relevant departments”, which has always been a relatively vague and sensitive concept for “relevant

departments”. This is in sharp contrast to the clarification of regulatory authorities in the previous part of this article.

Table. 4 Division of Liability of Violating Subjects

Responsible subject	The severity of the violation			
	General	Moderate	More serious	Serious
Illegal unit	Impose a fine of 30,000 yuan up to 50,000 yuan; Order to suspend business and production;	Fines of more than 3 times and less than 10 times; Order to suspend business and production; Cancel the record; Revocation of cosmetics license;	Fines of more than 5 times and less than 20 times; Order to suspend business and production; Cancel the record; Revocation of cosmetics license;	Fines of more than 15 times and less than 30 times; Order to suspend business and production; Cancel the record; Revocation of cosmetics license; No filing or licensing applications will be accepted within 10 years;
Legal representative of the offending unit and related responsible personnel	Impose a fine of 10,000 yuan up to 30,000 yuan;	A fine of more than 1 time and less than 2 times the annual income; Prohibit engaging in the cosmetics industry within 5 years;	A fine of more than 1 time and less than 3 times the annual income; Prohibit engaging in the cosmetics industry within 10 years; Constitute a crime, be held criminally responsible;	A fine of more than 3 time and less than 5 times the annual income; Prohibit engaging in the cosmetics industry for life; Constitute a crime, be held criminally responsible;

In addition, Article 7 mentions that the Consumers Association and other consumer organizations shall exercise social supervision functions in accordance with the law to protect the legitimate rights and interests of consumers, but this article requires the Consumers’ Association and other consumer organizations to actively or passively conduct social supervision. When social supervision is carried out without a clear statement, this article may eventually go to the road of “people do not appoint officials but not investigate”.

Finally, Article 9 of the General Provisions mentions that the state encourages and supports units and individuals to conduct cosmetics-related research and innovation, and protects their legal rights and interests. However, it is still unclear whether or not they will support them. Regarding the protection of legitimate rights and interests, it is not clear what specific measures are taken and how to proceed.

3.2. Raw Materials and Products of Chapter 2

The second chapter includes 15 articles in the raw materials and products, which mainly defines and categorizes cosmetic raw materials and cosmetics, and regulates the registration and filing of cosmetic raw materials and cosmetics.

Among them, Article 11 and Article 16 respectively define and categorize cosmetic raw materials and cosmetics. After comparison, there are differences in the definitions of special cosmetics and new cosmetic raw materials with higher risk (see Table. 5), which are used as perm, how to deal with the raw materials used in special cosmetics that prevent hair loss and claim new effects if there is a high degree of risk? In particular, the raw materials that may be involved in cosmetics that claim new effects should have more uncertain risks.

Table. 5 Definition comparison

Definition statement	The same part of definition	The different part of definition	Define classification	Define attribution
have	Sunscreen, hair dye, freckles and whitening	Coloring, anti-corrosion	New cosmetic raw materials	New cosmetic raw materials with higher risk
Used for		Perm, prevent hair loss, claim new effects	Cosmetics	Special cosmetics

In addition, the first paragraph of Article 13 mentioned that the technical review agency is responsible for the review of relevant application materials. Cosmetics and raw materials currently involve many interdisciplinary subjects. It is difficult for general organizations and individuals to have such complex knowledge. For technical review agencies , What kind of qualifications are required is not clearly stipulated in the relevant management regulations. The latter part of Article 13 mentions that the new raw materials will be announced to the public after the registration and filing are approved. In this regard, whether there are market access protection measures to protect the legitimate rights and interests of units and individuals to obtain research results is also unclear.

In addition, Article 14 stipulates that the three-year reporting period for new cosmetic raw materials for registration and filing is established. What is the basis for determining the three-year period? Can you shorten or extend the time? In addition to the time factor, need to consider factors such as the number, frequency and scope of use of new cosmetic raw materials during the reporting period? Will there be problems in the reporting period due to small-scale, low-frequency, and low-volume use that are safe and no abnormalities, but large-scale, high-frequency, and large-scale abnormalities?

In addition, Article 18 requires cosmetics registrants and filing parties to have a quality management system that is compatible with the registered and filing products. The registrants and filing parties mentioned in the Regulations can produce cosmetics themselves or entrust other companies to produce them. For cosmetics, if the registrant and the filing person are only the entrusting party, can the entrusted manufacturer be regarded as the supplier for management? In addition, can the evaluation capabilities of the adverse reaction monitoring and evaluation capabilities required by the registrant and the recorder be entrusted to professional institutions?

The next Article 20 proposes that the changes to the registered special cosmetics are relatively vague. For special cosmetics, in addition to the production process and efficacy claims, factors such as the model, origin and manufacturer of the main raw materials are also very important. . In addition, for ordinary cosmetics, it is required to be announced to the public within 5

working days after filing, but how to determine whether the materials submitted by the filing party are compliant without mentioning the relevant links? Will this cause the risk of the consumer to bear?

The following Articles 21 and 32 mentioned the job requirements of safety assessors and quality and safety leaders, as long as they have relevant professional knowledge and have more than 5 years of relevant work experience. As for such an important professional role in the cosmetics quality risk prevention process, whether it is possible to consider setting up professional qualifications by the state to prevent the phenomenon of overfilling and ensure that professional positions correspond to professional personnel.

Finally, the supporting basis mentioned in Article 22 of the product efficacy claims, such as literature, research data or efficacy evaluation data, etc., how to ensure whether it is authentic, effective, scientific, advanced, safe and reliable Factors such as sex? Otherwise, this may be the same as the announcement of Article 20 of the product after filing, and the risk will be transferred to consumers, allowing consumers to pay for the above risk factors.

3.3. Production and Operation of Chapter 3

The third chapter contains 20 articles in the production and operation section, mainly related to the application of cosmetics production license, cosmetics production and cosmetics business links.

Among them, Article 38 stipulates that cosmetics-related business operators shall not perform cosmetics preparation operations. However, in reality, there may be a need for cosmetics business operators to subpackage cosmetics. If the cosmetics business Responsible for the act of repackaging, is it also forbidden for this different case of repackaging?

There is also Article 44. Regarding product recalls, if the registrant and recorder of cosmetics discover problems, they can implement active recalls. In addition, for problems discovered by the regulatory authorities, the registrant and recorder of cosmetics can also be ordered to implement passive recalls. However, the "Regulations" only require the implementation of the recall to report to the supervisory department, and there is no provision for review and verification of the authenticity and compliance of the recall.

3.4. Supervision and Management of Chapter 4

Chapter 4 Supervision and Management has a total of 13 articles, which mainly stipulate the supervision and inspection, sampling, inspection, adverse reaction monitoring, safety risk monitoring and evaluation of cosmetics production and operation.

In Article 51, if a cosmetics manufacturer or business operator who has objections to the results of the supervision and inspection needs to apply for re-inspection, in addition to the original sampling inspection department or its superior department, it should also be able to apply for re-inspection. When the supervisory department submits an application, the supervisory department in the jurisdiction where the cosmetics manufacturer is located will interface with the original sampling inspection department for re-inspection.

In addition, Article 57 stipulates that the cosmetics supervision and management department may take measures to supervise the rectification if it finds that the cosmetics production and operation entity has hidden safety hazards in the daily supervision and inspection and fails to make timely corrections. However, it is still unclear whether the cosmetics supervision and management department has the ability to carry out the inspection of potential safety hazards.

3.5. The Part of Legal Responsibility of Chapter 5

Chapter 5 Legal Responsibility has a total of 18 articles, which mainly stipulate the corresponding legal responsibilities of the subjects responsible for illegal activities related to cosmetics production and operation, inspection and supervision.

Among them, Article 59 to Article 61, Article 64, Article 65, Article 70, Article 71, the legal persons, main responsible persons, direct persons in charge, and Other directly responsible personnel are prohibited from engaging in cosmetics production and operation activities and inspection work, but it is not known how to implement it in specific operations and whether it can be implemented.

In addition, Article 73: Cosmetic manufacturers and inspection agencies shall not recruit or employ personnel who are not allowed to engage in cosmetics production, operation and inspection. This is the same as the above-mentioned questions. How to implement in specific operations and whether it can be implemented is a very realistic problem.

3.6. The Supplementary Provisions of Chapter 6

There are a total of four articles in Chapter VI, which mainly stipulate the management methods of toothpaste, soap and the original special-purpose cosmetics that have adjusted the scope of special cosmetics. In this chapter, except that soap meets the concept of cosmetics but does not belong to cosmetics management, there are no special questions in other aspects.

4. Conclusion

The promulgation and implementation of the new "Regulations" will, in essence, further regulate the production and operation of cosmetics, ensure the quality and safety of cosmetics, promote the healthy development of the cosmetics industry, better protect the rights and interests of consumers, and further promote the scientific management of cosmetics in China , The rule of law, internationalization and modernization process, to follow the international trend and show the Chinese style of cosmetics supervision road, as a participant in the cosmetics industry, we must take precautions, actively respond to changes, seize opportunities in the changes, and bend in the changes. Overtaking, turning the cocoon into a butterfly in change, contributing to the beautiful cause of Chinese, and contributing to the better life of the people! In addition, due to limited personal knowledge and experience, there may also be biases in understanding. Therefore, this article only represents the author's own words. I hope that industry experts can advise me if it is not available.

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