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**The Chinese Cosmetics industry: an attractive Market for  
Foreign Companies. A scenario of its Characteristics and  
Regulations with Chinese-English Terminological Records.**

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## Index

前言 .....	1
<i>Introduction</i> .....	5
<i>Part I - A scenario of the Chinese cosmetics Industry: its Characteristics and Regulations.</i>	2
<b>CHAPTER 1 - Beauty model in China: Social and cultural perspectives</b> .....	3
<b>1.1 The beauty evolution development: a historical summary</b> .....	3
1.1.1 The economic reform and the drive for consumption .....	4
1.1.2 The demographic expansion and the consumers' market .....	5
1.1.3 The arrival of foreign companies .....	9
<b>1.2 The cultural influence</b> .....	11
1.2.1 The Hofstede's cultural dimensions theory applied to China consumers .....	12
1.2.2 The importance of <i>mianzi</i> 面子 and <i>guanxi</i> 关系 .....	17
<b>1.3 The beauty model of the Chinese consumer</b> .....	21
<b>CHAPTER 2 - A scenario of the current cosmetic market in China and its main regulation</b> .....	25
<b>2.1 The high-speed growth of the cosmetics market in China</b> .....	25
2.1.1 Chinese consumer preferences and influences .....	26
2.1.3 The consumption of high-end cosmetics increases as a result of consumer upgrades .....	28
2.1.4 Domestic vs International players .....	29
<b>2.2 Main cosmetic regulations in China</b> .....	33
2.2.1 The intersection between Cosmetics and Drugs .....	35
2.2.2 Definition, scope and classification of Cosmetics .....	36
2.2.3 Management of cosmetic Ingredients .....	39
2.2.4 Technical Requirements about Safety and Efficacy .....	40
2.2.5 Efficacy and Claim Substantiation .....	42
2.2.6 Future development for the Cosmetic Science in China .....	43
<b>2.3 Background of Animal testing in China</b> .....	45
2.3.1 Safety Assessments and Alternative methods .....	48
<b>CHAPTER 3 - Analyses of the effects caused by the latest changes in China and worldwide</b> .....	51
<b>3.1 Consumers reaction to cruelty-free cosmetics proposed by manufacturers and retailers</b> .	51
3.1.1 Do Chinese consumers support cruelty- free cosmetics? .....	54
<b>3.2 Why China should keep moving forward with the Animal testing regulation</b> .....	55

3.2.1 What China’s beauty regulation change means for foreign companies .....	59
<b>3.3 How Covid-19 affected the cosmetic industry worldwide .....</b>	<b>62</b>
3.3.1 The pandemic impact on the Chinese beauty market.....	65
3.3.2 Chinese beauty industry constraints after the pandemic .....	67
<b><i>Part II: English – Chinese Terminological Records .....</i></b>	<b>69</b>
<b>Terminological records .....</b>	<b>70</b>
<b>Bibliographic records.....</b>	<b>173</b>
<b>English – Chinese quick reference table .....</b>	<b>178</b>
<b>Chinese - English quick reference table .....</b>	<b>181</b>
<b>Concluding remarks on the glossary .....</b>	<b>184</b>
<b><i>Bibliography and Webography .....</i></b>	<b>185</b>
<b><i>APPENDIX.....</i></b>	<b>199</b>
<b>APPENDIX A .....</b>	<b>200</b>
<b>APPENDIX B.....</b>	<b>218</b>
<b>APPENDIX C .....</b>	<b>222</b>

## 前言

化妆品行业在中国一直是增长最快、最具吸引力的产业之一。论文的核心部分概述中国化妆品市场，并解释国际化妆品公司应在该市场如何维持和通过哪些方式寻求投资。此论文分为两大部分：第一部分通过描写中国化妆品市场和讲明中国化妆品市场是怎样影响外国企业并且为其带来巨大机遇。第二部分将叙写第一部分提到的中英文术语记录。

引言阐述社会和文化观点如何影响中国市场、美容方式及其发展演变。中国拥有数千年的化妆品使用历史,文章通过观察中国的美容演变历史来总结过去的事件如何影响现代文化，特别是在毛主席去世和人口扩张之后，化妆品行业面临了一场翻天覆地的变化。第一章还解释了消费者的市场群体，主要描写了 Z 世代，因为是最具代表性且市场占有份额最大的群体。此外，本章还说明了国际公司是如何在 80 年代初抓住机会进入中国市场，以及中国加入 WTO 是如何促进外国企业进入国内市场。文化影响在中国化妆品市场是一个重要的因素，因此第一章通过描述面子和关系的重要性，进一步考察霍夫斯泰德反映的中国消费者的文化维度理论。本章通过阐明这些概念来讲述对于一家国际公司来说，了解中国消费者与世界其他地区消费者之间的差异是至关重要的。国际公司不能忽视文化差异并且还要特别关注中国消费者当前的审美观以及在购买化妆品时各方面的需求，只有这样才能适应中国化妆品市场。随着新潮流的出现，西方美容理念正在逐渐失去多年来对全球美容带来的影响。随着时间的变化，人们对美的观念也在逐渐变化，因此化妆品公司面临这种情况时应该学会迅速做出反应并解决当前危机。”面子”和”关系”这两个概念是了解中国文化的基础，可以解释如下：”面子”是与个人在社区或整个社会中的地位有关。在社会等级中，一个人的声誉取决于他在社区、学校、家庭或工作中的威望。

每个人的所作所为都是为了避免失去颜面。为此，作为一个中国人，当着别人的面滑倒是一种非常不自在并且会因此感到丢脸或者尴尬的情况。

“关系”，属于一种社会关系中的重要组成部分，是人和人或者人和事物之间的某种性质的联系。在以关系为主的社会中，每个人都要了解自己在社会中的地位和履行职责，因为人们是确定性群体的一部分。

中央章节重点介绍了中国美容市场的现状以及与其他国家的对比。具体而言，这一章考察了中国化妆品市场是如何高速增长及其与国际参与者进入的相关性。此外，比较国内与国际品牌极为重要，通过对比可以了解消费者对奢侈化妆品的需求，尤其是年轻消费者。事实上，在可预见的未来，化妆品行业将会成为中国增长最快且前景广阔的贸易领域之一。自 2020 年以来，中国成为仅次于美国的全球第二大美容和个人护理市场。美容和个人护理的发展体现了由于城市化、可支配收入的发展和社交媒体效应下，人们对优质名品的新兴需求。为了更细致的描绘，中国化妆品市场价值在 2009 年是 740 亿元，在短短的十年时间里已超过 3400 亿元（526 亿美元）。中国消费者对成本效益和品牌要求要求一定的保障。正如前一章所述，中国消费者非常看重品牌和品质提供的保障，通常对西方美容品牌有更高的选择偏好。另一个数据点是美容 KOL 和名人代言的推荐，这表明了一家公司在新媒体和营销方式的投入是及其重要的，他们能影响到消费者的购物偏好，所以对于一家公司来说这些信息至关重要。此外，比较国内和国际品牌的分析将显示对人们奢侈化妆品的需求增加，尤其是年轻的消费者。1990 年代，一些中国化妆品企业开始出现在市场上，但并没有持续多久。在中国化妆品市场疲软的情况下，国际品牌趁机进入中国。西方知名企业凭借其高质量产品以及创新的营销策略，以惊人的速度抢占市场份额，引发了东西方之间的商品的选择冲突，导致国产品牌被排挤。本章还强调了外国企业面临的另一个障碍：中国的法律法规，特别是安全评估法规的变化。

近几年，中国消费者在选择化妆品时越来越谨慎，客户们不仅越来越重视产品质量，同时也很注重化妆品的健康和安全性方面。因此国内化妆品企业抓住机会进军网络营销，利用电商渠道扩大市场份额。2021年，CSAR（化妆品监督管理条例）生效，在考察主要法规及与其他国家的差异时，把注意力集中在了安全性和有效性。这项最新的法规改革将化妆品和药品区分开来；用于判断产品标签和定义功能。此外，在安全性和有效性方面也取得了巨大进步：对动物试验禁令有了重大改进，该规定证明进口产品不能在动物身上试验化妆品。该法令让产品的安全性和有效性向前迈出了一大步。在中国，动物试验一直是一个非常具有争议的话题，因此本文对这一规定进行了进一步的分析。本章探讨替代方法和中国化妆品未来的科学发展，试图指出该法规对进入中国市场的国际公司所带来的影响。在中国市场，西方品牌经常被要求修改其产品以满足中国消费者的特定美容需求。

第三章分析了中国与世界的变化所产生的影响。随着消费者的意识增强，中国有必要继续制定动物试验法规。道德购物不再是一个小众行业，人们越来越意识到他们的购买可以改变现状。大多数企业已经认识到道德的价值，并将其纳入他们的商业计划。因此近几年研究消费者的道德购物行为至关重要，成为可以影响其购买意图的因素。推动无残忍化妆品购买意愿的因素受社交媒体、利他主义和环境知识的影响。事实上，这将是国际公司进入市场并利用新的道德消费概念的大好机会。根据该领域的最新研究，它还能引起大量消费者的购买兴趣。一些公司试图说服动物试验是必要的：进行动物试验可以确保产品对人类的安全。但是动物试验并不是确保成分安全的唯一方法，因为如今已出现了更多更佳方案。中国已宣布从2021年开始；不再对“质量一般”的进口化妆品上市前进行动物试验。本章还研究了COVID-19对中国和全球美容市场制造的影响和限制。过去几年，全球美容行业一直保持弹性和高销售；然而它也没能逃过疫情

带来的不利影响，但是该行业对应对危机反应良好，公司马上转向生产洗手液和清洁化学品，并为急救人员提供免费美容服务。尽管流感影响了市场的多个方面，但消费者将他们注意力转移到有机产品上，并在购买时变得更加有意识。此外，营销策略也做了相应的调整，改为更加专注于互联网平台的销售。本章将从不同方面来解释并概述最新事件如何改变行业及消费者的需求。

最后，基于论文第一部分提出的主题，中英文术语记录将分析和研究不同的方面，以便更好的了解中国化妆品规则。字典集合对整个调查过程中遇到的术语进行了深度的研究，并促进了一家国际公司对中国化妆品市场的投资。由于文化、法规和语言障碍，在中国市场开展业务可能不是特别容易。事实上，语言可能是一个实质性的障碍。上述审查可以证明外国公司对如何进入中国市场缺乏准确的了解。词汇表的起草是按照TERMIT数据库的标准编写的。



## Introduction

China's cosmetics industry has been and will continue to be one of the fastest growing and most attractive business sectors. The following dissertation aims to present an overview of the cosmetics market in China as well as an explanation of the multiple reasons international cosmetics companies should maintain and pursue investments in that market. The thesis is divided into two parts: Part I will focus primarily on explaining the cosmetics market in China by illustrating the massive opportunity it represents for foreign enterprises. Part II will consist of a Chinese-English terminological record based on the topic presented in the first part.

An introduction explains the social and cultural perspectives that influence the market, the history of the beauty model in China, and its evolution. China emphasizes a long story of cosmetic utilization that crosses thousands of years, from the imperial dynasties up until the recent days. Starting with the beauty evolution in China through a historical summary and presenting how past events influenced the present, specifically after the death of Mao and the demographic expansion, the significant changes that the cosmetics industry faced will be analyzed. The first chapter also explains the segmentation of the consumer, specifically the Gen Z generation that represents the most effective and most lucrative segment. Moreover, the chapter illustrates how international companies seized the opportunity to enter the Chinese market in the early 80s and how the latter's entrance into WTO facilitated access to foreign businesses. Cultural influence is an essential factor when analyzing the cosmetics market in China, therefore the first chapter goes through the importance of the *mianzi* and *guanxi* with a further examination of Hofstede's cultural dimensions theory reflecting the Chinese consumer. These concepts are clarified through the chapter, and it is essential for an international company to be aware of all the divergences between the Chinese consumers as opposed to the rest of the world. Particular attention is also given to the current beauty ideal and what the Chinese consumer look for when buying cosmetics: neglecting cultural variations is no longer viable, and international companies must adjust to the Chinese cosmetics market's circumstance.

A central chapter highlights the current status of the Chinese beauty market and its principal regulations compared with other countries. Specifically, it examines the high-speed growth of the cosmetics market in China and its correlation to the entrance of international players. Moreover, an analysis comparing domestic and international brands will demonstrate an increase in the demand of luxury cosmetics, in particular from young consumers. Another obstacle for foreign business is highlighted in this chapter: Chinese main regulations and particularly the latest change on the Safety Assessment.

In 2021, CSAR (Cosmetic Supervision Administration Regulation) entered force. While investigating the main regulations and their differences with other countries, the latest developments of *Technical Requirements about Safety and Efficacy*<sup>1</sup> are given special consideration. This newest regulation reform draws the difference between cosmetics and drugs; a definition to judge product labeling and define the functional area. Furthermore, there has been enormous progress regarding *Technical Requirements about Safety and Efficacy*: significant improvements have been made regarding the animal testing ban and this regulation proves that imported products no longer have the requirement to test cosmetics products on animals. Evidently, an evaluation of toxicological research and risk assessment of both ingredients and outcomes will still be needed, but it is already a big step forward. In China, animal testing has always been a contentious topic, consequently further analysis about this regulation is examined in the dissertation. Investigating the alternative methods, and the future development for cosmetics science in China, the chapter endeavors to indicate the regulations' impact on international companies entering the Chinese market.

The third chapter analyzes the effects caused by the latest changes in China and worldwide. As consumers become more conscious, it is essential for China to keep working on the animal testing regulation. In fact, it would be an opportunity for international companies to enter the market and tap into the newer ethical consumer base. It would also draw interest from a large number of consumers, according to the latest research in the field. For decades, this report has prevented foreign cruelty-free brands from exporting products to China and selling them on e-commerce markets or local retailers. The chapter also examines the COVID-19 effects and constraints on the beauty market in China and worldwide. Even though the pandemic affected several aspects of the market, consumers shifted their focus to organic products and became more conscious. Moreover, marketing strategies had to adjust, focusing on internet platforms. The chapter will interpret these different aspects and provide an overview of how the latest events modified both the industry and the consumer's needs.

Finally, based on the topics presented in the first part of the dissertation, a Chinese-English terminological record will analyze some of the field-specific terms faced during the research to better understand Chinese cosmetic regulations. The lexicographic collection gives a fascinating study of the terms encountered throughout the investigation and promotes an

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<sup>1</sup> In 2020 China National Medical Products Administration published the draft *Technical Guidelines for Cosmetic Safety Assessment* for public consultation, one of CSAR's subsidiary measures and the revised version of the previous *Guidance for Cosmetic Safety Risk Assessment*.

international company engaged in funding the tremendous Chinese cosmetics business. Developing a business in the Chinese market might not be attainable due to the culture, regulations, and language barrier. In fact, the language might be a substantial impediment. The examination mentioned above could support that a foreign company lacks an accurate understanding of how to proceed in the Chinese market. The drafting of the glossary was compiled following the standards of the TERMIT database formerly kept by SSLMIT of Trieste University and can be used in Computer Assisted Translation Software like Trados™ in Multiterm™ module.

**Part I - A scenario of the Chinese cosmetics Industry: its  
Characteristics and Regulations**

# CHAPTER 1 - Beauty model in China: Social and cultural perspectives

## 1.1 The beauty evolution development: a historical summary

China features a long history of cosmetic utilization that spans thousands of years, from the imperial dynasties to the present days, and offers a deep insight into the beauty ideals and cosmetic industry developments. The improvement of advertising during the centuries has always been influenced by both the contemporary amenities and the social changes of the nation. For this purpose, as society changes, so does the perception of attractiveness and beauty, turning to a sequential change within the cosmetic industry<sup>1</sup>. In ancient China, clothing and personal grooming were indicators of one's social status within the societal hierarchy. Chinese individuals ordinarily carried out long washing routines to care for their skin and perfumes: for instance, ladies were used to reducing body hair and lightening their skin pigmentation with rice powder so as to be as light and smooth as imaginable. Chinese ladies have an extended story of seeking after whiter and brighter skin and of realizing that brilliant gleam; generations of women have counted exfoliation, brightening, and moisturizing as their key steps. Long hair combed into awe-inspiring haircuts has continuously been the norm for the Chinese tradition as well as nail care, which took off amid the Zhou dynasty, and where the hone of artificial nails was started: artificial nail tips were created to be worn over the top of the fingers, colored and adorned with gemstones.

Adjacent to the historical changes of the nation, beauty practices grew as well. For illustration, the fast growth of the nation and the frequent contacts with foreign countries brought a period of success amid the Tang dynasty (618-907)<sup>2</sup>, creating a loose social environment, where ladies may wear colorful cosmetics, and wore men's clothes. In addition, haircare was a concern during this period, and respectable ladies at court adorned their hairstyle with a 步摇 *buyao*, a decoration that swung anytime the wearer moved. On the other hand, the Song dynasty (960-1279) inquired subjects for less striking beauty, taking off to the royal family the honor to wear a more different kind of make-up. Amid the Ming dynasty (1368-1644), Chinese individuals founded the practice of tinting their nails with natural ingredients to make a long-lasting polish; Confucian values were instead the saying of the Qing dynasty

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<sup>1</sup> Erin KENNY, Elizabeth G. NICHOLS, *Beauty Around the World: A Cultural Encyclopedia*, ABC-CLIO, 2017.

<sup>2</sup> Ilan ALON, (ed.) *Chinese economic transition and international marketing strategy*, Praeger, 2003.

(1644-1911) exhibited themselves within the style perfect of femininity. Ladies had to be virgins and humble, regard their spouses and look for internal morality. For these reasons, show off of decorations were not empowered, whereas an elegant and honest nature was appreciated. In any case, despite its long habit in cosmetic utilization, the modern manufacture of beauty items only begun in 1830 with the opening of Xiefuchun Cosmetic, the first cosmetic company in Yangzhou City, Jiangsu Province.

Nonetheless, after the emperor's downfall and the rise of the People's Republic of China, beauty benchmarks and customs changed significantly. With the starting of the Maoist days, the party-state's emphasis on consolidating the national culture suppressed any conflict in identities. The communist basis of balance removed any division between genders and discouraged utilizing merchandise identified with the capitalistic bourgeois values.<sup>3</sup> Simplicity in dress and individual grooming had to ponder the release of the model and gender hierarchies, promoting the significance of equality between men and ladies. The purpose of utilization was deemed to reveal political commitment, such as any item that persuaded loyalty to the Communist Party was an assurance against Red Guards, that amid the Cultural Revolution, may utilize appearance as a reason to persecute citizens within the title of the protection of the Communist Revolution<sup>4</sup>. For this cause, for example, eye-catching makeup was discouraged, and makeup was worn only by performing artists and on-screen actors. In contrast, ordinary people had access to a minimal range of beauty products.

### **1.1.1 The economic reform and the drive for consumption**

Only after the passing of Mao and the ascent of Deng Xiaoping as the country's guide, the government's approach towards consumption changed, and China began to experience a few significant alterations in its economy, shifting from a socialist model to an overall market economy. In 1978, amid the third plenary session of the XI National Committee of the Communist Party, two critical decisions concerning the long run of China were taken: the primary one concerned the economic modernization of the nation, whereas the second one was related to the foundation of an advancement technique that must have pushed to the financial liberalization. Deng's plan for the country's economic development was based on industrial

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<sup>3</sup> Ip HUNG – YOK, "Fashioning appearances: Feminine beauty in Chinese communist revolutionary culture", *Modern China*, 29, 2003, pp. 329-361.

<sup>4</sup> Barbara E. HOPKINS, "Western cosmetics in the gendered development of consumer culture in China", *Feminist Economics*, 13(3-4), 2007, p., 287-306.

efficiency and faith within the regard of consumption, which led to the return of separation among sexual category and the modification of the social hierarchy. As a result of the trade opening, Western items entered the Chinese market, in specific fashionable products and cosmetic goods, of which the purchase represented the modern bourgeois shopping ideal. The change had, in truth, restored womanliness as crucial.

This mindset change reflected itself within the booming consumption of items that underlined the gender separation, such as beauty items and clothes: sometime recently in the 1980s, the annual sales of beauty care products were less than 500 million RMB, whereas, by the 1990s, sales reached 4 billion RMB<sup>5</sup>. Since that event, the expression of femininity was considered in diverse characteristic ways. According to Hopkins in “Western cosmetics within the gendered development of consumer culture in China”<sup>6</sup>; the restoration of womanliness was translated in two ways: one way to separate from the past and distinguish the individual from to the community personality declared by the Communist Party; the other one, it was related to the return of women’s subordination, due to the omnipresent display and pictures of women in more common domestic actions. Nevertheless, the increment within the utilization of products that show femininity can be related to the reality that the purchase of beauty care products, adornments, and the utilization of plastic surgery was not an expression of the women’s internal self but was also a way to portray the modern wealthy way of life and the economic possibilities. Consequently, given that beauty care products were the cheaper choices for anybody that did not seem to bear costly surgeries, they instantly got to be the image of breakage with the persistence and androgyny of the past.

### **1.1.2 The demographic expansion and the consumers’ market**

One of the primary sources of economic growth in China has been the extraordinary availability of workforce size. Due to the expansion in population that China faced, from the opening of trade routes in 1978, living standards improved, and more numerous citizens transcended poverty. As a consequence, the population increased from 987.05 million in 1980 to 1400.05 million people in 2019<sup>7</sup>. Until 1978, the agricultural sector hired more than 80 % of the Chinese community. Next, a significant movement of investments and innovation entered the country,

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<sup>5</sup> *Opportunities in Ten Major Industries*, “Hong Kong Trade Development Council”, 2000, <https://info.hktdc.com/alert/chwto0011a.htm>, accessed on: 2/06/2021.

<sup>6</sup> B. HOPKINS, *ibidem*.

<sup>7</sup> C. TEXTOR, *Estimated population of first and new first tier cities in China in 2020*, by city, in “Statista”, 2021, <https://www.statista.com/statistics/992683/china-population-in-first-and-second-tier-cities-by-city/>, accessed on: 10/07/2021.

which led to the modernization of agriculture. Additionally, other towns and small enterprises were built, emerging from the significant emigration to other areas, counting 4.38 million laborers that left the countryside to move to cities<sup>8</sup>. The urbanization of China, the process of people migrating from rural to urban areas, during which towns and cities were formed and increase in size, rose from approximately 20% in 1980 to higher than 60% in 2019, surpassing the number of farm citizens in 2011<sup>9</sup>.

Nevertheless, urbanization did not include all Chinese cities uniformly, as some cities grew more quickly than others. Notably, the East and South countries outlined China's "growth markets". These areas held regions like Guangdong, Fujian, Hainan and Hong Kong, Shanghai, Jiangsu, and so on, and were the first to be urbanized and grow in population<sup>10</sup>. To this day, the largest Chinese cities are located in these districts: Chongqing with 31 million in 2018, Shanghai being the second largest with 26.3 million people in 2019, followed by Beijing with around 20 million inhabitants<sup>11</sup>. As a result of the quick and robust urbanization and new employment in non-agricultural sectors, many Chinese people increased their wealth. They started having more disposable earnings, leading to the so-called "middle class". Nevertheless, the importance of this organization started to be consistent in modern years, since still in 2006, fewer than 10 % of China's population joined the middle class: it was estimated that around 90 million people met the qualifications to enroll in this group, whereas the United States middle class already counted more than 200 million in the same period. The subsequent years saw more accelerated growth, moving around 730 million middle-class people by 2016, with an average growth of 60 million persons per year. This demographic inflation resulted from millions of people changing their jobs into more productive employment with greater earnings<sup>12</sup>.

The well-paid wages made a consistent change in buyers' behavior. Until the edge of the Cultural Revolution, Chinese consumers afforded only the essential products, but nowadays the demands and wishes of consumers turned<sup>13</sup>. "The spending structure has shifted "from 'necessity' to 'discretionary', [...] so discretionary categories, such as transport,

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<sup>8</sup> Marco Giorgio ERCOLANI, Zheng Annie WEI, "An Empirical Analysis of China's Dualistic Economic Development: 1965–2009", *Asian Economic Papers*, vol. 10 no. 3, 2011, p. 1.

<sup>9</sup> C. TEXTOR, *Degree of urbanization in China from 1980 to 2020*, in "Statista", 2021, <https://www.statista.com/statistics/270162/urbanization-in-china/>, accessed on: 10/07/2021.

<sup>10</sup> G. CUI, Q. LIU, "Regional market segments of China: opportunities and barriers in a big emerging market", *Journal of Consumer Marketing*, vol. 17 no. 1, 2000, p. 5.

<sup>11</sup> C. TEXTOR, *Estimated population of first and new first tier cities in China in 2020*, by city, in "Statista", 2021, <https://www.statista.com/statistics/992683/china-population-in-first-and-second-tier-cities-by-city/>, accessed on: 10/07/2021.

<sup>12</sup> Homi KHARAS, Meagan DOOLEY, "China's Influence on Global Middle Class", *Global Governance and Norms/ global China: assessing China's growing role in the world*, 2020, p. 9.

<sup>13</sup> K. FRITH, "The Rising Dragon: Chinese Consumerism", *Advertising Studies*, vol. 25, 1995.



recreation, education, luxury goods, and financial products, will benefit the most as they will achieve a higher share of wallet”<sup>14</sup>. For example, “China is the world’s largest smartphone market, accounting for 20 % of Apple’s iPhone trades, such as presenting a vast home demand for local Chinese labels. Chinese people took 300 million holidays and business tours in 2019; 166 million were abroad, and 140 million were within China. Over 90 % of Chinese own their own home” as it shows a potent status symbol<sup>15</sup>. Chinese consumers prioritize their emotional EoV (Elements of Value) over the functional EoV (meaning investments related to “enjoyment, social status, self-identity, and societal contribution”<sup>16</sup>), and are thus less price-sensitive, with the result of consuming more quickly. This drift guided China to be listed as “the largest middle-class consumption market”, with \$7.3 trillion investments in 2020 on the whole \$41 trillion of global middle-class market value, exceeding the United States which count \$4.7 trillion middle-class expenditures in the same year. Thanks to the speedy improvement of the Internet and e-commerce in China, young people are the most significant users<sup>17</sup>.

Understanding the incredible potential of the new generations is essential to take a move backward to 1979 when the “One Child Policy” – formally named “Family Planning Policy” – was executed. This policy came from the increasing concern Party members and researchers had concerning the robust demographic expansion in China, which they examined to be unsustainable. Various research foretold that the genetic sources were not acceptable and that such a significant increase in population would break Chinese economic development instead of supporting it. Therefore, they decided to attempt this complicated and often criticized “One Child Policy” among Han ethnicity; This policy allowed Han-race couples to have one child and forced the legal age for marriage to 22 and 20 years of age for males and females respectively. The punishments for breaking this law were of a financial and social nature. This policy pushed many couples to undertake abortions<sup>18</sup>. The result was a rate of 104.5 males per every 100 females in 2019, whereas the top difference from the policy implementation was 106.7 males per every 100 females in 2000<sup>19</sup>.

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<sup>14</sup> Nayyar SARITA, Ingilizian ZARA, “Future of Consumption in Fast-Growing Consumer Markets: China”, *World Economic Forum*, 2018, p. 9.

<sup>15</sup> H. KHARAS, M. DOOLEY, op. cit., p. 2.

<sup>16</sup> World Economic Forum, op. cit., p. 9.

<sup>17</sup> H. KHARAS, M. DOOLEY, op. cit. p. 10

<sup>18</sup> David HOWDEN, Yang ZHOU, “China’s One-Child Policy: Some Unintended Consequences”, in *Economic Affairs*, 2014, 34(3), 353-69.

<sup>19</sup> C. TEXTOR, *Sex ratio in China from 1935 to 2020*, in “Statista”, 2021, <https://www.statista.com/statistics/251102/sex-ratio-in-china/>, accessed on: 10/07/2021.

Because of this extreme and unnatural limitation on births, the fertility rate fell from 4.8 in 1975 to 3.1 in 1980 and decreased to 1.61 in 2005<sup>20</sup>. Consequently, the Chinese population has converted older: data show that the population aged 60 and older grew from 7.5% in 1980 to 17.4% in 2020<sup>21</sup>. This dramatic rise is not prognosticated to stop, as researchers predict that by 2027 more than 320 million Chinese – 22% of the population – will be older than 60 years. Unquestionably, this will generate social pressure and rising demand for products and services addressed explicitly to the elderly. This segment of customers spends on health-related expenses while focusing less on housing, clothing, and so on<sup>22</sup>. However, this gathering saves a lot since the social protection net is variable, so their spending power diminishes considerably.

However, the generation to consider as a large part of consumer spending is the so-called “Gen Z”. They are rising as the most significant and most lucrative segment. Gen Z includes people born between 1996 and 2010 who are growing up “during the fastest sustained expansion of a major economy in history and are consequently used to rapid improvements in their standard of living”<sup>23</sup>.

Jia Zhou and other researchers profiled the Chinese Gen Z by studying approximately 3,000 buyers in China aged between 18 and 54. They reported “China’s Gen Z are coming of age: Here’s what marketers need to know (2020)”<sup>24</sup>. Gen Z are “more likely to buy products on the go”, but the most unpredictable ones are Chinese. They tend to spend more to receive immediate pleasure, and they rely on their emotional EoV, especially those related to social status and self-identity. This automatic spending performance comes from a positivist vision of their future: Chinese Gen Z has “robust confidence in their future earnings”, so they feel less stress on paying more for something they may not require and even overspending their budget sometimes. They attribute themselves as “the moonlight clan”, frequently consuming their entire wage that corresponding month, hence living “paycheck to paycheck”. It is a new behavior for Chinese people since, culturally articulating, they have a long-term orientation: they focus on the future. They do not rely on instant benefits, so they tend to save their capital.

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<sup>20</sup> Aron O’ NEIL, *Total fertility rate in China from 1930 to 2020*, in “Statista”, 2021, <https://www.statista.com/statistics/1033738/fertility-rate-china-1930-2020/>, accessed on: 10/07/2021.

<sup>21</sup> C\_TEXTOR, *Estimated population of first and new first tier cities in China in 2020*, by city, in “Statista”, 2021, <https://www.statista.com/statistics/992683/china-population-in-first-and-second-tier-cities-by-city/>, accessed on: 10/07/2021.

<sup>22</sup> World Economic Forum, 2018, *ibidem*.

<sup>23</sup> J. ZHOU et al., “China’s Gen Z are coming of age: Here’s what marketers need to know”, *China consumer report 2021*, 2020, p. 139.

<sup>24</sup> J. ZHOU et al., *ibidem*.

Globalization absolutely represents a significant role in this difference in performance, as the Chinese appear to be influenced by the American lifestyle, as they have a short-term orientation and spend money without caring that much about savings<sup>25</sup>. Gen Z is involved in brands that offer them customized items since they look for uniqueness and show off. Personalization will become an important factor for companies to be competitive and meet these generations' higher standards. The focus is on offering personalized products by leaving the mass market and concentrating on some particular niches. Moreover, Gen Z is very loyal to brands they identify with and, due to their high knowledge and awareness of technologies, have no problem buying online. Collectively with the elderly and middle class, these new generations' characteristics make it obvious that the Chinese market is huge and differentiated. Each section has many needs to fill. Hence, international businesses that enter the Chinese market must learn this variety of potential customers, analyze them, and develop the best way to approach their demands and needs.

### **1.1.3 The arrival of foreign companies**

The economic reform and the ensuing expanding worldwide integration included numerous changes within the Chinese cosmetic industry. The economic change invigorated the interest of foreign investors that saw within the Chinese design and beauty showcase an incredible opportunity to extend overseas and make a benefit. The primary international brands arrived within the early 1980s, offering items for high-income citizens in state-owned department stores, that at the time were essentially the only distribution channel accessible in major cities<sup>26</sup>. The first international cosmetic company which entered the Chinese market was the Japanese firm Shiseido, which in 1981 began to offer its beauty items in Beijing. The method of changing and internationalization advanced and the beauty showcase cleared out the ground. The success was so extraordinary that in 1983 the Japanese company chose to sign an innovative tie-up agreement with Beijing<sup>27</sup>. The Shiseido's path was recently followed by other major corporations. For instance, Procter & Gamble signed their first joint venture headquarter in Guangzhou in 1988; in 1990 the American based Avon entered the market with the technique of direct selling. Because of the low cost of laundry items in China, Procter & Gamble took the

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<sup>25</sup> Andrea PONTIGGIA, "Organization, People and Culture: Management to China", *McGraw-Hill Education*, McGraw Hill, 2020, <hdl.handle.net/10278/3734033>.

<sup>26</sup> G. JONES, *Beauty imagined: a history of the global beauty industry*, Oxford University Press on Demand, 2010.

<sup>27</sup> Maki UMEMURA, Stephanie SLATER, Reaching for global in the Japanese cosmetics industry - 1951 to 2015: the case of Shiseido, *Business History*, 59:6, 2017, p. 877-903.

decision to enter within the cosmetic division, including hair care and skincare products. In Guangzhou, Procter & Gamble made a joint venture with a domestic partner to produce Head & Shoulders; what they decided to sell were most of all single-use packages in order to assist low-income customers in affording their products. In the recent nineties, China became the brand's fifth-largest market. However, the crucial element that determined the success for the American firm was not only the famous international brand name, but also the Avon ladies factor: 雅芳小姐 *Yafang xiaojie*, what they were offering on the market was a make-up training session to the clients, something revolutionary in the cosmetic sector<sup>28</sup>.

Nevertheless, the first whole-owned foreign cosmetic company that open in Shenzhen was YueSai (YuXi), created by the Chinese American television celebrity Yue-Sai Kan, to open in Shenzhen, with the aim of establishing the first Chinese global beauty brand. By and large, the victory of foreign brands was frequently due to the choice to set up production plant in China in order to dodge import limitations, higher duties and to be more mindful of the standard of the good to be taken after. To bolster the desires of foreign companies, an incredible bargain of small to medium manufacturing firms were set up and by the conclusion of 1999, the Chinese licensed cosmetic producers came to the number of 3514 units; in expansion, attracted by the promising extension of the beauty market, numerous other driving international names chosen to establish 22 joint ventures or wholly owned firms within the 1990s, totaling speculation of 1.5 billion US\$<sup>29</sup>. Therefore, the conspicuous presence of outside capital and the product innovation made a competitive environment that was anticipated to warm up after China's access to WTO. Between the 1980s and the 1990s, thanks to its booming economic development, China emerged as a major player withing the worldwide economy. Being one of the tops ten exchanging nations in the world with record sums of FDI for the 1990's decade led China to become the second biggest beneficiary of foreign coordinate investments after the USA<sup>30</sup>. In spite of its extraordinary performance, the Chinese market remained coordinated within the world's economy: the state control on imports, inspections, safety permitting and technical prerequisites, high duties, and a sort of discrimination on outside items were a few of the reasons for its shallowly integration. In any case, a complete integration was required to attain the benefits of an export-driven financial growth, which is the reason why it was

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<sup>28</sup> B. HOPKINS, *ibidem*.

<sup>29</sup> *Opportunities in Ten Major Industries*, in "Hong Kong Trade Development Council", 2000, <https://info.hktdc.com/alert/chwto0011a.htm>, accessed on: 2/06/2021.

<sup>30</sup> NICHOLAS R., Lardy, *Issues in China's WTO Accession*, in "Brookings", <https://www.brookings.edu/testimonies/issues-in-chinas-wto-accession/>.

fundamental to end up one of the World Trade Organization (WTO) members. In reality, the entrance within the WTO would have ensured the move to a market economy and more ventures within the financial, media transmission, and supply chain; moreover, and most important the commitment of China to comply with the international benchmarks.

Subsequently, China's long way to connect the WTO had an extraordinary effect on the development of the cosmetics industry. In truth, in becoming part of the WTO, China agreed to lower taxes boundaries on beauty goods, along with other items, and to streamline the method to obtain the import licenses. In this way, worldwide companies were incentivized to keep investing within the nation, and local companies might take advantage of the decrease of the duties for their own importations.

Apart from the reduction of tariffs, a regulatory institution was also needed. This type of institution had to hold up both the move towards the new control system and the equality of domestic and international players. In truth, a change from the traditional state-owned ventures, whose reason was only that of fulfilling the inside demands, to one where supervisors had to bargain with the new regulations was required as well because it was vital to ensure the equality between foreign and domestic enterprises, maintaining a strategic distance from the creation of a special treatment for Chinese producers. It is imperative to underline how these new directions were not a demonstration of the Chinese solid commitment to become a more market-oriented economy but represented more an incalculable commercial opportunity for those foreign players working within the nation. Given that numerous foreign cosmetic brands had already set up manufacturing plants in China, where production costs were likely to be lower than in other portions of the world, such as Europe or America, the local presence would have ensured them better positioning to draw out the new regulations to design a country-specific marketing strategy.

## **1.2 The cultural influence**

The colossal economic improvement that China has been encountering has attracted the interest of numerous foreign companies. Indeed, even though the world is more interconnected day by day and boundaries to exchange keep on falling down, countries show numerous differences that make it difficult for companies to embrace the same approach to each one of them. In particular, culture is one of the primary perspectives to be taken into consideration when addressing foreign markets. It is essential to consider the culture of a country in order to make adequate and successful promoting activities that will benefit to the company. The culture was

characterized in 1945 by Ralph Linton as “the configuration of learned behavior and results of behavior whose component elements are shared and transmitted by the members of a particular society”<sup>31</sup> therefore culture develops as unwritten rules which allow people to live together. It is often difficult to agree on a common definition of culture, for instance Pontiggia definition agrees with some fundamental experts such as Hofstede and Weber, by considering culture as: “A system of values and norms that are shared among a group of people and that when taken together constitute a design for living. By values, we mean abstract ideas about what a group thinks to be good, right, and desirable [...]. By norms, we mean the social rules and guidelines that prescribe appropriate behavior in any situation. We shall use the term society to refer to a group of people sharing a common set of values and norms”<sup>32</sup>. However, elements of different cultures can be in contrast with each other; therefore, comparison could lead to erroneous perceptions, so it is crucial to dig deep into a country’s culture to really understand it. Furthermore, although a society may be matching to a country, at the same time some countries may host few different societies and subcultures. Subsequently, indeed the event that national societies frequently depend on the thought of inside homogeneity and outside contrasts, it is really difficult to recognize all the nuances of a culture, because it has such numerous levels that it’s simple to fall within the trap of generalizations. In fact, the division of countries by culture is extremely hard to perform and though the discussion of the homogenization of cultures is becoming increasingly well known, particularly thanks to the media and the immigration process, the social change remains moderate, and the heterogeneity is still persistent.

### **1.2.1 The Hofstede’s cultural dimensions theory applied to China consumers**

A framework used to understand the several differences between countries and to support the business done all over different cultures is the Hofstede’s cultural dimensions theory. This theory is based on a Valued Survey Module that identifies six dimensions of culture, using a scale from 1 to 100.

Gerard Hendrik Hofstede was an anthropologist and psychologist who lived in the Netherlands, broadly studied culture, in particular the relations of people within a society. In

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<sup>31</sup> Jean Claude USUNIER, Julie Anne LEE, *Marketing Across Cultures*, UK, Pearson, 2013, p. 4.

<sup>32</sup> Andrea PONTIGGIA, *International Organizational Design and Human Resources Management to China*, London, McGraw-Hill Education, 2016, p.217.

his study *Cultures and organizations: Software of the mind* (1991)<sup>33</sup>, he aims to determine the dimensions in which cultures vary.

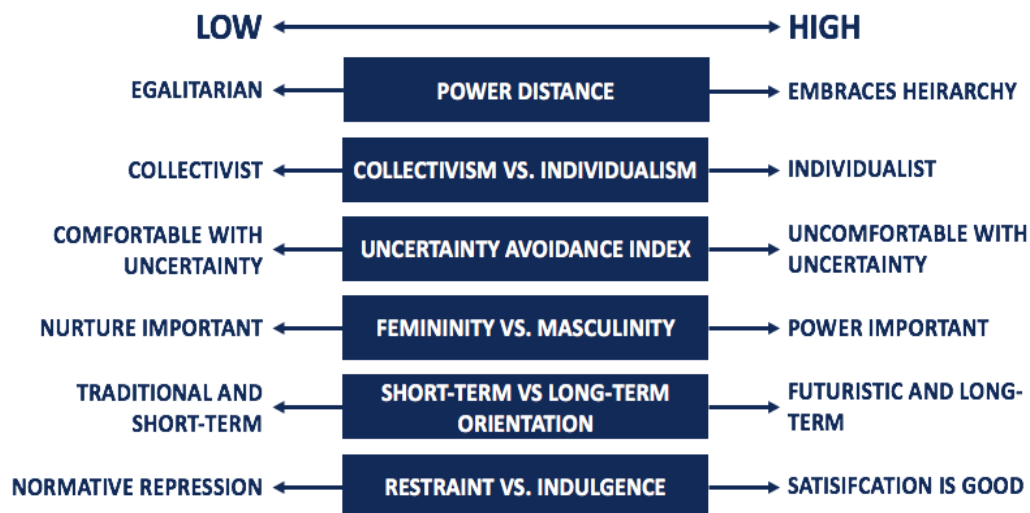


Fig. 1. Hofstede's dimensions

Source:<https://corporatefinanceinstitute.com/resources/knowledge/other/hofstedes-cultural-dimensions-theory/>

### 1. Individualism and collectivism

Individualism and collectivism are terms that allude to the relationship between people and the degree to which an individual is integrated into society. In individualistic societies, there is a preference for a near social system where people remain in small groups and pay attention to themselves and their close relatives. According to Hofstede, its inverse is the collectivistic culture, where a tightly knit system is favored. In collectivistic societies, people can anticipate their relatives or companion to care for them in trade for unquestioning loyalty. As shown by Fig 1.2, China has a 20 score of individualism, which results low according to Hofstede's value system. This result classifies China as a collectivistic society, and it is strongly related to the Chinese ancient tradition of living in extended families. For thousands of years, a household has included several generations, from grandparents to great-grandchildren, thus creating the first in-group people. In these in-groups, the importance falls to the "we", not the "I", characterized by trust and loyalty.

<sup>33</sup> Geert HOFSTEDE, *Cultures and organizations: Software of the mind*, McGraw-Hill International, London, 1991.

However, Wang and Xu found a modern trend of youthful Chinese individuals through a study of 380 Chinese college students; the younger era has more inclinations towards individualism, which is likely due to the reality that globalization has permeated each perspective of life worldwide<sup>34</sup>. People are in close contact with distinctive cultures and ways of life each day, which unavoidably shape and impact behavior and values. The students “attach less importance to the causal relationship between family, harmony, and success”<sup>35</sup>. The One-Child Policy and the social changes that happened within the final decades drove most people to grow up in restricted families of three people, the parents and the child.

The modern values make a modern consumption pattern, characterized by an individualistic approach: the research students expressed that they look for freedom in their shopping behavior, needing to express their uniqueness through their buys. Customarily, individuals of a collectivist society want approval from the gather, they want to “save face” by adjusting to others, so this modern behavior goes astray from the standard one.

## 2. Power distance

Power distance portrays “the extent to which the less powerful members of institutions and organizations within a country expect and accept that power is distributed unequally”. In a high-power distance society, individuals acknowledge the chain of command, as they know they have somebody over them whose job is also control over them. The values of families depend on compliance and respect for adults<sup>36</sup>.

China positions among one of the nations with higher power distance, accounting for 80 (figure 1.2), as the Chinese acknowledge to be subordinated by their superiors.

## 3. Uncertainty avoidance

Uncertainty avoidance: it expresses how the individuals of society feel uncomfortable with the future’s instability and ambiguous circumstances. There are essentially two ways to bargain with this kind of circumstance: societies with a solid uncertainty avoidance think that vulnerability is awful and so build up strict regulations, whereas social orders with a powerless uncertainty avoidance accept that individuals must deal with the reality that long term is not perfectly predictable and so tend to preserve a more relaxed state of mind in which practice is more vital than norms.

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<sup>34</sup> Fengling WANG, Xu SHUCHAN, “Impact of Cultural Values on Consumption Behavior: A Survey of Contemporary Chinese University Students”, *Intercultural Communication Studies*, vol. 18 no. 1, 2009.

<sup>35</sup> Fenling WANG, Xu SHUCHAN, *ivi*, p. 12.

<sup>36</sup> Marieke MOOIJ, Geert HOFSTEDE, “Cross-cultural consumer behavior: A review of research findings”, *Journal of International Consumer Marketing*, 23(3-4), 2011, p.181-192.



China is considered to have a low instability evasion with 30 of the score, and usually due to the pragmatism penetrated within the Chinese culture within the final decades. Laws and rules are adaptable and may adjust to specific times and situations, as truth itself may be a relative concept. This equivocalness can also be seen within the Chinese language, full of homophonic words that can create mistaken assumptions. As already said, individuals of low uncertainty avoidance societies tend to be more entrepreneurial. Specifically, in China, there are numerous – 70 to 80 % – tiny and medium measured enterprises that compete in a situation of vast and powerful multinationals.

#### 4. Masculinity and femininity

The refinement between femininity and masculinity lies within the values a society holds. Manly society puts victory over anything else, so competition is solid from early years, and aspiration is fundamental. People struggle to be the leader and to appear as such to others whom they do not care about. Indeed, even though masculine behavior does not consider the benefits of society but as one of the people who accomplish the most excellent results, manliness can be found in collectivist societies such as Japan, other than in individualistic ones.

Femininity societies hold the inverse values compared to manly ones: taking care of others is the fil rouge of this society, where human beings develop with educating of compassion and tolerance towards others. In addition, individuals flourish in a life of quality and quietness, distant from the need to stand out or be the most excellent. In differentiating with masculine society, where role separation between males and females is solid, genders are at the same level in feminine realities. Female societies focus on advancing well-functioning and equitable welfare and school systems, which are regularly free. At 66 on the scale, China is considered a masculine society. Chinese are exceptionally competitive, particularly young generations who grew up beneath the One Child Approach when parents weighted all their trust and desires on their only child. Besides, people give up family and time to attain their objectives, so disappointment is not an alternative.

#### 5. Short-term orientation and long-term orientation

This measurement characterizes the society's correlation with its history and conventions and measures its orientation to the longer term. Short-term orientated societies have a solid dedication to their culture, and the latter reflects and impacts each aspect of people's lives. At the same time, people are suspicious and, to some degree, anxious about the long term. In addition, they focus on momentary satisfaction through short-term objectives and destinations since they are more oriented to the past and present. On the opposite, long-term arranged societies point to the longer term. Individuals hold values that will not give short-term delight;

for occurrence, they tend to spare cash for the longer term and pursue their objectives through perseverance and resilience. Due to the influence of the Confucian philosophy, the Chinese are too willing to construct long-term connections with other individuals through generosity and tolerance. In reality, gift-giving is one of the bare acts of caring between two individuals. China has a place in this last-mentioned category with a score of 87. It was able to attain such quick improvement thanks to pragmatism and eagerness to enter the longer term and actively participate. Chinese individuals can preserve their traditions by adjusting them to better fit the display. In any case, Wang and Xu’s study indicates a tendency of young generations toward a short-term introduction. Indeed, even though they still hold values like solid will and complex work, they accept less because achievement only comes from effort. This way of considering is primarily due to the reality that youthful Chinese have numerous openings in contact with everything and everybody.

6. Restraint and indulgence

It recognizes the degree to which society permits a moderately free and immediate gratification of essential and ordinary human fancies. In liberal societies, individuals can fulfill their personal needs, whereas limited ones annihilate satisfaction and seriously control behaviors through the application of regulations. China scores 24 of indulgence, so it is considered a restrained culture. As previously mentioned, concerning masculine and feminine society, the Chinese are willing to sacrifice leisure time to accomplish their purposes. Giving time on something which does not make people closer to their goals is a waste, and it should be avoided or limited as much as possible.

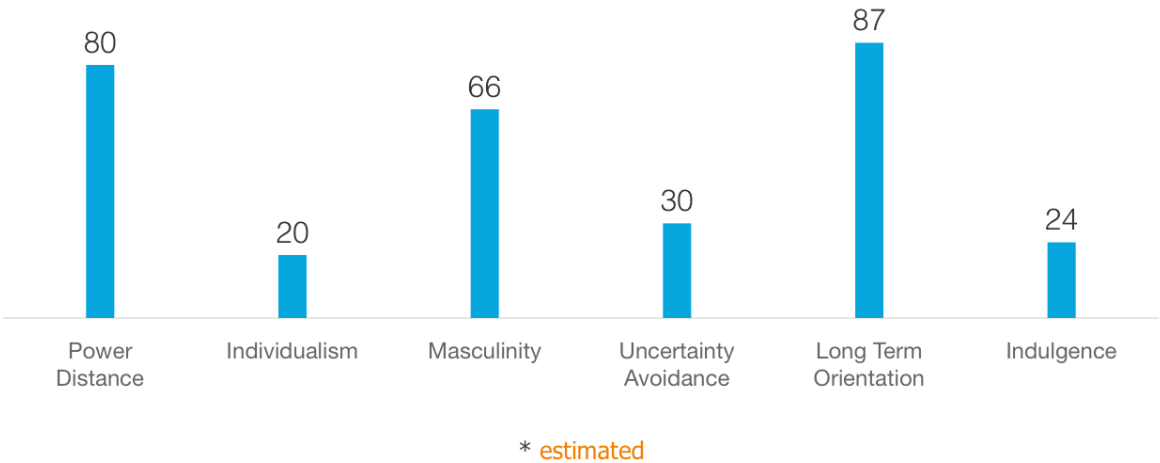


Fig. 1.2. Chinese Hofstede’s dimensions

Source: <https://www.hofstede-insights.com/country-comparison/china,the-usa/>

Hofstede's dimensions model is the most common method to analyze cultures across countries. However, no matter which kind of investigation will be conducted to study a culture, what matters is to underline how important the study of cultural differences investigate the peculiarity of a market and examine how the marketing and buying process shifts from one country to another. Many suggestions of consumer behavior are culture-bound. Therefore, it is improbable to find a tool that can comprehensively describe consumers' decision-making process beyond different cultures.

### 1.2.2 The importance of *mianzi* 面子 and *guanxi* 关系

The Chinese culture has been undoubtedly affected by several established and traditional factors that have made a strong structure of values transmitted through various ages. It does not mean that values have never changed over centuries, but that portion of the traditional value framework has remained through the national development, heading to a contemporary society that combines the traditional Confucian concept with the communist ideas and the contemporary Western leadership. For instance, Confucianism highlights harmony with nature and between men, acknowledges the family as the nucleus tile of society where filial devotion and the roles are the central pillars, and state a simple and humble lifestyle. People strive for the ideals of kindness, fairness, individual behavior, integrity and wisdom, and need to be capable of building a robust network of connections, based on the idea of 关系 *guanxi*, and to handle accurately, saving their faces, 面子 *mianzi*<sup>37</sup>.

These two concepts are part of the basis to understand the Chinese culture, and they can be interpreted as follows:

1. 面子, *mianzi* or "face" relates to an individual's status in the community's eye or society at large. In a highly hierarchical organization, one's reputation depends on the prestige one merits amidst its community, at school, home, or work. Everyone behaves to avoid public errors. For this purpose, as a Chinese, it is supposed to be uncomfortable to perform a slip in front of other people and consequently, to lose one's face or 丢面子 *diu mianzi*, is deemed highly embarrassing.

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<sup>37</sup> Ilaria GALLO, *mianzi e guanxi nella cultura cinese: due concetti fondamentali per capire la Cina*, in "Asiablog.it", 2016, <http://www.asiablog.it/2016/07/13/mianzi-guanxi-cultura-cinese/>, accessed on: 10/06/2021.

Goffman defines *mianzi* as “the positive social value a person effectively claims for himself by the line others assume he has taken during a particular contact”<sup>38</sup>.

In order to maintain this image, people should actively perform a “facework” focused on two points of views: “a defensive orientation toward saving their own face and a protective orientation toward saving the face of others”<sup>39</sup>. Instead, Brown and Levinson focused more on the positive and negative aspects of face, stressing the fact that people struggle to maintain a positive face among others to be accepted by these latter and fit into the society<sup>40</sup>. Amongst various features of Chinese people’s lives, *mianzi* leverages consumer behavior overall. Face consumption is explicated as “the motivational process by which individuals try to enhance, maintain or save self-face, as well as show respect to others’ face through the consumption of products”<sup>41</sup>. It has three principal components:

- Obligation: as consumption is the method to keep face and acquire prestige from others, purchasing objects is not only something characters do if they desire to, although it converts an obligation.
- Distinctiveness: to stand for face, people do not only must purchase what the organization believes is a product linked to *mianzi*, but they likewise must prove that they brought something that stands out, which could be a branded or valuable product that the whole group urges.
- Other orientation: frequently, others’ minds result to point the balance towards the purchase of a product alternatively of another one, with the result that people buy something because they perceive others might appreciate it, instead because he/she wants that particular thing. Furthermore, other orientation is also explicated within gift-giving or by inviting friends or co-workers to a banquet.

Regarding these three concepts, the investigation of Li Lin and other researchers, “Public face and private thrift in Chinese consumer behavior”<sup>42</sup> shows the dichotomy within the

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<sup>38</sup> Ervin GOFFMAN, “On face-work: An analysis of ritual elements in social interaction”, *Journal for the Study of Interpersonal Processes*, vol. 18, p. 5, 1955.

<sup>39</sup> Lin TAO, “Face Perception in Chinese and Japanese”, *Intercultural Communication Studies*, vol. 26, no. 1, 2017, p. 152.

<sup>40</sup> P. BROWN, S. C. LEVINSON, “Questions and politeness: Strategies in social interaction”, *Universals in language usage: Politeness phenomena*, in Esther N. Goody, (Ed.), *Cambridge University Press*, 1978, p. 12.

<sup>41</sup> Julie Juan LI, Chenting SU, “How face influences consumption - A comparative study of American and Chinese consumers”, *International Journal of Market Research*, vol. 49 no 2, 2007, p. 240-242.

<sup>42</sup> Li LIN, Xi DONG, “Public face and private thrift in Chinese consumer behavior”, *International Journal of Consumer Studies*, vol. 37, 2013, p.8.

consumption behavior for properties used in public and those used in private, thus showing the importance attributed to *mianzi*.

The answers and choices of the surveyed personages declared a decision-making process centered on one singular viewpoint: the approval from others. More specifically, the Chinese mind is investing less – or not even buying – home devices that could be helpful and time-saving, like dishwashers and clothes dryers. Because these objects are not shown to others, the Chinese are more thrift concerning their investment. On the other hand, objects shown in public, such as telephones, are seen as something that helps people obtain face - respondents classified as necessary to purchase and use high-tech products, famous brands, and luxury items.

Being approved by others appeared the most significant factor. Consequently, *mianzi* is not given by purchasing itself but by the perception by others of having something valuable and marked. Hence, keeping the *mianzi* and having the approval of colleagues and associates impact the purchasing decision of Chinese people, making them spend more on some things only because they are used in public.

In the same way, Chinese people also want to maintain their prestige when two or more persons interact. As previously mentioned, the Chinese are used to providing gifts to their colleagues, co-workers, and family to show their attachment to them, and *mianzi* is one of the most critical aspects they consider when choosing which gift to buy. People often spend much money on something essential to show that they consider and be well-seen by others and the beneficiary themselves. The more extended someone consumes, the more fame he has inside a gathering of people. One of the objectives gift-givers have is to create a positive impression among people around them. The gift-giving ritual very often happens at public events, like anniversary parties, spiritual celebrations. Therefore, gifts are a method to build and maintain relationships, but they are also indispensable in creating a great response, enhancing the prestige someone owns. Prestige is acquired through the gesture itself, but the real gift is also crucial: products carry a more important purpose of *mianzi* than others. For instance, people prefer to donate gadgets from famous brands, as these categories are more engaging for everyone. Furthermore, by knowing the brand, people are also conscious of a product's value – symbolic or monetary. Hence, it is easier for the gift provider to make a good impression. Moreover, culture requires more expensive products for people of more excellent social status, and the Chinese accept this as they recognize the hierarchy that exists among people.

The other aspect that must be taken into consideration is:

2. 关系, *guanxi* or “relations”, belongs to the system of social relationships and can be designed as an informal connection among two individuals based on shared responsibility and commitment. In a relationship-oriented society, it is primary for anyone to understand their social position and satisfy duties because people are supposed to be part of well-determined groups.

People’s relationships are not random, but they can acquire them thanks to particular requirements and conditions. It all begins with a *guanxi* base, an inherited tie – the *guanxi* existing in the family or because of sharing commonalities. The first *guanxi* base is also the strongest: for Chinese people, kinship relationship comes before all other types of connections someone can develop. The commonality *guanxi* base, or “relationship by nature<sup>43</sup>” comes from some external characteristics that people share and could represent the starting point for developing a relationship. These could be the neighbors or people living in the equivalent city, which are appearances that individuals encounter daily. Sharing the same place of origin permits people to feel more alike even when they are distant from home as China is a vast country with many different regional cultures. Going to the same school or working in the same place is also a significant *guanxi* base. In the first case, young people acquire a strong attachment with their classmates during their teen years, usually lasting into the future. The *guanxi* performed inside colleagues is more utilitarian than emotional, and it is also subject to disputes and dissimilarity.

Furthermore, as far as the *guanxi* base is present and solid between two people, the growth of a real connection is not guaranteed. People must commit to others and show them their eagerness to preserve the connection through *guanxi* methods such as gifts, courtesies, dinners, and so on. These signs enhance mutual obligations and are established through two main issues: the object of the exchange and following specific rules. These proposals imply the identification of two theories: *renqing* 人情 and *xinyong* 信用:

- *renqing* 人情: means “favor”, which is what gets traded during the *guanxi* relationship. Nevertheless, it is not a standard or real favor, but it is a more comprehensive concept that includes intangible things such as opportunity or affection. Though, it is also “highly particular because it can be repaid only by a particular person in particular way”<sup>44</sup>. Chinese *renqing* concept changes from the Western one in various forms. For example, *renqing* cannot be calculated due to its intangibility, thus making the exchange

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<sup>43</sup> Fan YING, “Questioning *guanxi*: Definition, classification and implications”, *International Business Review* vol. 11 no. 5, 2002, p. 547.

<sup>44</sup> C. ZHANG, S-J HONG, op. cit., p. 27.

between the parties always unequal. Ordinarily, these unbalances weigh more on the person who receives the favor and has to return it. In fact, “if you have received a drop of beneficence from other people, you should return them a fountain of beneficence”<sup>45</sup>. Although the *renqing* trade does not stop with the joint repayment of favors, it is an ongoing process where people give gifts and make favors one to another. This method can go on for a long time because *renqing* can also not be returned promptly, as Chinese culture is long-term oriented. An added aspect of Chinese *renqing* which distinguishes it from the Western concept of favor is that for Chinese people, business and personal favors are not two isolated concepts, whereas, for Western, the two things cannot mix.

- *xinyong* 信用: indicates “trustworthy” or “credible”, and it refers to the ability of a person to return the favor once received. The presence of *xinyong* between two people is the prerequisite for developing *guanxi*, since nobody wants to favor someone who they do not trust. If the *renqing* rule is not respected, the *guanxi* relationship cannot be established, and the person loses both *xinyong* and *mianzi*.

Consequently, Western companies must perform an effort to adjust and conform to these characteristics because they would face a wall if they tried to adopt the same strategies, they implement in the home country. They should build and strengthen long-term relationships with Chinese partners, which will benefit both parties. Once understood the game's rules that cover China, meaning once they “passed the gate” and became insiders, the relationship will undoubtedly be long-term and profitable.

### 1.3 The beauty model of the Chinese consumer

Due to its strong relation with culture, it is challenging to determine beauty and standards accepted in different countries. Ordinarily speaking, beauty is defined as “a combination of qualities, such as shape, color, or form, that pleases the aesthetic senses, especially the sight”<sup>46</sup>. For ages, what has been proposed was an aesthetic based on the right mixture of four primary components, “clarity, symmetry, harmony and vivid color”<sup>47</sup>.

Moreover, several philosophers, painters, and anthropologists have tried to develop the beauty recipe that could determine the ideal beauty standards, flopping poorly. The truth is, as “beauty is in the eye of the beholder”, it converts tough to imagine a universal beauty ideal

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<sup>45</sup> HWANG-KUO, *Face and favor: The Chinese power game*, in *American Journal of Sociology*, vol. 92, 1987, p. 954.

<sup>46</sup> “Beauty” (definition of), in *The Oxford English Dictionary*, retrieved from <https://en.oxforddictionaries.com/definition/beauty>.

<sup>47</sup> Nancy ETCOFF, *Survival of the prettiest: The science of beauty*, Anchor, 2011.

because what is recognized as beautiful by some may not be uniformly agreeable by others. This conceptualization is even questionable regarding how cultural differences influence our judgment. History, traditions, art, and philosophy are just some of the factors that have shaped the beauty ideal of each country; hence, Western companies that aim to face the international cosmetics market must be conscious of the diversity in the beauty perception across the world. The traditional Chinese beauty standards are very different from the Western ones, so foreign players cannot attempt a standardization strategy. However, it becomes imperative to examine the varieties and to develop new solutions. Hence, for ages, Western cosmetics companies that refused to adjust to the differences worldwide had to collect and deliver items with different characteristics that could adjust to a different skin tone or hair.

No one can doubt the unbelievable power of Western beauty standards on the Chinese beauty model and the resulting conception of a particular blend of classical and new criteria. For example, while the traditional adoration of white skin is still regarded as one of the leading beauty standards to aspire to, recently big and wide-open eyes, especially with double-fold eyelids are now a must. Some ideas of female beauty standards come from both Taoist and Confucian teachings. Nevertheless, the beauty standards offered by the traditional doctrines were almost the reverse: contrastingly oriented to sensual attractiveness, and Taoism intensified physical beauty; instead, moral virtue and a kind attitude were featured by Confucianism<sup>48</sup>. Notwithstanding the symbolic contrast between the two concepts, both the physical appearance and the inner virtue are devoted to developing feminine beauty standards. This dualistic vision of femininity remained beyond ages. Traditionally, Eastern Asian women aimed to be sweet and gentle mannered. The message is conveyed that the most beautiful women prepare themselves charmingly and simply.

It is possible to identify some primary standards that are pursued by the majority of Chinese women:

- Big eyes with a prominent “double-eyelid”. Chinese women believe that 大眼睛 *da yanjing*, wide and large eyes are the most attractive as they are associated with an innocent, doll-like kind of beauty and are linked with some conventional aspects of women behavior: obedience, femininity, and submission. As generally believed, the trend did not originate from Western beauty models, but it was previously existent in China and was supported by Western influence. Western standards have emphasized

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<sup>48</sup> Wen HUA, *Buying beauty: Cosmetic surgery in China*, Hong Kong, Hong Kong University Press, 2013.



this trend, as many Chinese women believe that big eyes can make them appear more 洋气 *yang qi*, foreign or international.

- High-bridged nose. In China, pointed and high-bridged noses are recognized as very charming. This nose is apparent from the side and has whole wings and almost imperceptible nostrils; it is contemplated sophisticated because it reduces the face width.
- Fair and white skin. Porcelain pale skin is probably the principal trait connected with Chinese beauty, to the point that 白富美 *baifumei* or “white, rich and beautiful” has become a trendy way to represent the ideal Chinese woman. The recognition of a white skin tone comes from antique times: in the past, people who had browned or tanned skin were those serving in the provinces, while rich people could glorify a white carnation<sup>49</sup>. Their light and porcelain skin showed their wealth status and placed them in a higher class. Nowadays, this trend is defined as 美女 *meinu*, a beautiful woman. Aside from whiteness, hydration, and creamy, unblemished complexion are essential.
- 瓜子脸 *guazilian*, “melon seed face”. Meaning the V-shaped with a sharp chin. Face shape is significant in China, as an oval or heart-shaped face is correlated with feminine, cute and sensitive characteristics<sup>50</sup>.
- Inclination. Added appreciated face shape is 鹅蛋脸 *e'danlian*, or goose egg face. Its symptoms are a more pointed chin and more above cheeks concerning the melon seed face shape and a “rounder” shape that looks like an egg.
- A delicate body and a slim shape are part of the beautiful model and, along with the oval face, are considered the principal features of a beautiful woman. This matter has been criticized many times because women often attempt to lose weight in various toxic ways: unsustainable nutrition, slimming products, and food substitutes are the more accessible choices for many girls, driving many of them to be sufferers of eating disorders at an early age.

These aesthetic models often disagree with the Western measures that glorify athletic supermodels with bronzed color and an extroverted and sensual attitude<sup>51</sup>. This variation

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<sup>49</sup> SARA Lynn, *Chinese standards of beauty*, in “TutorMing China Expats & Culture Blog”, 2015, <http://blog.tutorming.com/expats/chinese-standards-of-beauty>.

<sup>50</sup> *Western vs Chinese Beauty Standards*, in Ninachese, 2016, <https://ninachese.com/blog/2016/05/12/western-vs-chinese-beauty-standards/>.

<sup>51</sup> Daniel KONG, *Unmasking East Asia's Beauty Ideals*, in “Business of fashion”, 2016, <https://www.businessoffashion.com/articles/global-currents/unmasking-east-asias-beauty-ideals>, accessed on: 10/07/2021.

correlates with the Chinese idea that beauty needs inner balance, health, and outer beauty, conveying moderate and well-being attractiveness. This idea is shared among various Asian cultures, for instance, the Japanese and the Korean ones, and consequently, the sub-cultures of these other countries have turned it<sup>52</sup>.

It is no longer possible to ignore cultural variations nowadays, and foreign companies must adapt to this situation. Western beauty ideals that for ages have determined the method and the knowledge of beautification global are now losing their purchases as new awareness is happening. The image of beauty can switch dramatically over time, and cosmetics companies must react quickly to this phenomenon, mainly Western brands. Japanese or Korean firms are regularly capable of following the developments of customers tastes quickly, not only because they share some beauty ideals with the Chinese but also for their geographical closeness to the market; instead, Western companies often must handle obstacles that stand from the cultural gap in the Chinese market. Beauty is part of a culture, and Western companies cannot rely just on their well-established brand images. However, they must conform to the market needs, must instruct their customers, and must be able to communicate effectively.

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<sup>52</sup> Tatjana MIHAJLOVIC, Tiziano VESCOVI, Andrea PONTIGGIA, *The Beauty Ideal in Chinese Luxury Cosmetics: Adaptation Strategies of Western Companies*, working paper n. 7, Department of Management of University of Venice Ca' Foscari, 2017, pp.1-19.

## **CHAPTER 2 - A scenario of the current cosmetic market in China and its main regulation**

### **2.1 The high-speed growth of the cosmetics market in China**

Since antiquated times, Chinese ladies have been attentive to their physical appearance. Over the last few years however, the trade of cosmetic items in China has seen steady and significant development. Due to the Chinese population's growing purchasing power, opportunities for cosmetics are expanding and Chinese e-commerce websites have provided more availabilities for the cosmetic labels to enlarge. China's cosmetics skincare companies are in the center of a time of renewed consumption, urbanization, and supply-side improvements<sup>1</sup>. Indeed, the cosmetic products industry is one of China's fastest-growing and promising trade ranges for the anticipated future. Since 2020, China moved to become the world's second-largest beauty and individual care market after the U.S. The beauty and personal care showcase cover a burgeoning request for excellent quality, premium name items due to urbanization, developing expendable income, and social media effect. To paint a clearer picture, the value of the cosmetics market in China expanded from 74 billion yuan in 2009 to more than 340 billion yuan (52.6 billion U.S. dollars) in 2020. Additionally, current trends show that more than half of cosmetics retail deals would be from e-commerce channels by 2024. The more significant part of cosmetic items sold online is from Alibaba's Tmall and JD.com yet, besides the rapid development of the online distribution, specialty cosmetic stores, general stores, and hypermarkets dominated offline deals. Multi-level direct selling of beauty products have declined drastically since 2008 due to modern, straightforward sales requirements, with online sales becoming the primary distribution route in China's cosmetics sector as the Internet has grown in popularity. The size of the internet buying market grew significantly between 2012 and 2017 with online shopping accounting for more than half of the overall sales volume. The online retail market was worth 62.2 trillion RMB in 2012, and it has risen to 154.4 trillion RMB in just four years. The size of the internet purchasing market is likely to continue to expand<sup>2</sup>: China's craving for cosmetic items has a notable worldwide character. In terms of product segments, skincare products rule the beauty care products showcase in China with the growth

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<sup>1</sup> Jixing, WANG, "High-Speed Growth of the Cosmetics Market in China", China Information Center of Daily Chemical Industry, *China Academic Journal Electronic Publishing China*, vol. 3 n. 4, 2018.

<sup>2</sup> *Selling cosmetics in China: Analysis of the cosmetics market in China*, in "daxueconsulting", 2020, <https://daxueconsulting.com/selling-cosmetics-in-china-beauty-and-personal-care-market/>, accessed on: 20/06/2021.

of the skincare market measured to nearly 245 billion yuan (around 38 billion U.S. dollars) in 2019. In contrast, the haircare industry is estimated at around 55 billion yuan (8.5 billion U.S. dollars). Whereas colored cosmetics account for the most noteworthy share of makeup deals universally, cosmetics are still a moderately new beauty division in China. Colored or beauty care products, which involve makeup cosmetics, appeared and achieved notoriety among more youthful buyers.

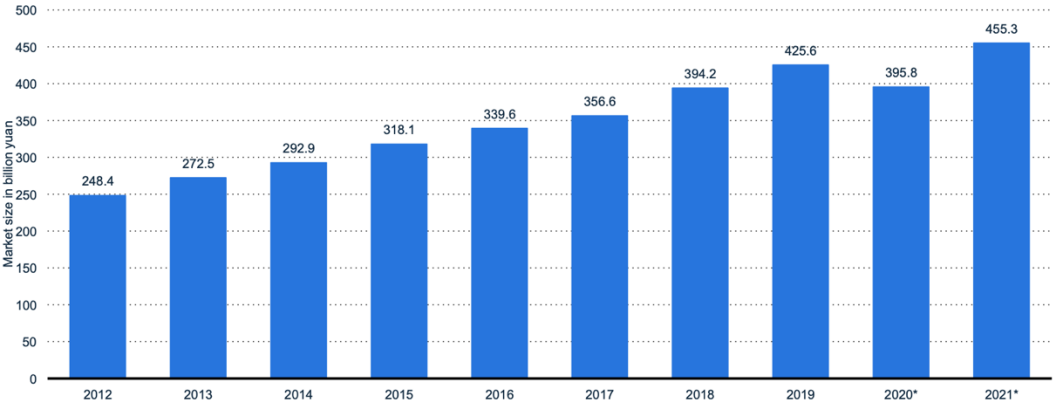


Fig. 2.1: Cosmetic market size in China from 2012 to 2019 with a forecast until 2021 (in billion yuan)

Source: Statista Dossier – Cosmetics market in China 2020<sup>3</sup>

As shown in figure 2.1, from 2012 to 2019, the size of the market increased significantly: from 248.4 billion yuan to 425.6 billion yuan in 8 years. This chart shows that within less than a decade, the size of the cosmetic market almost doubled. The forecast analysis predicts that by the end of 2021, the size of the cosmetic market in China will increase further reaching 455.8 billion in yuan. To give a comparison, the US cosmetic market revenue in 2021 is predicted to be around 93.332.8 million US dollars corresponding to 605.36 billion in yuan.

**2.1.1 Chinese consumer preferences and influences**

It is significant to highlight what are the Chinese’s most weighted factors in their decision to purchase a cosmetic product. According to the graph showed below, ingredients and effects mattered most when buying beauty products, with almost 53% of respondents stating so. Another two significant aspects to consider among Chinese consumers were cost effectiveness

<sup>3</sup> Yihan, MA, *Cosmetics market in China - statistics & facts*, in “Statista”, 2021, <https://www.statista.com/topics/1897/cosmetics-in-china/>, accessed on: 3/07/2021.

and brand assurance. As explained in the previous chapter, the Chinese consumer is very attracted by brand names and the guarantees offered by a brand, usually with a strong preference towards western beauty brands. Another data point which reveals how important it is for companies to remain up to speed to new media and new ways of marketing are the recommendations from beauty KOLs and celebrity endorsements. Their influence on the purchase is significant and it is crucial for companies to take this information into consideration.

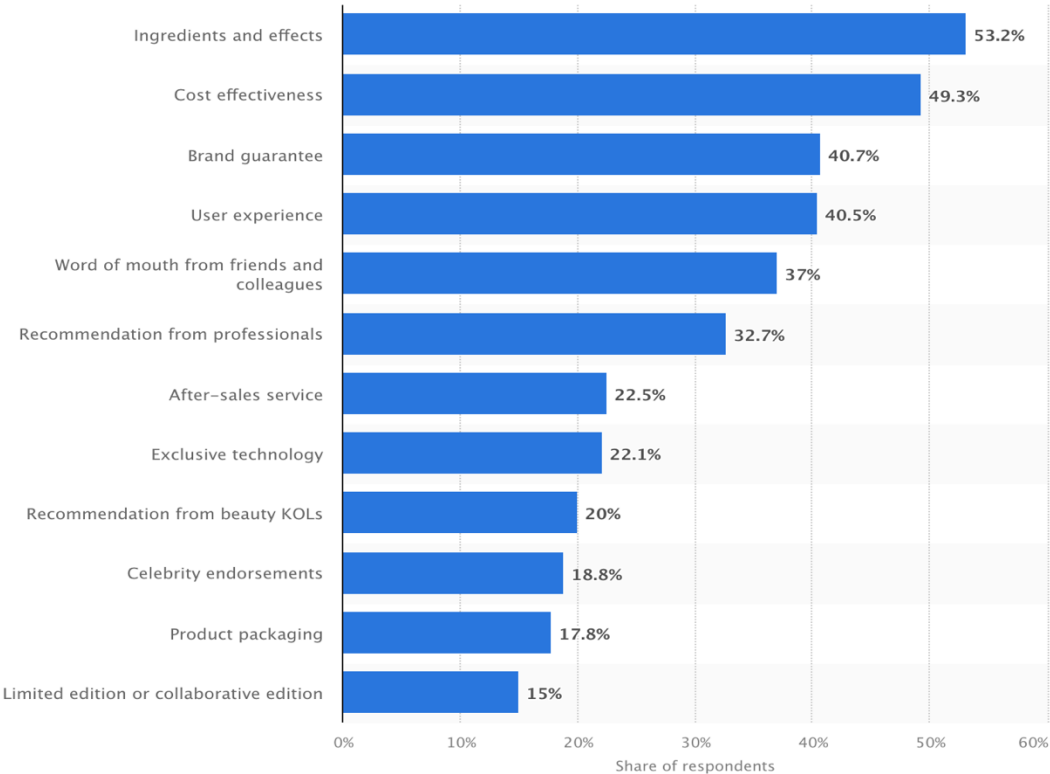


Fig 2.2: Leading factors concerning Chinese consumers when purchasing cosmetic and skincare products as of August 2020

Source: Statista Dossier – Cosmetics market in China 2020

When looking for cosmetic products, the Chinese demand for more particular items evolves as Chinese cosmetics industry consumers become more familiar with the diversity of products offered. With regards to skincare: whitening, freckle removal, hydration, and antioxidant are all areas which are becoming more popular among Chinese consumers. On the other hand, when marketing cosmetics in China, Western brands are frequently required to modify their products to meet the specific beauty requirements of Chinese consumers. For example, the preference of consumers in China’s cosmetics industry leans towards cosmetics created from natural materials, in addition to the functional benefit, and consumers in China are

more mindful of the safety of cosmetics as a result of regular safety issues with goods in the Chinese market. Interest in products created with natural or herbal substances has also grown significantly. The increased performance of enterprises that specialize in making cosmetics using herbal elements demonstrates this. The sales volume in this area was 5.3 times higher in 2018 than it was five years before, and the consumer base was 4.2 times larger. In the future, cosmetics containing natural components are only expected to gain market share<sup>4</sup>. Finally, because of their increased spending capacity, Chinese cosmetics consumers are migrating to higher-end brands, demonstrated by the gains in Chinese market share experienced by upper-tier brands.

**2.1.3 The consumption of high-end cosmetics increases as a result of consumer upgrades**

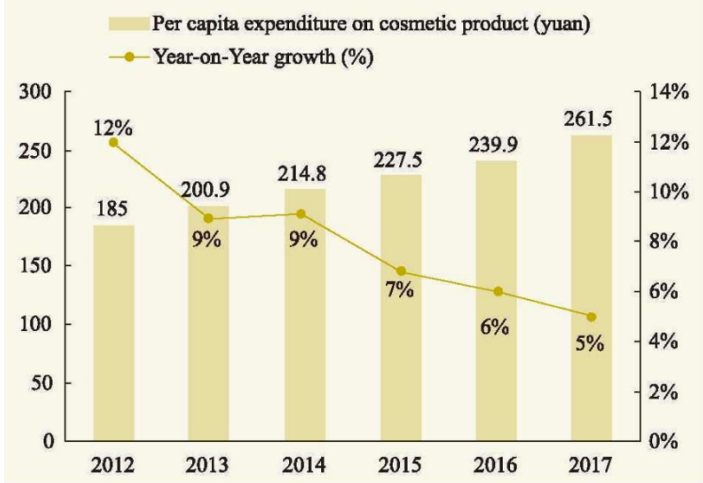


Fig. 2.3 The per capita expenditure on cosmetic products in China, 2012-2017

Source: Euromonitor International

With the popularization of e-commerce, the consumption model and consumption customs of Chinese people underwent a shift. As a consequence, the income level of residents grew, and the demand for cosmetics by residents in third and fourth-tier cities increased significantly, with the per-capita expenditure for cosmetics in China growing from 185 yuan in 2012 to 261.5 yuan in 2017. Chinese consumers are becoming more careful when selecting cosmetic goods, not only in terms of quality but also in terms of health and safety. Domestic

<sup>4</sup> *Selling cosmetics in China: Analysis of the cosmetics market in China*, in “daxueconsulting”, <https://daxueconsulting.com/selling-cosmetics-in-china-beauty-and-personal-care-market/>, 2020.

cosmetics companies seized the opportunity to move out of internet marketing and used e-commerce channels to increase their market share. As a result, the market share of local brands began to recover progressively<sup>5</sup>.

### **2.1.4 Domestic vs International players**

In the 1990s, some Chinese cosmetics firms began to appear in the market, but did not remain long. While the Chinese cosmetics market was weak, international brands took the chance and accessed China. Notable companies from the West were gaining ground at extraordinary speeds due to their products' excellent quality and their innovative marketing tactics, giving birth to a fierce conflict between the West and the East which led to national brands being pushed away. R&D expenditure was the solution to enhance the competing positions of products. In this area, there has been an improvement in domestic brands lately. The main driver of progress can be attributed to research and development, in which Chinese companies have invested massively. For example, in 2017, the R&D spending of Shanghai Jahwa was estimated at 2.48 %, and Proya's was 2.29 %. However, the R&D spending of domestic companies are still below comparing to L'Oreal's of 3.82 %. In 2017, Shanghai Jahwa invested 161 million yuan in R&D, while Proya spent 40.83 million yuan, L'Oreal spent 6.843 billion yuan, and Estee Lauder spent 1.21 billion yuan. The current scenario is hard to shift in the next few years, and international brands will continue to have advantages in product advancement due to their size. More than half of Chinese beauty care products shoppers favor international brands over local ones. In particular, half of China's imported cosmetic items come from Japan and South Korea, whereas brands from France, Singapore, and the U.S. esteem more than 30 % of makeup imports. Unshockingly, four out of five driving makeup showcase players in China are international brands such as Lancôme, Estée Lauder, and L'Oréal Paris. Amid domestic names, mid-segment skincare and cosmetics name Chando and long-established brand Pechoin were the foremost local market leaders in 2019. Due to the fast growth of e-commerce and the emergence of the third and fourth-tier mass consumer market, some local brands that invested into market technology research and development gained market share.

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<sup>5</sup> Tatjana, MIHAJLOVIC, Tiziano, VESCOVI, Andrea, PONTIGGIA, *The Beauty Ideal in Chinese Luxury Cosmetics: Adaptation Strategies of Western Companies*, working paper n. 7, Department of Management of University of Venice Ca' Foscari, 2017, pp.1-19.

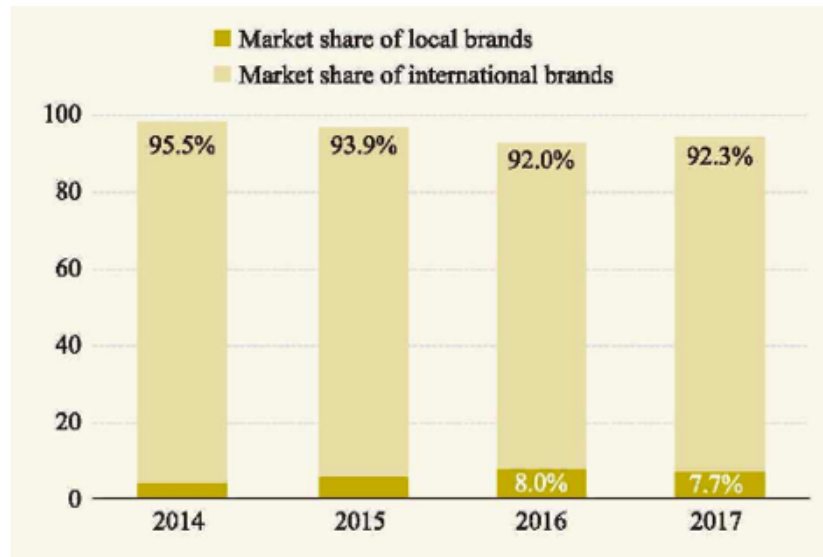


Figure 2.4: Market share of top 40 companies in high- end beauty market

Source: Euromonitor International

Another factor to take into consideration is that China’s skincare business has shifted towards the high-end, with multinational players controlling the cosmetics market in China. According to Euromonitor International, between the TOP 40 companies in China’s high-end cosmetics market in 2017, the market share of foreign brands was 92.3%, while national brands valued for only 7.7% (figure 2.4).

A study regarding the youth’s consumption behavior on high-end cosmetics was conducted among 400 respondents in Guangzhou. The information was assembled and analyzed based on gender, occupation, age, and background to understand the sample’s main characteristics fully. Furthermore, the test was conducted with 30 respondents to guarantee the authenticity and efficacy of the questionnaires. The result showed that while brand awareness does not harm the purchaser’s attitude on high-end cosmetics, other factors like product involvement, perceived quality, subjective norm, and word-of-mouth significantly influenced consumers’ behavior and consumers’ perspective on high-end cosmetics<sup>6</sup>. Nevertheless, with the coming about of an upgrade in consumption, Chinese consumer demand for high-end cosmetics has risen rapidly: China’s high-end cosmetics market has increased from RMB46.85 billion to RMB84.5 billion from 2012 to 2017, a 12.53 % CAGR. The growth speed of the high-end cosmetics market in 2017 even reached 24.95 %, while the growth rate of mid-and- low-

<sup>6</sup> Bhumiphat GILITWALA, Amit Kumar, NAG, “Factors Influencing Youngsters’ Consumption behavior on high-end cosmetics in China”, *Journal of Asian Finance, Economics and Business*, Vol 8 No 1, 2021, 443-450.



end that year was only 5.46 %. High-end cosmetics in China have excellent growth potential in the future, although with international brands having notable advances in China's cosmetic market's competition. McKinsey stated that Chinese customers have more confidence in big international brands as compared Chinese national brands and agree to more expensive costs for global brands. From the viewpoint of purchasing channels, e-commerce channels' enrichment to the entire cosmetics market in China grew from 10.2 % in 2012 to 23.3 % during 2017. The real CAGR of Chinese cosmetics sold through e-commerce platforms from 2012 to 2017 increased by 27 %. On the other hand, cosmetics sales C/ARG of all offline channels in China (excepting specialty stores) showed a slow uptrend or even a declining trend over 2012-2017.

Although Chinese consumers have traditionally had a positive attitude toward foreign brands, McKinsey's China Consumer Report 2020 indicated that this is changing. "Respondents ... had a clear preference for Chinese brands over foreign ones in 13 out of 19 categories"<sup>7</sup> according to the consumer study for lifestyle products. Furthermore, "consumers are also likely to pick local brands for more expensive premium products" such as "higher-end digital devices, skincare, cosmetics, and red wine" according to the survey<sup>8</sup>.

Moreover, although the business size of the Chinese cosmetics industry is vast, experimental research regarding consumer behaviors in this market is limited. Current studies about consumer behavior in China were carried from the demographics forecast of consumers to define the overall performance of Chinese consumers in the cosmetics market. The research was mostly based on the relationship between the marketing promotion factors and the consumption behaviors of Chinese consumers in the cosmetics market. Indeed, from the viewpoint of cosmetics brands or corporates, recognizing the relationship between marketing advertising factors and the consumption habits of Chinese consumers is more significant in managing marketing strategies. The typical items sold in China incorporate skincare, color makeup, haircare, and toiletries. The Chinese cosmetics business includes an ever-expanding amount of cosmetic goods. According to the contemporary regulation on imports, they are classified into two principal areas: ordinary cosmetics and special use cosmetics. From 2012 to 2017, the number of domestic players in China's top 20 cosmetics companies increased from 6 to 8, and their combined market share progressed from 7.6 % to 14.3 %. In 2017, Shanghai

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<sup>7</sup> S. LIU, P. PERRY, G. GADZINKI, "The implications of digital marketing on WeChat for luxury fashion brands in China", *Journal of Brand Management*, vol. 6 n. 4, 2019, p. 395-409.

<sup>8</sup> Liang Li JUN, Li WENXI, Wang ZEYANG, Wang ZIWEI, Zhang XINYAO, "The future of marketing Chinese Luxury Brands: analysis of current Consumer behavior and future implications", *Atlantis Press*, 2021.

Jahwla, Jala, Pechoin, Kans, Yunnan Baiyao, and other local cosmetic businesses were named among the top 20 companies by market share in China, with a market share steadily on the rise thanks to low prices, great marketing, and the rapid growth of e-commerce.

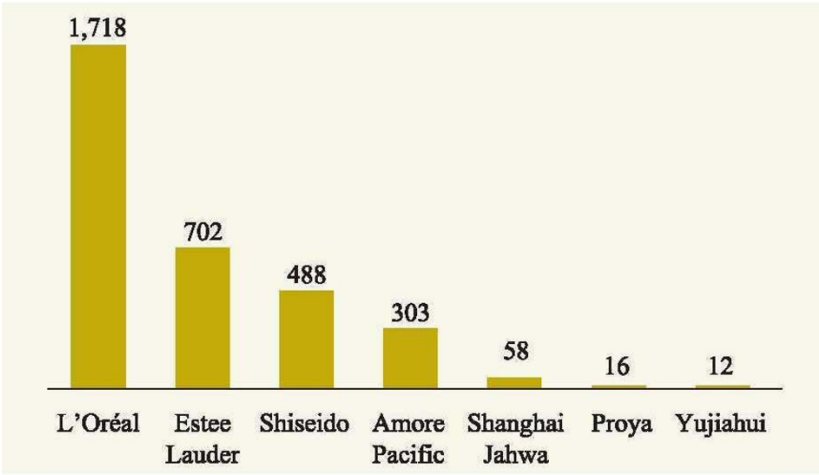


Fig. 2.5: Sales of local brands vs. sales of international brands (100 million)

Source: Euromonitor International

Foreign brands have stayed in the dominant market position. The top three companies, Procter & Gamble from the United States, French L’Oreal, and Japanese Shiseido, gained 21.8 % of the Chinese beauty and personal care market profits. This achievement is due to their wide product ranges, authenticated prestige and quality, and dominance in the premium and medium cosmetic markets. However, frequently Chinese domestic companies such as Shanghai Jahwa, Proya, and Yujiahui, which dominate the lower end of the market can compete with the significant global names in China’s cosmetics market.

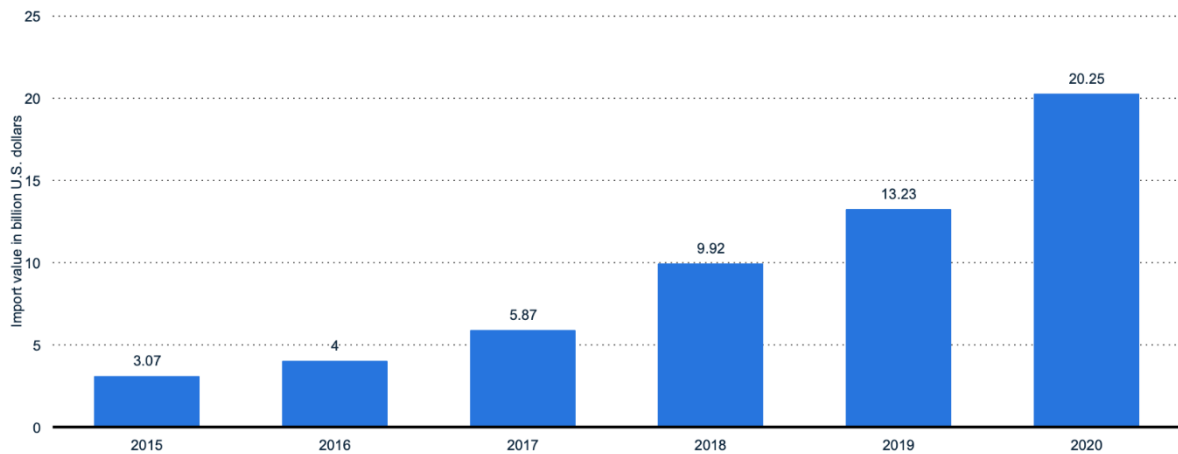


Fig 2.6: Import value of personal care and cosmetics products into China from 2015 to 2020  
(in billion U.S. dollars)

Source: Statista Dossier – Cosmetics market in China 2020

The graph below shows the import value of the personal care items in China in a range of the past five years. From 2015 to 2020, the value increased from 3.07 billion US dollars to 20.25 US dollars. This is another indicator that explains the importance which foreign brands carry inside the Chinese cosmetic market and the opportunity to expand their brand in the market. Additionally, this data makes the Chinese cosmetic market worthy of exploring for international companies.

## 2.2 Main cosmetic regulations in China

On the 1st of June 2021, the broadening cosmetic regulation *Cosmetic Supervision and Administration Regulation (CSAR)* in China, substituted the recent *Cosmetics Hygiene Supervision Regulations (CHSR)*<sup>9</sup>. By entering into the strength of the CSAR, China’s cosmetic field is now ushering in a new era. The progress of supervisory focus in CSAR compared to CHSR can be related to the evolution of names: CHSR puts more attention on the hygiene qualification of cosmetic products. In other words, if CHSR was strongly related to the idea of “hygiene”, CSAR focuses more on “safety” and “quality”. In 2015, related changes occurred

<sup>9</sup> Chemlinked cosmetic team, *China Mainland Cosmetic Regulation*, in “Chemlinked”, 2021, <https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation>.

when the professional regulation for cosmetics, the “Hygienic Standards for Cosmetics”, was changed into “Safety and Technical Standards for Cosmetics” (STSC)<sup>10</sup>.

The new ordinance is intended to improve the antiquated administrative structure and approach cosmetic pre-market and post-market control issues in different circumstances, such as cosmetic classification, new ingredient supervision, efficiency evaluation, safety assessment, online cosmetic direction, accountability system, and punitive actions. China has been publishing and will perform a series of subsidiary arrangements to promote the new ordinance in the following few years.

Given that, the CSAR proposed some new requirements for cosmetic companies, and transitional measures were published. Before completing the subsidiary regulations on registration and notification, the registrants and notifiers will submit enrollment and notification dossiers following the current rules and requirements, with the report deemed completed after the submission of notification dossiers. The medical products administration departments will carry out the registration management in accordance with the methods and deadlines specified in the CSAR.

There are six chapters and 80 articles in CSAR, while the previous CHSR had only 35 articles. It is composed of six chapters: general provisions, ingredients and products, production and distribution, supervision and administration, legal liability, and supplementary provisions. Essential points concerning cosmetics are also designated in CSAR. For instance: the definition, product group, ingredient control, filing and notification, conditions of production, post-market supervision and examination, and the roles and responsibilities in cosmetics-related activities. Additionally, CSAR implements a foundation for specific rules and technical certificates. The NMPA for example has established a legislation disposition to create the CSAR-related regulatory practice, including procedure practices and technical direction. In summary, these subordinated laws and records can be split into four parts. The first section concerns registration and notification, including the procedural and technical requirements for ingredients and final products. The second part regards production and distribution, taking producers and enterprises as the central objects of administration, the third part is about the regulation concerning toothpaste. Furthermore, the latter is for standardized management of labeling. Additionally, more numerous laws and certificates have been drafted and revised.

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<sup>10</sup> Su ZHE, Luo FEI-YA, Pei XIN-RONG, Zhang FENG-LAN, Xing SHU-XIA, Wang GANG-LI, “Final Publication of the Regulations on the Supervision and Administration of Cosmetics and New Prospectives of Cosmetic Science in China”, *MDPI*, 2020.

In 2018, China undertook a massive institutional change. In the cosmetics industry, there are currently three key competent agencies:

1. State Administration for Market Regulation, 国家市场监督管理总局 (SAMR): it practices overall management of market administration of food, cosmetics, pharmaceuticals, and medical articles. Its principal duties include market supervision, quality and security surveillance, uniformity in work<sup>11</sup>.
2. National Medical Products Administration 国家药品监督管理局 (NMPA): NMPA is built under the governance of SAMR to take all the work initiated by the previous CFDA. It is liable for filing imported/domestic unique cosmetics, generic cosmetics whose origin is imported, and the documentation and information of new cosmetic ingredients. Different restrictions cover safety surveillance management, regulation management, quality control, post-market risk management, supervision and inspection, and international trade and cooperation. Instead, pharmaceutical goods administration departments of provinces, autonomous regions, and municipalities directly under the Central Government are accountable for the administration and management of cosmetics in their administrative areas, including general domestic cosmetics and the issuance of production permissions for cosmetic companies.
3. General Administration of Customs 中华人民共和国海关总署 (GAC): is liable for the customs import and export investigation and quarantine of cosmetics.

### 2.2.1 The intersection between Cosmetics and Drugs

Some medications can be applied to the skin or other exterior portions of the human body and perform similar roles to cosmetics. Thus, setting a line between cosmetics and pharmaceuticals is a widespread practice. In the EU, for example, a guideline document and a particular handbook were created to explain the scope of cosmetic rules and help distinguish cosmetics from pharmaceuticals, medical devices, toys, biocides, and other commodities. The term “cosmeceutical” has been increasingly popular in recent years, and consumers sometimes misunderstand it as cosmetics with medicinal benefits<sup>12</sup>. In reality, the term “cosmeceutical” is still debatable<sup>13</sup>. The Federal Food, Drug, and Cosmetic Act (FD&C Act) do not recognize any

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<sup>11</sup> Zaidi, GUO, Li, BAI, Shunlong, GONG, “Government regulations and voluntary certifications in food safety in China: A review”, *Trends in Food Science & Technology*, 2019, 160-165.

<sup>12</sup> Food and Drug Administration, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, 2020, <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Cosmeceutical>.

<sup>13</sup> National Medical Products Administration, *Frequently Asked Questions about Cosmetics Supervision and Administration*, 2020, <https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdz/20190110093701592.html>.

such category as “cosmeceutical”, according to the US Food and Drug Administration (FDA)<sup>14</sup>. Cosmetics, in comparison to pharmaceuticals, are intended for specific uses. Ingredient use, risk characteristics and management, tolerance for adverse responses, legal requirements, monitoring systems, and other essential features differ. Furthermore, cosmetics are meant for average individuals, whereas medications are designed for people who have health problems, and some should only be used under the supervision of a doctor.

When people mistake drugs for cosmetics, they may underestimate the potential side effects, posing additional risk to users; when people mistake cosmetics for drugs, they may miss out on a valuable opportunity to seek competent medical help. The NMPA clarified in January 2019 that claiming “medicated cosmetics” or “medical skincare products” in China is not legal<sup>15</sup>. This approach will be followed when CSAR is implemented. Furthermore, foreign quasi-drugs and drugs can only be imported as cosmetics if they fit China’s definitions and conditions, including the product’s legal compliance and the possibility of labeling information adaptation.

### 2.2.2 Definition, scope and classification of Cosmetics

In the guidance regarding cosmetics, it is essential to establish a definition to judge product labeling and define the functional area. Different interpretations of cosmetics in various countries are reviewed and analyzed. As the result exhibits, utilization method and practice purpose are the essential and traditional details in the descriptions, and some also arrange the involved area. Furthermore, in the reports in Japan and Korea, it is also highlighted that cosmetics should moderate and beautify the human body. With any modification in these aspects in the definition, the actual extent of cosmetic products can be varied. The illustration in China does not include teeth, mucous membranes, or other oral cavity parts.

Nevertheless, according to CSAR, toothpaste shall be regulated in a comparable way to overall cosmetics. Hence, toothpaste is also a product section beneath the regulation of NMPA. Soaps, saving for those challenging the effectiveness of unique cosmetics, are free of administration by CSAR.

Country / Region	Definition of Cosmetics
China <sup>16</sup>	Daily chemical industry products intended to be applied by spreading, praying or other similar ways to human body surfaces,

<sup>16</sup> “Zhonghua renmin gongheguo guowuyuan ling di 727 hao”, 中华人民共和国国务院令, 第 727 号, Order of the State Council of the People's Republic of China, No. 727, 2020, [http://www.gov.cn/zhengce/content/2020-06/29/content\\_5522593.htm](http://www.gov.cn/zhengce/content/2020-06/29/content_5522593.htm), accessed on: 27/05/2021.

	such as skin, hair, nails, and lips, for the purpose of cleaning, protecting, beautifying and decorating
<b>EU<sup>17</sup></b>	Any substances or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nail, lips and external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.
<b>US<sup>18</sup></b>	Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap.
<b>Japan<sup>19</sup></b>	Applied by spreading, sprinkling or other similar ways for the purpose of cleaning, beautifying, promoting attractiveness, altering appearance, or keeping the health of skin hair, with a moderate effect on the applied site. Not including the products also having pharmaceutical purpose or quasi-drugs.
<b>Korea<sup>20</sup></b>	Articles applied by spreading, rubbing, sprinkling or other similar ways, with the effect of cleaning or beautifying, in order to promoting attractiveness, altering appearance, and keeping or

<sup>15</sup> Food and Drug Administration, Code of Federal Regulations, *Antiperspirant Drug Products Over-the-counter Human Use*, Title 21, Part 350, 2021, <https://www.ecfr.gov/cgi-bin/text-idx?SID=58025e96360c4105ae8364a55fedde8f&mc=true&node=pt21.5.350&rgn=div5>.

<sup>16</sup> “Zhonghua renmin gongheguo guowuyuan ling di 727 hao”, 中华人民共和国国务院令, 第 727 号, Order of the State Council of the People's Republic of China, No. 727, 2020, [http://www.gov.cn/zhengce/content/2020-06/29/content\\_5522593.htm](http://www.gov.cn/zhengce/content/2020-06/29/content_5522593.htm), accessed on: 27/05/2021.

<sup>17</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council, of 30 November 2009, on Cosmetic Products; Official Journal of the European Union, 2009, [https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/cosmetic\\_1223\\_2009\\_regulation\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf)

<sup>18</sup> United States Code-Federal Food, Drug, and Cosmetic Act, <https://uscode.house.gov/browse/prelim@title21&edition=prelim>.

<sup>19</sup> Japan Ministry of Health, Labour and Welfare of Japan, 医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律, 2014, [https://www.mhlw.go.jp/web/t\\_doc?dataId=81004000&dataType=0&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=81004000&dataType=0&pageNo=1).

<sup>20</sup> Korea Ministry of Food and Drug Safety, Cosmetic Law, [https://www.mfds.go.kr/eng/brd/m\\_60/view.do?seq=69876](https://www.mfds.go.kr/eng/brd/m_60/view.do?seq=69876).

	enhancing the health of skin or hair, with a moderate effect on the human body. Not including pharmaceutical products.
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Even though the definition of cosmetics remains the same, the interpretation of this definition and the scope of cosmetic products, in reality, are different. CHSR contains nine different categories of special cosmetics: body beauty products, hair perm, items for hair dye, deodorant, depilatory products, spot corrector, sunscreen, breast care, hair perm, and hair growth goods. In CSAR, out of nine products only five remain as special cosmetics, including products for/hair dye, hair perm, spot corrector/skin whitener, sunscreen, and preventing hair loss (instead of products for hair growth). Furthermore, there is an innovative section in special cosmetics named “cosmetics with new efficacy claim”.

Additionally, the description of cosmetics in CSAR persists unaltered instead of CHSR, and cosmetics are classified into special and general cosmetics in both CHSR and CSAR. Special cosmetics are managed with registration and must get consent before production or importation, relinquishing specialized approval from the National Institutes for Food and Drug Control (NIFDC), a related institution of NMPA. General cosmetics, instead, are directly sent into the market with the completion of a notification. Apart from those descriptions explained below, there is also a classification of cosmetics that must be considered: domestic and imported cosmetics. The first section includes products whose last process of contacting cosmetic contents is completed in the Chinese Mainland. Instead, the second category incorporates all the items whose final process of contacting cosmetic content is conducted outside the Chinese Mainland, in addition to the products for which the last process of contacting cosmetic contents is conducted in Hong Kong S.A.R, Macao S.A.R, or Chinese Taipei. In that case, it shall be managed regarding the qualifications of imported cosmetics. Ordinarily, the last process of contacting cosmetic contents is the filling process. If the components utilized are imported, but the product contents are filled in a Chinese factory, they relate to domestic cosmetics. Instead, if the cosmetics have finished the filling process in China and have the packaging process (without contacting contents) abroad, they belong to domestic cosmetics.

With such a wide range of cosmetic items, it will be beneficial to establish a classification system to reflect each product’s qualities. For illustration, in the Voluntary Cosmetic Registration Program (VCRP), the US FDA uses a set of category numbers to assist



describe a cosmetic product<sup>21</sup>. A list of approximately 56 admitted effectiveness claims for cosmetics exists in Japan, which could also be a description of product features. In July 2020, the NMPA released a draft of “Rules and Catalog for Categorization of Cosmetics” for public feedback. With this rule, a cosmetic product can be characterized in five dimensions and assigned a unique category code. Efficacy claim, application area, product form, users, and exposure method are the five dimensions (rinse-off or leave-on). Detailed products and descriptions are listed term by term in these dimensions, each with a numerical code. Industrial development and newer emerging techniques are also considered in this collection. For example, the efficacy of “restoring and protecting” is gathered in light of rising consumption needs<sup>22</sup>, and freeze-dried powder is also collected as a product form, which has been increasingly popular in recent years<sup>23</sup>. When none of the number codes can solve a problem, a capital letter code, which denotes “other,” is chosen. Any capital letter in the efficacy claim, the applied area, or the users could indicate “cosmetics with novel efficacy claim,” the newly included special cosmetics in CSAR. For instance, a facial lotion with sunscreen and moisture functions can be coded 0409-05-02-01-02, which means “moisture and sunscreen-face-lotion-general population-leave on”; The category code is a recent addition to China’s cosmetics control and administration. With the code, a quick sketch of the product information can be quickly outlined, and this method will aid inaccurate statistics and analysis. Furthermore, by reading the category code and other submitted information, such as the formula knowledge, a high-throughput (the automation of experiments such that large scale repetition becomes feasible) automated judgment of regulatory compliance can be made, which is envisaged to replace some laborious work in cosmetics technical review eventually.

### **2.2.3 Management of cosmetic Ingredients**

Regarding the management of cosmetic ingredients, the security of cosmetic goods significantly depends on the ingredients. Concerning the European Union, forbidden substances, restrained substances, approved colorants, certified preservatives, and admitted ultra-violet (UV) filters are, individually, collected in the additions of the “Regulation (EC) No 1223/2009

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<sup>21</sup> Food and Drug Administration, *Cosmetic Product Category Codes*, <https://www.fda.gov/cosmetics/paper-registration-voluntary-cosmetic-registration-program-verp/cosmetic-product-category-codes>.

<sup>22</sup> M.J. CORK, “The importance of skin barrier function” in *Journal of Dermatological Treatment*, 2009, S7–S13.

<sup>23</sup> Zoe DRAELOS, “New treatments for restoring impaired epidermal barrier permeability: Skin barrier repair creams”, *Clinics Dermatology*, vol. 30, 2012, 345–348.

on Cosmetic Products”<sup>24</sup>. Focusing on China, there are further restricted records of cosmetic components. In STSC, high-risk ingredients are assembled in the files of forbidden substances, restricted ingredients such as approved preservatives, UV filters, colorants and hair dyes. The application of those components needs to rigorously match the conditions and professional criteria defined in STSC. The contemporary STSC was announced in 2015 and undergoes review all the time.

Another critical point in the administration of cosmetic ingredients in China is distinguishing between “existing ingredient” and “new ingredient”. New cosmetic ingredients lead to the natural or artificial components utilized in cosmetics for the primary time inside China. To adequately help recognize new ingredients, an Inventory of Existing Cosmetic Ingredients in China (IECIC) was issued in 2014 and revised in 2015, producing a selection of 8783 ingredients. Following CHSR, new ingredients are allowed to be utilized after approval. In CASR, the system is optimized by distributing new ingredients within various risk levels: ingredients that operate as a preservative, colorant, UV filter, hair dye or spot corrector/skin whitener are supposed to be relatively high-risk and will be arranged including a registration-based scheme by NMPA continuously; furtherers can be immediately utilized subsequent to notification to NMPA. Based on scientific advancement, NMPA can apply to set the area of high-risk components. Innovative management for using new ingredients in CSAR is the three years of monitoring following registration or notification. Within the three years, the registered person shall submit a feedback statement to NMPA about the use and safety positions each year, and any emergency must be reported promptly. When a critical safety problem happens, this registration or notification can be canceled by NMPA. To preserve the benefit of businesses and promote the advancement of new ingredients, the component will however be viewed and managed as an innovative ingredient: some other character who plans to use the element shall form the registration or notification of each individual or receive consent from any prior registration person or notification person. Components successfully passing the three-year monitoring session will have the possibility to be included into IECIC.

## **2.2.4 Technical Requirements about Safety and Efficacy**

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<sup>24</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council, of 30 November 2009, on Cosmetic Products; Official Journal of the European Union, 2009, [https://ec.europa.eu/health/sites/health/files/endocrine\\_disruptors/docs/cosmetic\\_1223\\_2009\\_regulation\\_en.pdf](https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf)

The safety of cosmetics is rigorously needed considering they are everyday utilized products by a broad community. For instance, regarding the EU model, in 2018, an “SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation” by the Scientific Committee on Consumer Safety (SCCS) were published in order to provide technical direction for safety evaluation of cosmetics<sup>25</sup>. Regarding the animal tests for cosmetic ingredients, the EU and some other countries have been banned<sup>26</sup>. Research on alternative systems has substituted a popular subject of interest these times, and SCCS has further highlighted replacement methodology in the current guidance reports. In China, the safety evaluation for cosmetics has evolved fast. In 2013, a report published by the former CFDA stated that toxicological analyses of final products are no longer mandatory requirements for general domestic cosmetics only if risk assessment can be proven. To advance the knowledge and practical purpose of risk assessment and safety evaluation in China, NIFDC has included a series of workshops and seminars and has built extensive collaboration with international authorities, research institutions, and foreign companies. Additionally, NIFDC has been improving the input in the examination and confirmation study of alternative approaches. Following 2016, six distinct alternative methods have been considered from the STSC as official test methods, and further different approaches are under development<sup>27</sup>. In 2018, NIFDC launched a Workgroup on Research and Validation of Cosmetic Alternative Methods in China, collectively with various excellent organizations in this department, further accelerating the growth, confirmation and validation, and practice of alternative approaches. In practice, according to article number 21 of CASR, before the registration or notification process of new ingredients and cosmetic products, the registration person or notification person must complete a safety evaluation by utilizing a licensed agency or by themselves. Safety evaluation will perform a significant function in the future, and it is required to set a practical and scientific method in China. On 29 July 2020, NMPA issued a sketch of “Notes of Guidance for Cosmetic Safety Evaluation” online for public annotations. This direction incorporates the general principles and conditions regarding evaluation work, toxicological research, risk assessment procedure, evaluator, and toxicological analysis. It implements practical guidelines for the security evaluation work of both ingredients and outcomes. Additionally, in the following years,

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<sup>25</sup> Scientific Committee on Consumer Safety, *The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation 10th Revision (SCCS/1602/18)*, [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_224.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf), 2018, accessed on: 10/07/2021.

<sup>26</sup> W.M.S. RUSSEL, R.L. BURCH, “The Principles of Humane Experimental Technique”, *John Hopkins Public Health Magazine*, 2021.

<sup>27</sup> F. LUO, Z. SU, J. WU, F. ZHANG, S. XING, G. WANGY LU, “The current status of alternative methods for cosmetics safety assessment in China”, *ALTEX*, n. 36, 2019, 136–139.

imported products satisfying particular requirements and with a successful result from safety evaluation can likewise be spared from toxicological tests of final products, just like the domestic ones.

### **2.2.5 Efficacy and Claim Substantiation**

Apart from the necessity of safety<sup>28</sup>, efficacy realization and proper claims are also a focus for cosmetics products. As a fundamental principle for consumers to preserve fair competition and the right to know, claims and labeling contents must provide the real functions and required substantiation. For instance, concerning the EU, whether implicitly or explicitly, cosmetics products must be supported by adequate and verifiable evidence, as Commission Regulation No. 655/2013 of the EU states<sup>29</sup>. In China, especially in the past, conditions concerning cosmetic efficacy were moderately restricted. Amidst all the special and general cosmetics, sunscreen was the only one to necessitate clinical tests (human trial). In STSC, the test methods for SPF value, the water-resistant performance, and the protection factor of ultra-violet A (PFA) value were collected. In the past, for specific products such as hair growth, breast care, and body beauty, it was mandatory to specify the functional ingredients and the presentation of the efficacy relation proof. Nevertheless, it has never been easy to evaluate the efficacy clearly without detailed requirements or standards concerning information submitted and data. According to CASR Article 22, there must be sufficient scientific proof for cosmetic efficacy and claims; the registration person or notification person must post the summary of evidence on a website approved by NMPA and accept public oversight. Furthermore, claims on the label must be based on the NMPA-drafted “Management Measures for Cosmetic Labeling”. The National Manufacturers Association (NMPA) released a draft of “Efficacy and Claims Substantiation Standards for Cosmetics” for public feedback on November 5, 2020. According to this update, functions or claims that can be directly identified by sensory perception, such as optesthesia (visual sensibility to light) and olfaction, can be excused from efficacy substantiation. A cleanser, fragrances, hair dye, hair perm, depilatory, and deodorant are some examples. Furthermore, those that work through physical mechanisms such as covering, sticking, or rubbing can be excused as long as the labeling clearly shows. Skin whitening

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<sup>28</sup> Vera ROGIERS, “A comparison study between Chinese and EU technical guidelines for cosmetic safety assessment”, in *UK- China business environment programme - standard strand*, bsi., 2021.

<sup>29</sup> Commission Regulation (EU) No 655/2013 of 10 July 2013 *Laying Down Common Criteria for the Justification of Claims Used in Relation to Cosmetic Products*, Official Journal of the European Union, 2013, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0655>.

solutions that use physical covering, exfoliators that use physical rubbing, and pore cleaners that use physical sticking and pulling are examples. This information also includes a basic concept of proof that must be followed for each efficacy or claim. A human study is required in some circumstances, such as hair loss prevention, spot corrector/skin whitener, sunscreen, acne products, and goods claiming skin-restoring or tear-free. Techniques for efficacy substantiation should be based on the original functions to be claimed for the “cosmetics with new efficacy claim,” the new special cosmetics in CASR. NIFDC published procedures for evaluating hair loss prevention and spot corrector/skin whitener online for public comment on November 12, 2020, and they are expected to be incorporated into STSC soon<sup>30</sup>.

## 2.2.6 Future development for the Cosmetic Science in China

CSAR expressly noted to encourage and support:

- Cosmetics research and innovation to fulfill customer needs.
- Sophisticated technology and management methods to improve the quality and safety of cosmetics.
- The use of a blend of modern and traditional resources.

More new technologies will be used in cosmetic R&D on the premise of safety, emulating industrial vitality, and inspiring scientific study and application. Furthermore, the positive policies in CSAR would encourage businesses to discover new components for goods with known efficacy claims. The technical evaluation of cosmetics will face new hurdles as a result of these changes, while the NIFDC will focus more on basic research and technical readiness. One of the outcomes is the development of a set of technical evaluation principles. In China, CSAR will undoubtedly enhance the development and use of safety evaluation. However, although toxicological examinations of finished products were once routinely conducted and regarded as a guarantee of safety, according to CSAR a significant number of toxicological tests, including certain animal testing, will not be mandatory in some cases due to safety concerns. To achieve reliable conclusions from a safety evaluation, the registration person or notification person must have a thorough and clear grasp of the product and its associated

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<sup>30</sup> National Institutes for Food and Drug Control, *Notice on Soliciting Public Opinions on the Analytical Method for Boric Acid and Borate in Cosmetics and others*, 2020, <https://www.nifdc.org.cn/nifdc/xxgk/ggtzh/tongzhi/20201112160508189.html>.

hazards, such as its safety data, sources, and risk chemicals. As a result, database development will become more valuable<sup>31</sup>.

Furthermore, the development of new methodologies and integrated approach techniques will be a top priority in the future, with efficacy and claim substantiation being two additional critical technical opportunities. To suit the different evolving needs of consumers, it is an unavoidable step of development: Enterprises will have greater self-discipline and self-responsibility to complete the substantiation work as a result of the public release of the evidence summary, and consumers will have more information to make an informed decision. As a result, cosmetic companies will face a new business competitiveness pattern, with those ready to put in more effort on actual innovation coming out on top. Furthermore, even more significant will be scientific research in related disciplines, such as active substances, functional mechanisms, evaluation methodologies, and dermatological examination. It will aid in translating essential research findings into practical applications, forming a positive and beneficial circuit between science and industry.

Additionally, NMPA has been offering a study program named “Regulatory Science” since 2019, with the goal of finding the optimal combination of scientific research and regulatory practice. A new regulatory structure and technical assistance for CSAR application have been studied and implemented by NMPA and its subordinated entities as one subject in this program. Furthermore, a merger of supervisory requirements and information technology has been investigated in order to increase overall efficiency with several e-systems being built or optimized using advanced designs, such as online submission, intelligent evaluation, and big data analysis.

Ultimately, CSAR policies are regarded as revolutionary and will have a significant impact on the Chinese market. Fundamental research, industrial investigation, comparative study of regulations, construction of technical standards, development of methodologies and approaches, and use of statistics and analysis will continue. More collaboration will be established, both locally and globally, in order to expedite and contribute to the advancement of “Regulatory Science” on cosmetics. Both the industry and cosmetic science will enter a new stage in the future, thanks to CSAR and its new regulatory structure, and supervision and administration will be improved.

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<sup>31</sup> Marleen PAUWELS, Vera ROGIERS, “Database search of safety information on cosmetic ingredients”, *Department of Toxicology, Dermato-Cosmetology and Pharmacognosy*, Vrije Universiteit Brussel (VUB), vol. 49 n.3, 2008, 49, p. 208–216.

## **2.3 Background of Animal testing in China**

Animal testing for cosmetic safety has always been a contentious topic, as it is frequently considered inhumane, owing to the suffering, if not outright death, of the animals involved. Animal testing was used in the early years of cosmetics and everyday chemical product R&D to determine product safety and allergenicity. Since then, tremendous technical improvements have occurred, to the point where some claim that animal testing is no longer necessary. As a result, animal rights activists have made significant progress in convincing countries to prohibit animal testing. China's compulsory animal testing laws have delayed the admission of several cruelty-free cosmetics brands from other countries. Cosmetic businesses were previously required to use NMPA-approved labs to conduct animal studies on their final products or ingredients, even if they had previously been deemed "safe" and marketed in other countries. To put it another way, NMPA technical review specialists refused to accept non-animal testing data. As a result of a growing number of China's trading partners enacting federal restrictions on animal testing in response to public demand for cruelty-free testing methods, the Chinese cosmetics sector now has some differences in standards and regulations compared to the larger international market. Consequently, China has gone to great efforts in recent years to phase out animal testing of cosmetics to match its cosmetics rules and industry capacities with global standards and trends. NMPA (at the time CFDA) released "Requirements for Filing of Domestic Non-Special Use Cosmetics" in 2013, stating that mandatory animal testing for domestic non-special use cosmetics might be avoided if reliable safety assessment reports were submitted. On June 30, 2014, the announcement went into effect.

It was an important milestone for China on its path to modernize its animal testing policy and re-align its legal framework with global cruelty-free trends, as it was the first time Chinese authorities put forward specific plans to reduce animal testing. China began a regulatory reform of its cross-border e-commerce policies in 2016, requiring required pre-market registration or file for CBEC-traded commodities. Nonetheless, because the reform prompted widespread opposition, a transitional policy was implemented in 15 CBEC pilot cities, including Shanghai and Hangzhou, that temporarily exempted the pre-market approval for first imported cosmetics, infant formula, and other products via the CBEC channel. The CBEC transitory policy was officially extended on November 21, 2018. According to the new rules, cosmetics imported in this manner will be supervised as personal products, free from customs import permission, and not subject to cosmetic standards. As a result, time and financial investments spent complying with Chinese labeling standards and mandated toxicological

testing requirements could be avoided. As a result, it provides an excellent way for foreign cosmetics companies to bypass animal testing and gain entry into the market.

Safety risk assessment is thought to be a good way to gauge cosmetic safety. On November 10, 2015, the previous CFDA released a Guidance for Cosmetic Safety Risk Assessment for public comment, which for the first time in China establishes a comprehensive technical standard for cosmetic risk assessment<sup>32</sup>. The draft version has nine sections that address a variety of topics related to cosmetic risk assessment, including risk assessment techniques, toxicological research, ingredient risk assessment, cosmetic product safety review, and risk assessment report compilation. The instruction comes at a time when China is in critical need of such a comprehensive technical reference to assist authorities in combating rising cosmetic safety concerns and improving market inspection efficiency. In recent years, the CFDA has taken intermittent steps to improve the risk evaluation of cosmetics. The “Risk Assessment Guidance for Potential Safety Risk Substances in Cosmetics” published in August 2010, and the “Notice Regarding Relevant Affairs of Adjusting Cosmetic Application and Record-keeping Management,” published in November 2013, were both positive steps toward addressing risk assessment requirements, but they fell short of providing systemic and comprehensive guidance for practical implementation. This guideline, on the other hand, has been pending and in the works for nearly five years. The NMPA released a new draft Technical Guidelines for Cosmetic Safety Assessment on July 29, 2020, to replace the 2015 advice, refining the safety assessment requirements, and it is hoped that this will be the final version before promulgation.

Alternative testing methods can lessen reliance on animal testing by serving as effective surrogate markers in the assessment of potential toxicities, adverse effects, and hazards/risks linked with the use of cosmetics. China added the 3T3 NRU Phototoxicity Test as a toxicology test technique to the Cosmetic Safety and Technical Standards for Cosmetics on November 11, 2016. The Skin Corrosion: Transcutaneous Electrical Resistance Test was then accepted as an *in vitro* test technique for skin corrosion on August 15, 2017.

On March 22, 2019, the National Manufacturers Association (NMPA) accepted nine testing methods and included them in the Cosmetic Safety and Technical Standards 2015, four of which are newly approved alternatives to animal testing. Short Time Exposure *In Vitro* Test Method (STE), Skin Sensitization: Local Lymph Node Assay: DA (LLNA: DA), *In Chemico*

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<sup>32</sup> Winnie XU, *China cosmetic Animal testing*, in “Chemlinked”, <https://cosmetic.chemlinked.com/cosmepedia/china-cosmetic-animal-testing-regulations>, accessed on: 20/07/2021.



Skin Sensitization: Direct Peptide Reactivity Assay (DPRA), and Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA are the four standards (LLNA: BrdU-ELISA)<sup>33</sup>. On January 1, 2020, they went into effect for applicable cosmetic registration/filing and post-market surveillance testing.

The year 2020 was a watershed moment in China's cosmetics industry, as the country's overall regulatory framework transitioned from the outmoded Cosmetics Hygiene Supervision Regulations (CHSR) to the modern Cosmetic Supervision and Administration Regulation (CSAR). China has made some hopeful policy moves under the new regulatory regime in regard to animal testing management, which is one of the industry's most pressing concerns. The second draft of the Instructions for Cosmetic Registration and Notification Dossiers was released for public feedback on November 5, 2020. A de facto ban on animal testing for general cosmetics is one of the draft's most high-profile changes. Except for specific cosmetics, such as hair dyes, hair perming products, freckle-removal, and whitening goods, sunscreens, anti-hair loss products, and cosmetics claiming new efficacy, general cosmetics refer to all products that meet the CSAR's definition of cosmetics. Appropriate toxicological testing for general products may be avoided if the manufacturer has achieved relevant GMP certification from the local government's cosmetic regulatory body and the product safety risk assessment results can completely validate the product's safety.

However, there are three situations in which animal experimentation is still required:

1. The notifier, domestic responsible person, and actual manufacturing enterprise are listed as the key supervision targets based on the quantitative grading result.
2. The product uses new cosmetic ingredients that are in the safety monitoring period.
3. The notifier, domestic responsible person, and actual manufacturing enterprise are listed as the key supervision targets based on the quantitative grading result.

General cosmetics qualifying for animal testing exemption can submit safety assessment reports rather than toxicological test reports when submitting for notification, according to the Instructions for Cosmetic Registration and Notification Dossiers. When filing for registration/notification, both toxicological test reports and product safety assessment reports should be submitted for items claimed to be used by infants and children.

As far as today's knowledge concerning the three different categories highlighted in the research, it possible to claim that:

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<sup>33</sup> *Regulatory updates of animal testing in 2020, China*, in "Chemlinked", 2020, <https://cosmetic.chemlinked.com/report/regulatory-updates-of-animal-testing-in-2020>.

- Regarding the Special cosmetics a toxicological test report and an abstract of the safety assessment are required.
- Concerning the General cosmetics there are two different approaches:
  - o The first approach includes the toxicological test report and the abstract of the safety assessment.
  - o The second approach involve the application for the toxicological test exemption and the safety assessment report.
  - o The last category are the cosmetics claimed to be used by infants and children, they require safety assessment report and the toxicological test report.

Furthermore, on July 29, 2020, a new safety assessment-related rule, the draft Technical Guidelines for Cosmetic Safety Assessment, was made available for public comment. The Instructions lay out the fundamental requirements for safety assessors, as well as the requirements and operational guidelines for safety assessment reports, as well as relevant samples and transitional steps to ensure a seamless transition to the new regulations.

### **2.3.1 Safety Assessments and Alternative methods**

Over the last 20 years, a variety of programs in Europe, North America, and the OECD have accelerated the adoption of alternatives to animal testing for regulatory toxicity assessment, including in silico approaches. These campaigns have been fueled by strong public sentiment against animal testing for cosmetics, scientific concerns about the dependability of animal tests, and economic considerations<sup>34</sup>. There is a global shift toward “cruelty-free” cosmetics, as evidenced by Regulation (EC) No. 1223/2009<sup>35</sup>, which forbids animal testing for cosmetic products and substances in the EU. Nonetheless, as detailed in SCCS/1602/18, the safety of the substances used in a cosmetic product is an essential feature for cosmetics safety<sup>36</sup>. Safety assessors examined historical data from animal research to rule out the possibility of substantial skin and eye irritation, skin sensitization, genotoxicity, and systemic toxicity. Alternative methodologies are required in light of cosmetics testing bans, most notably in the EU, and the wider push to shift away from risk assessments based on animal test data. While many

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<sup>34</sup>K. TAYLOR, L. Rego ALVAREZ, “Regulatory drivers in the last 20 years towards the use of in silico techniques as replacements to animal testing for cosmetic-related substances”, *Science Direct*, 2020.

<sup>35</sup> Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products Off. J. Eur. Union Luxemb., 2009, 342, 59–209.

<sup>36</sup> U. BODIN, L. BERNAUER, Q. Chaudry, P.J. COENRAADS, M. DUSINKA, J. EZENDAM, E. GAFFET, , C.L. GALLIGRANUM, ROGIERS B., et al, *The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation*, vol. 10, Belgium, 2019.

alternative testing methods are now available, such as the bacterial mutation test (Ames test), the Hen’s egg test on chorioallantoic membrane (HET-CAM) assay, the bovine corneal opacity and permeability (BCOP) assay, the direct peptide reactivity assay (DPRA), and the human cell line activation test (h-CLAT), systemic toxicity can only be addressed in part, for example, when modes of action are identified<sup>37</sup>.

On March 22, 2019, China approved four new alternatives to animal testing methods in the Cosmetic Safety and Technical Standards 2015. These four new techniques went into effect on January 1, 2020, bringing the total number of alternatives to seven. As stated in the latest Technical Guidelines for Cosmetic Safety Assessment in 2021, listed on the 5<sup>th</sup> paragraph, there are all the direction concerning the toxicology test 毒理学试验, *dulixue shiyan* <sup>38</sup>.

Effective Date	Testing Method	Testing Item	Range of Application
December 1, 2016	In-vitro 3T3 Neutral Red Uptake Phototoxicity Test Method for Chemicals used in Cosmetics	Skin Phototoxicity	Cosmetic Ingredient
August 21, 2017	In Vitro Skin Corrosion Transcutaneous Electrical Resistance Test (TER) for Chemicals Used in Cosmetics	Skin Corrosion	Cosmetic Ingredient
January 1, 2020	Short Time Exposure In Vitro Test Method (STE)	Eye Irritation	Cosmetic Ingredient
	In Chemico Skin Sensitization: Direct Peptide Reactivity Assay (DPRA)	Skin Sensitization	Cosmetic Ingredient
	Skin Sensitization: Local Lymph Node Assay: DA (LLNA: DA)	Skin Sensitization	Cosmetic Ingredient
	Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA (LLNA: BrdU-ELISA)	Skin Sensitization	Cosmetic Ingredient

Figure 2.4: Alternative methods accepted in China on imported cosmetic

Source: Chemlinked.com

As show in the scheme below, there are four new testing methods that have been approved in 2020. This implies that companies that export their product is China will be now allowed to sell cosmetics that follow the cruelty-free lines and that have been tested following the four methods below.

<sup>37</sup> F. STEINMETZ, J.C. WAKEFIELD, R.M. BOUGHTON, “Fractions of Concern: Challenges and strategies for the Safety Assessment of Biological Matter in Cosmetics”, *MDPI*, vol. 8, n. 34, 2021.

<sup>38</sup> “Guojia yao jian ju guanyu fabu “shipin anquan pinggu jishu dao ze (2021 nianban)” de gonggao (2021 nian di 51 hao), 国家药监局关于发布《化妆品安全评估技术导则（2021年版）》的公告（2021年第51号）, Announcement of the State Food and Drug Administration on the issuance of the “Technical Guidelines for Safety Evaluation of Cosmetics (2021 Edition)” (2021 No. 51), NMPA, 2021, <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210409160436155.html?type=pc&m=>, accessed on: 3/06/2021.

The majority of the approaches are for cosmetic ingredients, with only one alternate method for determining photo allergenicity in completed products. International alternatives recognized by an international authoritative alternative validation agency can be accepted for the notification or registration of new cosmetic ingredients, according to the Instructions for New Cosmetic Ingredient Registration and Notification Dossiers released on November 5. Companies must meet two requirements in order to exploit data obtained through international exchanges:

- Based on the properties of the novel chemical and the specific toxicological endpoint, the appropriate Integrated Approaches to Testing and Assessment (IATA) will be chosen to evaluate the toxicity.
- The submission of supporting papers demonstrating the compatibility of the results obtained from the alternatives and existing toxicological testing methods in China is required.

Related research papers and scientific works that have been openly published and include full analyses or testing reports provided by internationally acknowledged Good Laboratory Practice (GLP) compliant labs can be used as supporting documents. They must comprise a brief description of the testing technique research procedure, comparative research data from at least ten test substances, result analysis, conclusions, and original writings, among other things.

To sum up, from the Western companies' points of view, after May 1, 2021, general imported cosmetics may be excluded from China's animal testing laws, but only if they match the approved cosmetic category and have the right certificates and documents from the competent authority<sup>39</sup>. Moreover, these changes in the regulation analyzed below do not indicate that China is on its way to banning animal testing on cosmetics. In fact, in the near future, this shift will allow all non-Chinese companies to sell their cruelty-free items in China.

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<sup>39</sup> *China Announces New Animal Testing Policy for Cosmetics After PETA Push*, in "PETA", 2021, <https://www.peta.org/media/news-releases/china-announces-new-animal-testing-policy-for-cosmetics-after-peta-push/>.

# CHAPTER 3 - Analyses of the effects caused by the latest changes in China and worldwide

## 3.1 Consumers reaction to cruelty-free cosmetics proposed by manufacturers and retailers

It is evident that consumers are becoming more conscious of animal welfare in their daily decisions, as this pattern can be seen all over the world. Particularly, in the United States, 84 % of citizens value better animal life circumstances<sup>1</sup>. In Canada, 47 % of people think it is critical that businesses treat animals humanely<sup>2</sup> while 82 % of European Union citizens agree that protecting the welfare of farmed animals is important, and that these creatures should be better protected than they are now<sup>3</sup>. The World Organization for Animal Health defines Animal Welfare as an animal's physical and mental wellbeing in relation to the conditions in which it lives and dies<sup>4</sup>. For instance, the food sector provides consumers with a multitude of requirements and labels to ensure animal welfare<sup>5</sup>. Efforts in hygiene and cosmetics have nearly followed this move, as evidenced by the growing number of companies making claims such as “cruelty-free” or “not tested on animals.” Indeed, when choosing a cosmetic product, these messages appear to be the primary factor of selection for 57 % of Americans<sup>6</sup>. While this pattern is more noticeable in the food industry, cosmetics retailers have also pledged to protect the animal cause. Meanwhile, countries are moving toward decreasing animal testing, if not outright prohibiting<sup>7</sup>. By 2020, 39 countries (including the entire European Union) will have

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<sup>1</sup> *Natural Food Labels Survey*, in Consumer Reports National Research Centre, 2016, [https://www.ftc.gov/system/files/documents/public\\_events/975753/cr\\_intro\\_and\\_2016\\_food\\_survey.pdf](https://www.ftc.gov/system/files/documents/public_events/975753/cr_intro_and_2016_food_survey.pdf), accessed on: 1/07/2021.

<sup>2</sup> *Sustainability practices: Animal welfare. Sustainability – Transparency*, in The Hartman Group, 2015, <https://www.hartman-group.com/reports/1875584538/sustainability-2015-transparency>, accessed on: 1/07/2021.

<sup>3</sup> *Attitudes of Europeans toward Animal Welfare - Special Eurobarometer 442*, in TNS Opinion and Social, 2015, <https://op.europa.eu/en/publication-detail/-/publication/9bc3a0b7-ec17-11e5-8a81-01aa75cd71a1/language-en>, accessed on: 1/07/2021.

<sup>4</sup> *Terrestrial Animal Health Code*, in “World Organisation for Animal Health”, 2019, <https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>, accessed on: 1/07/2021.

<sup>5</sup> M.J. SCHRÖDER, M.G. MACEACHERN, “Consumer value conflicts surrounding ethical food purchase decisions: a focus on animal welfare”, in *International Journal of Consumer Studies*, Vol. 28 No. 2, 2004, pp. 168-177.

<sup>6</sup> NIELSEN, *Package this: Beauty consumers favour “cruelty free” and “natural” product claims*, in “faunalytics”, 2015, <https://faunalytics.org/package-this-beauty-consumers-favor-cruelty-free-and-natural-product-claims/>, accessed on 1/07/2021.

<sup>7</sup> D. SREEDHAR, N. MANJULA, S.P PISE, V.S. AJAY LIGADE, “Ban of cosmetic testing on animals: a brief overview”, *International Journal of Current Research and Review*, Vol. 12 No. 14, 2020, p. 113.

passed legislation prohibiting these tests in the cosmetics industry. Prior studies on cosmetics and personal care items revealed that particular values could impact the formation of customers' attitudes and behaviors by encouraging them to seek out products that meet their own values<sup>8</sup>. Concerns about health, the environment, and attractiveness, for example, may explain why people prefer to use organic cosmetics<sup>9</sup>. Concerns for animal rights and animal well-being may play a significant part in these preferences, and cruelty-free cosmetics benefit from very high attitudinal and behavioral assessments<sup>10</sup>.

To illustrate, a questionnaire was conducted by 450 individuals who were chosen from the social network of a cosmetics and personal hygiene brand in Quebec, Canada<sup>11</sup>. Following a partial least squares structural equation model analyzing the data, the research showed that when consumers reveal a good impression of the reliability of cosmetics claims in general, and especially the "not tested on animals" claim, their attitude toward the cosmetic product with that claim improves. This study validates and extends the findings of MacKenzie and Lutz in 1989<sup>12</sup>, who found that perceived credibility of ads in general positively influenced the perceived credibility of a specific advertising stimulus on a given presentation occasion, as well as consumers' attitudes toward that stimulus, while also verifying and broadening personal caring. Additionally, the findings showed that when people reveal their psychosocial internal values for animal welfare and personal beauty, it has a beneficial impact on their opinion toward a cruelty-free cosmetic product and, as a result, on their purchase intention (directly or mediated by attitude.) As a result, this study quantitatively verifies previous findings about cruelty-free personal care goods, demonstrating that supporting animal rights is positively correlated with both attitude and purchase intent of cruelty-free companies. Second, the stronger a consumer believes a brand or retailer is engaged in sustainable manufacturing or retailing, such as fighting animal testing and promoting animal welfare, through TV commercials or in-store digital

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<sup>8</sup> Hee Yeon KIM, Jae Eun CHUNG, "Consumer purchase intention for organic personal care products", *Journal of Consumer Marketing*, Vol. 28 No. 1, 2011, pp. 40-47.

<sup>9</sup> Chomsaenack PHOTCHAROEN, Chung, R., Sann R., "Modelling Theory of Planned Behavior on health concern and health knowledge toward purchase intention on organic products", *International Business Research*, Vol. 13 No., 2020, 8, p. 100-116.

<sup>10</sup> K.B. SHEEAN, J. LEE, "What's cruel about cruelty free: an exploration of consumers, moral heuristics, and public policy", *Journal of Animal Ethics*, Vol. 4 No. 2, 2014, pp. 1-15.

<sup>11</sup> Cindy G. GRAPPE, Cindy LOMBART, Didier LOUIS, Fabien DURIF, "Not tested on animals" how consumers react to cruelty-free cosmetics proposed by manufacturers and retailers?", *International Journal of Retail & Distribution Management*, 2021, p. 1-22.

<sup>12</sup> Scott B. MACKENZIE, R.J. LUTZ, "An empirical examination of the structural antecedents of attitude toward the ad in an advertising pretesting context", *Journal of Marketing*, Vol. 53 No. 2, 1989, pp. 48-65.

displays<sup>13</sup>, with or without underlying documentation and despite of their interpretation of the claim, the stronger he agrees that this brand or retailer is safe. Similarly, whether shops are grocery stores or more specialized channels, providing consumers with “responsible” products like cruelty-free cosmetics and personal care will help them improve their ethical image.

Ethical shopping is no longer a niche sector, and people are increasingly aware of their purchasing power and believe they can make a difference by doing so. Most businesses have recognized the value of ethics and have included it into their business plans. As a result, it’s critical to research consumers’ ethical shopping behaviors and the elements influencing their purchasing intents. Factors driving the purchase intention for cruelty free cosmetics are influenced by social media, altruism and environmental knowledge<sup>14</sup>.

Companies who sell in countries that do not prohibit or restrict animal testing of beauty treatments, such as the United States or Canada, should explore the most recent solution, as it is the only true engagement and reassurance for customers. Given the strength of the “not tested on animals” charge, brands have a genuine interest in investing more effort into animal welfare. Indeed, the slogans “cruelty-free” and “not tested on animals” are so appealing to customers that they employ them heuristically, despite evidence showing the concepts are meaningless<sup>15</sup>. In regions where regulations are uncertain, legislators should at the very least penalize untruthful marketing on animal testing in cosmetics and personal care goods. From a strategic viewpoint, businesses’ educational commitment to consumers to promote transparency, fluency, and comprehension of labels and messages, particularly the “not tested on animals” claim, is increasingly essential. To be regarded as more socially responsible by consumers, brands should seek certified, independent third-party certifications and labeling systems.

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<sup>13</sup> R. VAN GIESEN, J. LEENHEER, “Towards more interactive and sustainable food retailing. An empirical case study of the supermarket of the future”, *International Journal of Retail and Distribution Management*, 2019, Vol. 47 No. 1, pp. 55-75.

<sup>14</sup> Taima ALAOUIR, Robin GUSTAVSSON, Nathalie SCHMIDT, *Factor driving purchase intention for cruelty-free Cosmetics*, bachelor’s degree Project, Jönköping University, 2019.

<sup>15</sup> K.B. SHEEHAN, J. LEE, “What’s cruel about cruelty free: an exploration of consumers, moral heuristics, and public policy”, *Journal of Animal Ethics*, 2014, Vol. 4 No. 2, pp. 1-15.

### 3.1.1 Do Chinese consumers support cruelty-free cosmetics?

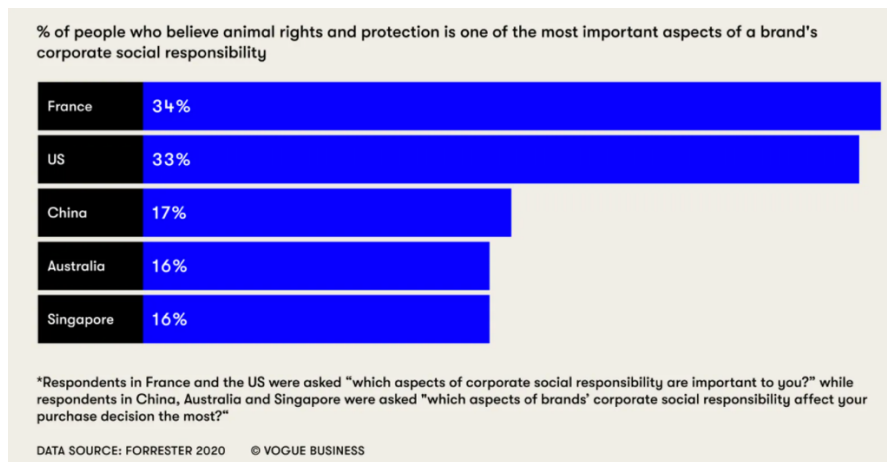


Figure 3.1: Chinese consumers' support of animal rights is on the same level as peers in Australia and Singapore

Source: Forrester 2020

In China, clean beauty, which encompasses cruelty-free and vegan products, ethical brands, and natural ingredient items, is still a niche market. Instead of high standards in animal or environmental protection, Chinese customers identify the phrase with products that have a healthier, gentler, and more trustworthy formula. Many Chinese domestic brands are cruelty-free or vegan and do not test on animals, but they do not advertise it. Functional advantages, not emotional benefits, are the primary purchasing motivations in the Chinese beauty industry, and firms will need to emphasize their functional benefits if they want to compete<sup>16</sup>. However, attitudes toward sustainability are shifting. An influx of cruelty-free and clean beauty companies may encourage local brands to promote their cruelty-free credentials. According to Zhao of Gartner, "every global brand entering China should expect a challenge from local brands". "This summer, I wouldn't be surprised if major local beauty brands launch new clean beauty product lines or sub-brands". For instance, Proya, a Shanghai-based brand, has already switched to a cruelty-free, vegan path, according to Xiaofeng Wang, senior analyst at Forrester therefore it is very likely that Chinese firms will follow.

<sup>16</sup> ANNACHIARA Biondi, *Why clean beauty brands are heading for China*, in "Vogue Business", 2021, <https://www.voguebusiness.com/consumers/china-animal-testing-provisions-clean-beauty-brands> accessed on: 2/07/2021.



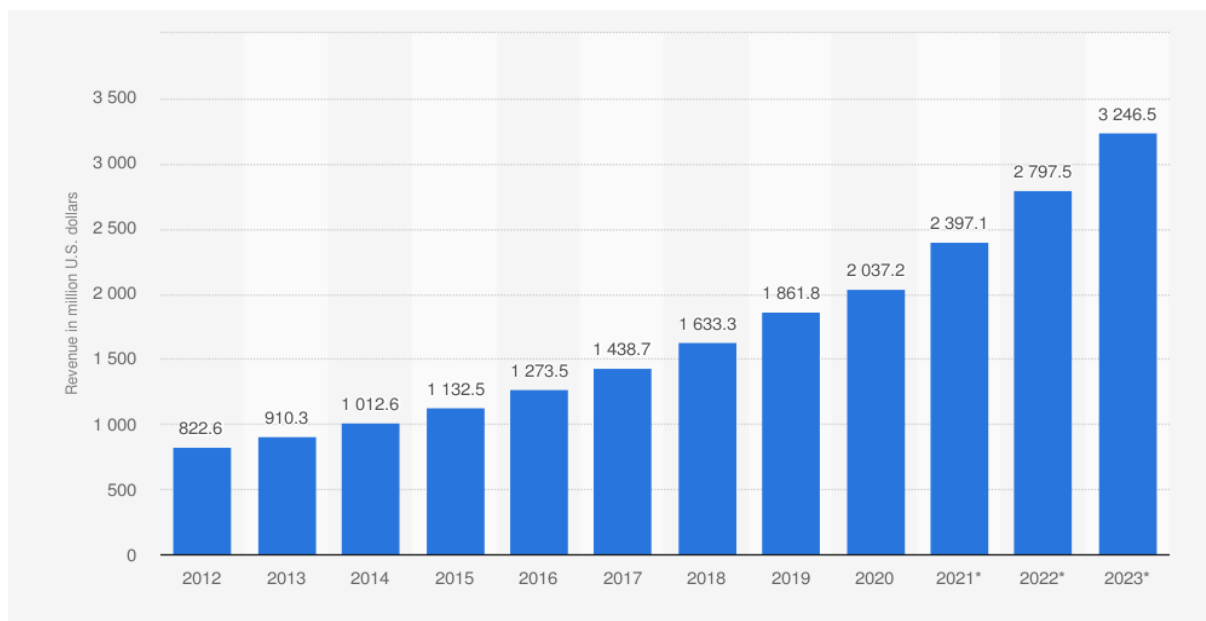


Figure 3.2: Estimated revenue of the natural and organic cosmetics market in China from 2012 to 2023 (in million U.S. dollars)

Source: Statista 2020

In support of what was stated, as the graph above shows, there will be substantial growth in China concerning natural and organic cosmetics. In 2020, China's natural and organic cosmetics market was worth over two billion U.S. dollars. By 2023 the market revenue was projected to be around 3.2 billion U.S. dollars. China's consumption customs have started to move to increase maturity and sophistication. This is perceived as a massive opportunity for organic brands to enter China. Competition in this business strengthens and is an essential factor for the progress' of the Animal testing regulation.

### 3.2 Why China should keep moving forward with the Animal testing regulation

Rather than domestic consumers, international consumers are the main source of pressure in China opposing animal testing. Entering China has become synonymous with performing animal experiments among eco-conscious international consumers. As a result, simply announcing that a cosmetics company is entering the Chinese market is enough to cause social media criticism. International cosmetic brands have been chastised for entering the Chinese market on multiple occasions. Nars, for example, received controversy in 2017 after announcing its entry into China, and was instantly attacked with the #boycottnars hashtag on

social media. Following the backlash, Nars responded with an Instagram post saying that, while the brand is opposed to animal experimentation, the decision was required in order to begin selling products in China<sup>17</sup>. Another notorious brand MAC had a similar experience. The company stated that it was unable to maintain a commitment to non-cruelty to animals while also selling in China. The corporation decided to target the Chinese market with its cosmetic items. As a result, some consumers reacted negatively to MAC.

In this regard, International organizations such as the Organization for the Protection of Animals and Cruelty Free International are working hard to put an end to cosmetics animal testing in China, while also supporting firms that refuse to do so. PETA (People for the Ethical Treatment of Animals) revealed in 2012 that cosmetics businesses were paying for animal testing in order to sell their products in China. As a result, they began to fund scientists who were researching non-animal testing methods. PETA has also worked with big foreign businesses that sell in China, such as Dove and Herbal Essences, to eliminate all animal testing.

Another important brand is Urban Decay, a French cosmetics company, and its case is a fascinating study. In 2012, Urban Decay expressed interest in entering the Chinese market, but after consulting with PETA, the brand decided against it owing to China's obligatory cosmetics animal testing. Urban Decay can now sell cosmetics in China while keeping to its ethical beliefs, thanks to the new legislation. This is also true for prominent overseas brands like The Ordinary from Canada, NYX and Marc Jacobs from the United States, and Essence makeup from Germany. They all declare on their official websites that they don't sell cosmetics in China since they don't believe in animal testing. In support to what stated below, animal experimentation is not only harsh, but it is also frequently useless. Many human diseases, such as major types of heart disease, many types of cancer, HIV, Parkinson's disease, and schizophrenia, do not affect animals. In order to replicate the human sickness, indications of these diseases are artificially produced in animals in laboratories. Such trials, however, minimize the complexity of human conditions, which are influenced by a wide range of elements such as heredity, socioeconomic considerations, deep-seated psychological difficulties, and a variety of personal experiences. It should come as no wonder that medicines that show promise in animals rarely function in humans. Not only are time, money, and the lives of animals being squandered (with a great deal of suffering), but effective treatments are

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<sup>17</sup> *Required cosmetics animal testing in China is loosening: "Ordinary" products no longer required to do animal testing*, in "daxueconsulting", 2021, <https://daxueconsulting.com/cosmetics-animal-testing-in-china/>, accessed on: 10/07/2021.

being overlooked while destructive treatments are being implemented. Animal testing proponents rely heavily on anecdotal information and, in our opinion, are not supported up by scientific evidence.

Despite decades of research, they still don't have dependable and entirely effective therapies for cancer, Alzheimer's disease, Parkinson's disease, diabetes, stroke, and AIDS in animals.

According to Cruelty-Free International findings<sup>18</sup>, 90% of medications fail in human trials despite passing preclinical tests (including animal tests) - either because they are unsafe or because they are ineffective. Cancer treatments have the lowest success rate (only 5% of them are approved after going through clinical trials), followed by psychiatry drugs (6%), heart therapies (7%), and neurology drugs (8%). Using dogs, rats, mice, and rabbits to determine whether a medicine is safe for people delivers little statistically useful information<sup>19</sup>. The study also found that drug experiments on monkeys are just as inefficient at predicting the effects on people as tests on any other species. Only 19% of 93 serious drug side effects could have been predicted by animal experiments, according to a new study. Only around 10% of over 1,000 putative stroke therapies that had been "effective" in animal experiments moved to human trials. None of them functioned well enough in humans.

According to Susan Rose there are several reasons why a consumer should decide to buy cosmetic products that are cruelty-free<sup>20</sup>. First of all, animal testing is considered to be extremely cruel. Experiment animals are not only kept in tight cages and subjected to harsh conditions, but they are also subjected to tests that are beyond cruel. They're tortured, wounded, blinded, and most of the times killed in the end leading to a life filled with fear and sorrow.

Nowadays, there are better solution than animal testing. Some firms try to persuade us that animal testing is necessary: experiments on animals are carried out to ensure that components and products are safe for humans. Animal testing isn't the only way to ensure the safety of ingredients. Many companies, for example, choose for in vitro testing, which has numerous advantages over animal testing. There are also computer models and cultivated cell tissues. As also explained in the previous chapter number 2, starting from the 1<sup>st</sup> of January in fact, China decided to approve few vitro testing methods for imported cosmetics. To support

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<sup>18</sup> *Arguments against animal testing*, in "Peta.org", <https://www.crueltyfreeinternational.org/why-we-do-it/arguments-against-animal-testing>, accessed on: 10/08/2021.

<sup>19</sup> Jarrod BAILEY, Shiranee PEREIRA, "Advances in neuroscience imply that harmful experiments in dogs are unethical", *J Med Ethics Published Online First*, 2018, 44, 47-52.

<sup>20</sup> Rose SUSAN, *15 Great Reasons to switch to cruelty-free Products right now*, in "Cruelty-free kitty", <https://www.crueltyfreekitty.com/cruelty-free-101/why-switch-to-cruelty-free/>, accessed on: 20/08/2021.

this point, according to a scientific experiment taken by Professor Tom Regan at North Carolina State University, this activity primarily violates the rights of the animals in question. He believes that animals have a basic moral entitlement to respectful treatment and this inherent value is not recognized when animals are reduced to being just equipment in a scientific experiment. The article was published by Lone Star College<sup>21</sup>. Animals, like people, can feel pain and are unable to offer consent before being compelled to participate in research. Another reason to avoid animal testing is that the results are not always applicable to people.

Moreover, there are about 7,000 cosmetic ingredients that are safe to use<sup>22</sup>. Companies can formulate their products using a list of over 7,000 substances that have been proved to be safe. This just demonstrates that there is no need to test additional substances on animals. The only corporations that choose to test more ingredients on animals do so in order to develop new, inventive ingredients that will boost their profitability.

Additionally, laboratory animals are classified as a distinct category of animals under the legislation, and they are not protected from animal cruelty or abuse. This viewpoint is both unethical and illogical<sup>23</sup>. Pets are protected from maltreatment, but laboratory bunnies, mice, dogs, cats, and other animals are not. Animals in the lab are also animals, and they should be safeguarded from brutal treatment. Also in medicinal animal research, cats and dogs are frequently utilized. In 2020, laboratories reported having roughly 43,000 dogs in their premises, according to the United States Department of Agriculture (USDA). Still in 2020, the vast majority of dogs were employed in studies, with only about 1,600 being used for breeding or being held but not used in experiments.

The choice to support cruelty-free businesses over those who utilize test on animals, sends a message to the entire industry. They understand that unless they discontinue testing on animals, they will lose consumers' business. Consumers can make a difference and convince more firms to go cruelty-free. According to Humane Society International, up to 500,000 animals are tested each year around the world, with the majority of these animals — over 375,000 in 2015 – utilized to meet test requirements in China alone<sup>24</sup>. While many of the brands in this directory have pledged not to test on animals, some, such as L'Oréal, contain a disclaimer that says “unless when compelled by law”.

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<sup>21</sup> Haileigh FARRELL, “How to Create a More Responsible Cosmetic Industry”, *White Paper Spring Term*, 2021.

<sup>22</sup> Six reasons to pick Cruelty Free Cosmetics Today, in “Seriouslyfab”, 2018, <https://seriouslyfab.com/blogs/news/six-reasons-to-pick-cruelty-free-cosmetics-today>, accessed on: 10/08/2021.

<sup>23</sup> *Cruelty to Animals in Laboratories*, in “Peta.org”, <https://www.peta.org/issues/animals-used-for-experimentation/animals-laboratories/>, accessed on: 10/07/2021.

<sup>24</sup> *Animal Testing in the cosmetics industry*, in “Ethicalconsumer.org”, 2017, <https://www.ethicalconsumer.org/health-beauty/animal-testing-cosmetics-industry>, accessed on: 10/08/2021.

Today, there are thousands of cruelty-free brands to choose from. Gone are the days when buying cruelty-free products meant buying patchouli lotion from a small, local store. Buying ethical does not really limit buyers by switching. These alternatives are preferred by science over animal testing because they are more conclusive, yet animal testing has the benefit of being less expensive. In addition, some governments around the world have already banned animal testing for cosmetics on finished products and ingredients. The European Union, Israel, India, Norway, Switzerland, South Korea, Taiwan, Turkey, Guatemala and New Zealand have all banned animal testing. So many governments across the world banning this practice should push all the other countries to move forward on this topic.

To sum up, in 2021, purchasing carefully is something that consumer should aim to do. Choosing companies that decided to be ethical is something strictly recommended. Being conscious about the purchase the person is making, is a choice that would benefit several aspects.

### **3.2.1 What China's beauty regulation change means for foreign companies**

For the past 20 years or so, China's cosmetics business has grown at a rapid pace, making it an appealing market. If multinationals have dominated the Chinese cosmetics sector for the past decade, they are now facing increased competition. The analysis highlighted in the previous chapter focuses its attention on the changes in the animal testing regulation in China. The importance is not only in the law itself, but also its concerning of the possibility for the Western companies to export their product to China and sell them in their market.

At a certain point, all large cosmetics companies had to choose between entering the Chinese market and sticking to their beliefs, owing to China's demand that all cosmetics be tested on animals. China, on the other hand, has relaxed its animal testing requirements as of May 1, 2021. In brief, pre-market animal testing is no longer required for the vast majority of "ordinary" products, provided the brand has secured a certification of good manufacturing standards (GMP) from the country's cosmetic regulatory authority. The regulatory organizations in France were the first to give certificates to producers. However, this does not rule out the possibility of cosmetics animal testing in China. There is still a requirement for "special" items, such as sunscreens and hair and skin colors, and if there is a safety issue, a product may be subjected to "post-market" testing, which may or may not be conducted on animals. Moreover, this new legislation comes at a time when the Chinese cosmetics market is experiencing tremendous growth as it recovers from a difficult 2020. In China, the year 2020

has been particularly significant in terms of animal experimentation for cosmetics. China has declared that beginning in 2021; it will no longer conduct pre-market animal testing on “general” imported cosmetics. Shampoo, blush, mascara, and perfume are examples of imported “general” cosmetics. However, animal testing is still required for so-called “special” cosmetics. Antiperspirant, deodorant, and sunscreen are examples of specialty cosmetics. Furthermore, animals are still used in post-market testing for non-standard tests such as consumer complaints. In the previous chapter, the regulation that came into force in 2021 has been analyzed, practically what will change for foreign companies will be:

- Animal testing is no longer required for “general” cosmetics items (which includes hair dyes, children’s products, whitening products, and sunscreen). However, if these “generic” products are removed off the shelves for safety reasons, they may be subjected to post-market testing. Animals may or may not be used in post-market testing. The reality remains that “general” Chinese cosmetics are exempt from animal testing.
- Animal testing is still required for special-purpose cosmetics, both imported and domestically produced, however animal testing is not required for “general” Chinese-made cosmetics for export.
- Animal testing has never been necessary for cosmetics purchased in China through a foreign e-commerce site.

In other words, only companies offering “general” cosmetics will be allowed, according to the new guidelines for foreign cosmetic businesses, to sell in China without undergoing mandatory pre-testing on animals. However, if these companies sell “special” cosmetics, they must pay for animal testing before entering the Chinese market. Furthermore, if they sell “generic” cosmetics, they may still be subjected to animal testing after they reach the market. When it comes to animal testing restrictions, overseas cosmetics businesses are now on the same footing as domestic brands. If they meet the following criteria, foreign enterprises can request an exemption from animal testing for “general” cosmetics:

Safety assessments thoroughly verify product safety, and manufacturers have gotten the relevant GMP certificate from their country’s cosmetics regulatory authorities. Hair colors, perms, freckle removers, whitening products, sunscreens, anti-hair loss products, and cosmetics that claim novel efficacy are all included in general cosmetics. Further, animal testing is still necessary in China for products that meet these conditions:

- Cosmetics designed specifically for children.
- Cosmetics containing novel components.

- According to the results of the NMPA’s rating methodology, the cosmetics manufacturer is identified as a priority subject of oversight. The cosmetics producer has a history of quality or safety issues.
- Companies that are introducing new substances into their products from other countries might contact a respected international validation agency.

To avoid testing cosmetics on animals in China, foreign cosmetics companies can approach a respected international validation agency, such as the OECD, ICCR, ICCVAM, EURL-ECVAM, JaCVAM, and others. Additionally, these two guidelines should be followed by businesses to assess toxicity: A comprehensive testing and evaluation procedures based on the properties of the novel chemical, and the specific toxicological endpoint. The results of alternative and existing toxicological testing methods in China must be consistent, according to the documents and research papers and scientific articles that have been formally published and provide a full analysis, as well as test reports from internationally recognized laboratories, can be used as supporting documentation. They should include a brief description of the test method’s research methodology, data from comparative studies of at least 10 test substances, and an analysis, conclusion and original texts of the test method’s results.

After its national agency for the safety of medicines and health products (ANSM) developed a dedicated platform allowing manufacturers to obtain necessary certificates and approvals, France has become the first EU country to qualify for exemptions on animal testing for general use cosmetics exported to China. Following a decree added into article R. 5131-2 of the French Public Health Code, each certificate request made via the site costs €1400 and might be accepted or refused once the dossier with all papers has been assessed<sup>25</sup>. Is this to say that overseas cosmetics companies no longer must worry about animal experimentation in China? Unfortunately, the answer is ‘definitely not’ for the time being. Even with the new standards, they will not be completely cruelty-free. Of course, firms selling “general” cosmetics can bypass animal testing before being on the market. In China, however, there is still a considerable possibility of cosmetics being tested on animals after they have been sold. Nonetheless, we might infer that eliminating the demand for at least “generic” cosmetics is a positive move.

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<sup>25</sup> Culliney KACEY, *French beauty firms can now qualify to export ‘ordinary’ cosmetics into China without animal testing*, in “Cosmetics Design”, 2021, <https://www.cosmeticsdesign-europe.com/Article/2021/01/18/France-ANSM-opens-portal-to-provide-exemption-on-animal-testing-for-cosmetics-exported-to-China>, accessed on: 2/09/2021.

### 3.3 How Covid-19 affected the cosmetic industry worldwide

As globalization reverses, the Covid-19 pandemic has precipitated the most significant and most profound collapse of GDP (Gross Domestic Product) in capitalism's history<sup>26</sup>. International supply chains, which were once the essence of well-organized production and the backbone of the trade, have crumbled, and a renewed focus on the domestic economy has emerged. Overseas travel and tourism have nearly ceased. Tens of millions of people have lost their jobs in the last months, and millions of small businesses and their suppliers have shut down. Banks, railways, airlines, airports, hotels, restaurants, and pubs were all on the edge of going bankrupt in Europe. Global financial markets have been thrown into disorder, stock prices have dropped, and foreign capital investment has come to a halt. On international markets, oil prices have fallen as demand for petroleum has decreased.

Over the past few years, the global beauty industry has been resilient; however, the impact of the pandemic has affected it as well. The sector has reacted well to the crisis, with companies switching production to hand sanitizers and cleaning chemicals and providing free beauty services to first responders<sup>27</sup>. At the same time, industry executives must do everything possible to ensure that their businesses thrive. As far as concerns the short-term prospect, there are indicators that the beauty sector may re-establish itself. In China, the industry's February sales dropped by 80% compared to the previous year. In March, the year-over-year drop was 20%, which was a quick turnaround given the conditions. Consumers in several markets said they plan to spend less on beauty goods shortly (primarily due to lower spending on color cosmetics) but more on other discretionary categories like footwear and clothing. When the cosmetics company's Leonard Lauder noticed an increase in lipstick sales during the 2001 recession, he coined the phrase "lipstick index" to describe the phenomena. People consider lipstick as an affordable luxury<sup>28</sup>, therefore sales tend to stay strong even when times are tough. Based on epidemiological trends and the efficiency of economic-policy actions, McKinsey has developed nine scenarios for the economy over the next few years. It was estimated that worldwide beauty-industry revenues would plummet 20 to 30% in 2020, based on the scenarios most foreseen by global executives and present trends. There are various ways in which beauty

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<sup>26</sup> Kalim SIDDIQUI, "The impact of Covid-19 on the global economy", *The World Financial Review*, 2020, p. 25-30.

<sup>27</sup> *How will the beauty industry adapt in a post-Covid world?*, in "CosmeticsBusiness", 2021, [https://cosmeticsbusiness.com/news/article\\_page/How\\_will\\_the\\_beauty\\_industry\\_adapt\\_in\\_a\\_post-Covid\\_world/176942](https://cosmeticsbusiness.com/news/article_page/How_will_the_beauty_industry_adapt_in_a_post-Covid_world/176942), accessed on: 10/07/2021.

<sup>28</sup> Emily GERSTELL, Sophie MARCHESSOU, Jennifer SCHMIDT, Emma SPAGNUOLO, "How COVID-19 is changing the world of beauty", *McKinsey & Company*, p. 1-8, 2020.



product sales are changing. The increase of online sales is one of the most relevant changes: some beauty-product businesses and retailers with ready-to-scale inventory and shipping operations are reporting e-commerce sales that are twice as high as they were before COVID-19. For example, Sephora's US online sales were up to 30% compared to 2019, as were Amazon's beauty-product sales for the ending April period<sup>29</sup>.

Another shift has been the one regarding the retailers group: while physical drugstores, supermarkets, and food stores are still open, consumer traffic and revenues have decreased. Between March 25 and April 3, 2020, overall sales at the Boots UK drugstore chain plummeted by two-thirds, with beauty-product revenues adding to the drop. Moreover, to help move the unsold inventory, retailers are offering huge discounts and promotion to capture promotion-oriented consumers.

There's also been a switch regarding the products that have been sold. Because of the reality of working from home, physical separation, and masking, wearing cosmetics and fragrance has become much less significant. When consumers return to work, many will continue to wear masks, delaying the recovery of makeup even further. Above-the-mask treatments could be an exception. In fact, by contrast self-care and pampering trends, such as skincare, hair-care, and bath-and-body products, appear to be boosting. Sales of luxury hand soap in France increased by 800% the week of March 16, 2020, according to NPD, a company that measures consumer spending and point-of-sale data<sup>30</sup>. Zalando, Europe's largest fashion and lifestyle e-commerce portal, reported a surge in pampering and self-care beauty categories such as candles, aromatherapy, and detox products; sales of skin, nail, and hair-care items increased by 300% year over year. That matches Amazon's findings, which show that most makeup sales in the United States are down somewhat compared to the same month last year, while nail-care products (218%), hair coloring (172%), and bath-and-body goods (65%) are all up significantly<sup>31</sup>.

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<sup>29</sup> Rao PRIYA, *How Sephora is incubating the 'next guard' online*, in "Glossy", 2020, <https://www.glossy.co/beauty/how-sephora-is-incubating-the-next-guard-online/>, accessed on 10/07/2021.

<sup>30</sup> *Confinement: Mauvaise passe pour les produits de beauté haut de gamme ... à deux exceptions près*, in "Fashion Network", 2020, <https://fr.fashionnetwork.com/news/Confinement-mauvaise-passe-pour-les-produits-de-beaute-haut-de-gamme-a-deux-exceptions-pres,1206019.html>, accessed on: 15/07/2021.

<sup>31</sup> *What Zalando customers are buying as they're asked to stay home*, in "Zalando", 2020, <https://corporate.zalando.com/en/newsroom/en/news-stories/what-zalando-customers-are-buying-theyre-asked-stay-home>, accessed on: 10/08/2021.

Focusing the attention on the long-term impact of COVID-19 on the beauty industry, some changes are likely to be permanent. There are three underlined aspects that might have major impact:

1. The popularity of digital continues to grow. Direct-to-consumer e-commerce, shoppable social-media platforms, such as brand websites, and marketplaces, will likely become more prominent in the run-up to COVID-19. Consumers all throughout the world say they plan to boost their online spending and participation. To attract and persuade the attention of existing and new clients, beauty industry operators will need to prioritize digital platforms. On the operations side, as worries about safety and hygiene fundamentally disrupt product testing and in-person consultations, the usage of artificial intelligence for testing, discovery, and personalization will need to increase.
2. The level of invention is intensifying. The world can change rapidly, as the COVID-19 crisis demonstrated, causing significant fluctuations in demand. Supply can't always keep up with demand. Brands were under pressure to revamp their product-innovation pipelines even before the epidemic, inspired by the ability of digital-native direct-to-consumer brands to move from concept to cabinet in less than a month. The need for speed has never been more vital. To do so, contract manufacturers may play a more prominent role, both to diversify (and therefore decrease manufacturing risks) and to serve as thinking partners in product development. There's also the possibility of more collaboration between brands and retailers, specifically within data sharing and inventory pooling.
3. Mergers & Acquisition activity is increasing as multiples fall. Many companies will need to find new funding sources as a result of the COVID-19 problem, which has caused severe harm to the balance sheets of brands, retailers, and suppliers. At the same time, given the impact of the recession on revenues and the global economy, multiples may decline from pre-crisis levels, when some brands were valued at more than eight times revenue or 10 to 15 times earnings. Despite the beauty business being in a better situation than other consumer categories, 2020 would be one of the worst years in its history. Rather than breaking new ground, the COVID-19 problem is expected to accelerate trends that were already affecting the market, such as the expansion of the global middle class and the utilization of e-commerce. Consumers worldwide are demonstrating that the simple joys of a self-care still bring them comfort.

Even before the pandemic, the concept of “beauty” was expanding, becoming increasingly global and interwoven with people’s sense of well-being. These tendencies are unlikely to change because of the COVID-19 impact, and there is cause to be optimistic about that.

### **3.3.1 The pandemic impact on the Chinese beauty market**

The current COVID-19 pandemic is both a public health and economic emergency. The Chinese government has implemented a range of counter-pandemic measures in response to the COVID-19 outbreak. A large-scale lockdown was imposed across China. As a result, the Chinese economy suffered a substantial setback<sup>32</sup>. Therefore, COVID-19 has affected practically every business in China, including the beauty industry. Most of all regarding the aspects of:

- The implementation of China’s new overarching cosmetic legislation will inevitably be delayed (CSAR).
- In addition, there are new requirements for submitting hardcopy versions of filing and registration dossiers, as well as customs clearance delays.
- The market is under pressure from both supply and demand, with nearly every link in the supply chain and associated value chain severely affected.

Analyzing the first aspect, on January 3, 2020, the China State Council passed the CSAR at its executive meeting. Soon after the Chinese New Year, the final CSAR was expected to be revealed. With NMPA capacity currently taken and the cosmetics industry reeling from the virus’s adverse impact on demand, CSAR is unlikely to be adopted until many weeks after the outbreak in China is resolved<sup>33</sup>.

Regarding the second point highlighted above, courier delivery of hardcopy filing materials is now required. In general, filing for non-special use cosmetics can be done via the internet. When hardcopy documents must be provided, they should now be sent by courier rather than delivered in person. International stakeholders will be unaffected by these changes<sup>34</sup>. Moreover, customs clearance is moving at a slower pace. During a pandemic, increasing market access for critically needed medical products takes precedence. Customs officials will be

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<sup>32</sup> Kerry LIU, “COVID-19 and the Chinese economy: impacts, policy responses and implications”, *International review of Applied Economics*, 2021, vol. 35, n. 2, p. 308-330.

<sup>33</sup> ANGELITA Hu, O’BRIEN Paul, *Covid-19 Impacting Implementation of cosmetic Regulatory Reforms*, in “ChemLinked”, 2020, <https://cosmetic.chemlinked.com/news/cosmetic-news/covid-19-impacting-implementation-of-cosmetic-regulatory-reforms>, accessed on: 5/07/2021.

<sup>34</sup> Chen YE, *How COVID-19 Is Affecting the Beauty Industry in China*, in “ChemLinked”, 2020, <https://cosmetic.chemlinked.com/news/cosmetic-news/how-covid-19-is-affecting-the-beauty-industry-in-china>, accessed on: 10/07/2021.

completely focused on speeding up the clearance of these items. As a result, we can anticipate severe delays in cosmetics clearance at customs.

As far as concern the impact on the market itself, there has been influence on different product categories. China has implemented a containment policy in response to the virus. As a result, the majority of individuals have had to stay at home. When people go outside, they must put on a face mask. Color cosmetics including facial make-up products, nail care products, lip care products, and eye make-up products, and scents have seen low demand in this scenario. We expect color cosmetics to rebound slowly because individuals will continue to use facemasks during the pandemic and for some time afterward. There are, nevertheless, some promising signs worth noting. Because video conferencing, video dating, selfies, and live streaming on social media are becoming increasingly popular, many young people will continue to wear makeup. The epidemic has also spawned “facial mask makeup trends,” which emphasize eye makeup. Data from JD and Suning backs this up: YoY growth rates for makeup palettes, eyeliners, and mascara were above 100% from February 23 to March 1<sup>35</sup>. Fragrances have seen a drop in sales and demand. There is less socializing during the outbreak. The usage of disinfection fluid/spray has also grown, resulting in a decrease in scent consumption. Moreover, body cleansing and skincare products are becoming more popular. The demand for hand wash and hand sanitizer has skyrocketed, and prices have followed suit. Face masks and frequent handwashing are both harmful to the skin, which has resulted in a rise in demand for skincare products and hand cream. Furthermore, antimicrobial-functioning items are in high demand. Antimicrobial items, which are labeled with “消” *xiao* in Mandarin Chinese, are in high demand. Sanitizers, hand sanitizers, mouthwashes, and parts of body lotions are among the products that use a unique registration number. CHANDO, SpringSummer from JALA Group, One Leaf from CHICMAX Group, Geoskincare, Manuka Bee, and other beauty brands have developed or are releasing hand sanitizers. On January 26, Geoskincare expanded its supply chain, and on February 16, additional goods were introduced to the market. Several million orders have already been placed with the company. Further, environmentally friendly items are the next big thing. Consumers have become more aware of health and environmental issues as a result of the Covid-19 epidemic. Consumers will likely embrace greater ethical

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<sup>35</sup> “Suning fabu “shang lian” da shuju: Yanying, yanxian bi xiaoliang fan bei”, 苏宁发布“上脸”大数据：眼影、眼线笔销量翻倍, *Suning releases “shanglian” big data: sales of eye shadow and eyeliner doubled*, in “Techweb”, 2020, <http://www.techweb.com.cn/news/2020-03-02/2779498.shtml>, accessed on: 10/07/22021.

consumption choices in the future, which implies clean-label, sustainable, and ecologically friendly products will become a more important driver of consumer desire.

Another interesting point of view is that consumers have shifted their focus to organic items as their understanding of sustainability and environmental protection has grown. This trend is even more pronounced among younger customers, with more than half of Gen-Z customers preferring plant-based skincare to traditional products. In China, any cosmetic product containing more than 95% organic raw materials can now qualify for organic certification<sup>36</sup>. Due to the recent tendency among young urban Chinese consumers to live a healthy lifestyle, these products are in high demand. Despite this, China currently lacks a single organic certification organization and a well-defined regulatory framework to reassure customers.

### **3.3.2 Chinese beauty industry constraints after the pandemic**

For the Chinese cosmetics industry, liquidity is a big concern. According to the “Tsinghua and Peking University, Joint Survey of 995 SMEs” published on February 5 by China-Europe Business Review, under China’s current containment strategy, 85.01% of enterprises can survive for up to three months, and less than 10% of enterprises can survive for more than six months<sup>37</sup>. The majority of cosmetics companies choose asset-based operations, and few have significant cash reserves. As a result, most cosmetic companies are under a lot of pressure.

Logistic is also an important matter when it comes to cosmetic businesses: although internet shopping has grown in popularity, transportation constraints have substantially influenced logistics, affecting both upstream and downstream supply chain connections. Retailers are having trouble delivering items to customers, while suppliers are having trouble keeping merchant stocks stocked.

Another aspect concerning the challenge of the beauty industry in China is the marketing field. E-commerce sales are mostly driven by marketing and advertising. During the outbreak, most companies and platforms suspended all marketing activity because to ethical concerns. The marketing of KOLs was also impacted. We anticipate a significant comeback in demand following the outbreak, therefore most brands have kept their marketing budgets in

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<sup>36</sup> Deffis PIERRE-ADRIEN, *The future of the Global Cosmetics industry in China*, in “chinatechblog”, 2021, <https://www.chinatechblog.org/blog/the-future-of-the-global-cosmetics-industry-is-made-in-china>, accessed on: 12/08/2021.

<sup>37</sup> Dai ROUCHEN, Hu JUNPENG, Zhang XIAO, *The Impact of Coronavirus on China’s SMEs: Findings from the Enterprise Survey for Innovation and Entrepreneurship in China*, in “Center for Global Development”, 2020, <https://www.cgdev.org/publication/impact-coronavirus-chinas-smes-findings-from-esiec>, accessed on: 1/07/2021.

place for 2020. Adjusting marketing strategy and focusing on internet platforms is one thing they need to accomplish<sup>38</sup>.

Furthermore, shutdowns influenced the entire supply chain. During the outbreak, several cosmetic production plants were shut down. Factory workers are still in their hometowns, making it difficult for factories to resume normal operations. Additionally, factories must undertake a rigorous procedure to petition for the resumption of normal operations. It is still ineffective if cosmetic factories can begin production, but raw material factories cannot. P&G, for example, has 387 suppliers in China, and these suppliers supply more than 9000 ingredients globally, affecting around 17600 goods. Schneider, L'Oréal, and a slew of other global corporations have just restarted labor and manufacturing.

Additionally, international shipping for cross-border e-commerce was also affected. Aside from slower customs processing and domestic logistics issues, CBEC players must also deal with worldwide shipping issues. On their websites, many cross-border transshipment logistics companies have made announcements. They claim that air freight has been harmed as a result of the current domestic epidemic and WHO public health incidents. The demand is strong, while supply is limited, which means the amount of time it takes to transship has been increased. While China's beauty business is distinct and evolving at a dizzying rate, analysts agree on one thing: the market will only grow in size. Therefore, international companies should continue to update Chinese regulations and invest in the Chinese cosmetic market.

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<sup>38</sup> “*Da taoloun: Yiqing qijian, mei zhuang pinpai daodi gai bu gai zuo guanggao xuanchuan?* 大讨论：疫情期间，美妆品牌到底该不该缩减广告预算？, (Big discussion: Should beauty brands reduce their advertising budgets during the epidemic?), 2020, (<http://www.jumeili.cn/News/View/37181.html>), accessed on: 8/07/2021.

## **Part II: English – Chinese Terminological Records**

## Terminological records

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> cosmetic

<Morphosyntax> noun

<Usage label> main term

<Standardisation> UNI EN ISO 29621:2017

<Source> ^NMPA 2019^: 1

<Lexica> Found in ^Oxford Wordpower Dictionary 2012^

<Definition> Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition, or correcting body odors.

<Source> ^EU1004/2014^

<Context> The terms cosmetic is at the core of the research; it is the objective of the regulations analyzed.

<Source> ^NMPA 2019^: 1

<Concept field> Cosmetic Management and Supervision

<Related words> ^make-up^, ^corrective^, ^cosmeceutical^, ^beauty^

<Type of relation> sub

<Equivalence en-zh> Between the terms “cosmetic”, and “化妆品” exists complete conceptual equivalence.

<zh> 化妆品

<Morphosyntax> noun group

<Usage label> main term

<Source> ^NMPA 2019^: 1

<Lexica> 按 ^汉典 2021 ^

<Definition> 为了美化、保留或改变人的外表(例如为了演戏)而用于人体的调剂(除开肥皂),或为了净、染、擦、矫正或保护皮肤、头发、指甲、眼睛或牙齿而用的调剂。



<Source> ^汉典 2021 ^

<Context> 化妆品监督管理。

<Source> ^NMPA 2019^: 1

<Concept field> 化妆品监管监督管理分析/ Analysis of Cosmetics Supervision and Management

<Related words> ^成分^, ^水份^, ^香粉^

<Type of relation> general

<Related words> ^美容手术^

<Type of relation> sub.

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<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> organization

<Morphosyntax> noun count.

<Usage label> main term

<Standardisation> ISO/TR 12309:2009

<Source> ^化妆品安全评估技术导则, 2021^: 12

<Lexica> Found in ^Oxford Wordpower Dictionary 2012^

<Definition> Any formally organized, named group that tries to influence the policy decisions of public officials. Most political organizations take the form of a voluntary association of persons or organizations that pools its members' and constituents' financial and other resources, and engages in conventional political actions to affect policy-making outcomes.

<Source> ^Encyclopedia.com^

<Context> The term refers to the foreign authoritative organizations. When selecting toxicological test methods or standards that are not included in the “Technical Guidelines for Cosmetic Safety” but they are issued by another domestic or foreign authoritative organizations, the source of the method, the principle of identifying toxicological hazards, and the scientific, accuracy of the results should be stated in the evaluation report.

<Source> ^化妆品安全评估技术导则^

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^interest group^, ^collective action^, ^pressure groups^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “organization”, and “机构” exists complete conceptual equivalence.

<zh> 机构

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Lexica> 按 ^ 汉典 2021 ^

<Definition> 泛指机关、团体或其他工作单位。国家教委下设许多教育。

<Source> ^Hanyu.dict.cn^

<Context> 选用其他国内外权威机构发布的《技术规范》未收录的毒理学试验方法或标准时，应当在评估报告中载明方法的来源、识别毒理学危害的原理，并分析结果的科学性、准确性和可靠性。

<Source> ^化妆品安全评估技术导则^: art. 5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> issue

<Usage label> main term

<Morphosyntax> verb

<Usage labels> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Lexica> Found in ^Merriam-Webster 2016^, ^Oxford Chinese Dictionary^

<Definition> The act of publishing or officially giving out or making available.

<Source> ^Merriam-Webster 2016^

<Context> The term indicates the action of releasing a document when selecting toxicological test methods or standards that are not included in the “Technical Guidelines for Cosmetic Safety Assessment”. Therefore, they are issued by other domestic and foreign authoritative, meaning the action of publishing.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^release^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “issue”, and “发布” exists complete conceptual equivalence.

<zh> 发布

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Lexica> 按 ^汉典 2021^

<Definition> 表示思想、观点、文章和意见等通过报纸、书刊、网络或者公众演讲等文字和演讲的形式公之于众，向外界传输消息的一种过程。

<Source> ^汉典 2021^

<Context> 选用其他国内外权威机构发布的《技术规范》未收录的毒理学试验方法或标准时，应当在评估报告中载明方法的来源、识别毒理学危害的原理，并分析结果的科学性、准确性和可靠性。

<Source> ^化妆品安全评估技术导则^: art. 5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related Words> ^发表^, ^发行^, ^颁发^, ^发给^

<Type of relation> general

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<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> source

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Lexica> Found in ^Cambridge Business English Dictionary 2011^

<Definition> The place something comes from or starts at.

<Source> ^Cambridge Business English Dictionary 2011^

<Context> The term refers to the “Technical Specifications”, included the toxicological test methods or criteria and the source of the method or the criteria in the assessment report that shall be included and specify.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Synonyms> ^Origin^

<Equivalence en-zh> Between the terms “source”, and “来源” exists complete conceptual equivalence.

<zh> 来源

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 事物所从来的地方;事物的根源。

<Source> ^现代汉语词典, 2005^: 2813

<Context> 选用其他国内外权威机构发布的《技术规范》未收录的毒理学试验方法或标准时, 应当在评估报告中载明方法的来源、识别毒理学危害的原理, 并分析结果的科学性、准确性和可靠性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^源头^, ^渊源^, ^发源地^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> analyse

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.5

<Lexica> Found in ^Oxford Wordpower Dictionary 2012^

<Definition> To look at or think about the different parts or details of something carefully in order to understand or explain it.

<Source> ^Oxford Wordpower Dictionary 2012^: 25

<Context> The term refers to the result of the toxicological test that must analyze the scientific, accuracy and reliability of the results.

Source: ^化妆品安全评估技术导则, 2021^: art. 6.1.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^experiment^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “analyse”, and “分析” exists complete conceptual equivalence.

<zh> 分析

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.5

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> {动}把一事物、一种现象、一个概念分成较简单的组成部分, 找出这些部分的本质属性和彼此之间的关系(跟”综合”相对)。

<Source> ^现代汉语词典, 2005^: 1415

<Context> 选用其他国内外权威机构发布的《技术规范》未收录的毒理学试验方法或标准时, 应当在评估报告中载明方法的来源、识别毒理学危害的原理, 并分析结果的科学性、准确性和可靠性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒性^

<Type of relation> sub.

<Synonyms> ^剖析^, ^解析^, ^剖解^

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> acute

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.1

<Lexica> Found in ^Merriam-Webster 2016^

<Definition> Having a sudden onset, sharp rise, and short course.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the toxicity of a cosmetic product. Including acute oral and/or transdermal tests. Acute toxicity tests can provide information on the safety hazards of short-term toxicity exposure.

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^toxicity^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “acute”, and “急性” exists complete conceptual equivalence.

<zh> 急性

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 发病急、变化快的。

<Source> ^现代汉语词典, 2005^: 2228

<Context> 急性毒性试验可提供短时间毒性暴露对健康危害的信息。

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒性^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetic

<Subfield> 化妆品安全/ Cosmetics safety

<en> toxicity

<Morphosyntax> noun unc.

<Usage label> main term

<Standardisation> UNI EN ISO 17516:2015

<Source> ^化妆品安全评估技术导则, 2021^: art. 1

<Lexica> Found in ^Cambridge English Dictionary ^, ^Merriam-Webster 2016^

<Definition> The quality of being poisonous, or the degree to which something is poisonous.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the acute toxicity tests can provide information on the health hazards of short-term toxicity exposure. The test results can be used as the basis for the toxicity classification of cosmetic raw materials and/or risk substances and the determination of repeated dose toxicity tests and other toxicological test doses.

<Source> ^化妆品安全评估技术导则, 2021^: art. 1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^skin test^, ^acute^, ^experiment^, ^classification^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “toxicity”, and “毒性” exists complete conceptual equivalence.

<zh> 毒性

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 毒物危害人或其他生物的特性。

<Source> ^cnki.net^

<Context> 急性毒性试验可提供短时间毒性暴露对健康危害的信息。试验结果可作为化妆品原料和/或风险物质毒性分级以及确定重复剂量毒性试验和其他毒理学试验剂量的依据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^急性^, ^皮试^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety



<en> skin test

<Morphosyntax> noun

<Standardisation> ISO 24442:2011

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> Found in ^Merriam-Webster 2016^

<Definition>A method for determining induced sensitivity (allergy) by applying an antigen (a llergen) to, or inoculating it into, the skin; induced sensitivity (allergy) to the specific antigen is indicated by an inflammatory reaction of one of two general kinds: 1) immediate, appears i n minutes and is dependent on circulating immunoglobulins (antibodies); 2) delayed, appears in 12-

48 hours and is not dependent on these soluble substances but on cellular response and infiltra tion.

<Source> ^Medical Dictionary^

<Context> The term refers to the dermal test that could provide information on the health hazard of the cosmetic product, including the toxicity exposure and classification.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “skin test”, and “皮试” exists complete conceptual equivalence.

<zh> 皮试

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 皮肤过敏试验的简称。多指为检验病人对某种药物(如青霉素) 或某种东西 (如花粉、尘螨)是否过敏, 在皮下注入少量针剂, 并观察有无过敏反应。

<Source> ^现代汉语词典, 2005^ : 3573

<Context> 包括急性经口和/或经皮试验等。急性毒性试验可提供短时间毒性暴露对健康危害的信息。试验结果可作为化妆品原料和/或风险物质毒性分级以及确定重复剂量毒性试验和其他毒理学试验剂量的依据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> short term

<Morphosyntax> adj

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> Found in ^Oxford Wordpower Dictionary 2012^

<Definition> lasting a short time; designed only for a short period of time in the future.

<Source> ^Oxford Wordpower Dictionary 2012^: 669

<Context> The term refers to the process of the toxicology test assessment. Acute toxicity tests can provide information on the health hazards of short term toxicity exposure.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “short term”, and “短时间” exists complete conceptual equivalence.

<zh> 短时间

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 毒物危害人或其他生物的特性。

<Source> ^cnki.net^

<Context> 包括急性经口和/或经皮试验等。急性毒性试验可提供短时间毒性暴露对健康危害的信息。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^短线^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> expose

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> Found in ^Oxford Wordpower Dictionary^

<Definition> To show something that is usually hidden.

<Source> ^Oxford Wordpower Dictionary^: 261

<Context> The term refers to the activity of the toxicology test to expose the toxicity of the cosmetic product that is being tested.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^toxicity^

<Type of relation> sub.

<Synonyms> ^reveal^, ^lay bare^

<Equivalence en-zh> Between the terms “expose”, and “暴露” exists complete conceptual equivalence.

<zh> 暴露

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> 按 ^cd.hwxnet^

<Definition> 显露出来: 暴露目标 | 暴露无遗。

<Source> ^cd.hwxnet ^

<Context> 急性毒性试验可提供短时间毒性暴露对健康危害的信息。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒性^

<Type of relation> sub.

<Related words> ^揭露^, ^接发^, ^揭穿^

<Type of relation> synonym ^揭露^, ^接发^, ^揭穿^

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> dosage

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO 11418-3:2016

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> Attested in ^Cambridge Business English Dictionary 2011^

<Definition> Dosage is defined as the physical form of a dose of a chemical compound used as a drug or medication intended for administration or consumption. Common dosage forms include pill, tablet, or capsule, drink or syrup, aerosol or inhaler, liquid injection, pure powder or solid crystal (e.g., via oral ingestion or freebase smoking), and natural or herbal form such as plant or food of sorts, among many others. The route of administration for drug delivery is dependent on the dosage form of the substance.

<Source> ^Pharma^

<Context> The test results can be used as the basis for the toxicity classification of cosmetic raw materials and/or risk substances and the determination of repeated dose toxicity tests and other toxicological test doses.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “dosage”, and “剂量” exists complete conceptual equivalence.

<Related words> ^dose^, ^quantity^

<Type of relation> synonym

<zh> 剂量

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Lexica> 按 ^cd.hwxnet^

<Definition> 医学上指药品的使用分量。也指化学试剂和用于治疗放射线等的用量。

<Source> ^cd.hwxnet^

<Context> 试验结果可作为化妆品原料和/或风险物质毒性分级以及确定重复剂量毒性试验和其他毒理学试验剂量的依据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.1

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^帖^, ^服用量^, ^一服^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> irritant

<Morphosyntax> adj

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> Attested in ^Oxford Chinese Dictionary^

<Definition> A measured amount of a medicine.

<Source> ^Cambridge Business English Dictionary 2011^

<Context> Chemical irritant are materials that cause reversible inflammation or irritation to a body surface, including eyes, respiratory tract, skin or mucous membranes, upon contact. Many chemical irritants also cause have other hazardous properties. Primary irritants exert no systemic toxic action. The degree of irritation depends on the chemical concentration, duration of contact, and personal factors (health status, sensitization).

<Source> ^EHRIS^

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^allergy^, ^skin test^

<Type of relation> general

<Equivalence en-zh> Between the terms “irritant”, and “刺激性” exists complete conceptual equivalence.

<zh> 刺激性

<Morphosyntax> adj

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> 按 ^ cd.hwxnet ^

<Definition> 兴奋神经的能力。

<Source> ^ cd.hwxnet ^

<Context> 包括皮肤和/或眼睛的刺激性/腐蚀性试验。确定和评价原料和/或风险物质对局部皮肤或眼睛是否有刺激作用或腐蚀作用及其程度。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^刺激性皮炎^, ^腐蚀性^

<Type of relation> general

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> corrosive

<Morphosyntax> adj

<Usage label> main term

<Standardisation> ISO 16128-1:2016

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> Attested in ^Oxford Learner's Dictionary^

<Definition> Tending to destroy something slowly by chemical action.

<Source> ^ Oxford Learner's Dictionary ^

<Context> The term refers skin and/or eye irritation/corrosion tests. Determine and evaluate whether raw materials and/or risk substances have irritation or corrosive effects on local skin or eyes and their extent.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> causticity

<Type of relation> synonym

<Equivalence en-zh> Between the terms “corrosive”, and “腐蚀性” exists complete conceptual equivalence.

<zh> 腐蚀性

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> 按 ^ baidubaike ^

<Definition> 腐蚀性是指金属与环境间的物理和化学相互作用，使金属性能发生变化，导致金属、环境及其构成系统受到损伤的现象。腐蚀可分为湿腐蚀和干腐蚀两类。

<Source> ^baidubaike^

<Context> 包括皮肤和/或眼睛的刺激性/腐蚀性试验。确定和评价原料和/或风险物质对局部皮肤或眼睛是否有刺激作用或腐蚀作用及其程度。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> skin

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> Attested in ^Cambridge Business English Dictionary 2011^

<Definition> The skin is the largest organ of the body, with a total area of about 20 square feet. The skin protects us from microbes and the elements, helps regulate body temperature, and permits the sensations of touch, heat, and cold.

<Source> ^Hoffman 2021^

<Context> The term refers to the human body surface. Cosmetics need to be tested before the launch on the market in order to avoid any skin negative reactions.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^skin test^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “skin”, and “皮肤” exists complete conceptual equivalence.

<zh> 皮肤



<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Lexica> 按 ^ 汉典 2021 ^

<Definition> 指身体的表面覆盖层,由复层鳞状上皮及毛发、汗腺和皮脂腺等构成,起保护、调节体温及排泄等作用

<Source> ^汉典 2021^

<Context> 皮肤光毒性试验评价化妆品原料和/或风险物质引起皮肤光毒性的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.2

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^致敏性^, ^光毒性^, ^光变态反应^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> allergy

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Lexica> Attested in ^ Merriam-Webster 2016^

<Definition> Exaggerated or pathological immunological reaction (as by sneezing, difficult breathing, itching, or skin rashes) to substances, situations, or physical states that are without comparable effect on the average individual.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the skin allergy test that determines whether repeated exposure to cosmetic raw materials and/or risk substances can cause allergies and its extent.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment <Equivalence en-zh> Between the terms “allergy”, and “变态反应” exists complete conceptual equivalence.

<zh> 变态反应

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Lexica> 按 ^ 汉典 2021 ^

<Definition> 指机体对某些抗原物质所引起的一种异常反应。如因食用鱼、虾或服用某些药物后而发生皮疹、呕吐、腹泻、哮喘、溶血、白细胞低下, 甚至休克等不良反应。其发生与人的体质或反应性以及抗原物质有关。

<Source> ^ 汉典 2021 ^

<Context> 皮肤变态反应试验确定重复接触化妆品原料和/或风险物质是否可引起变态反应及其程度。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> test

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> A critical examination, observation, or evaluation, specifically the procedure of submitting a statement to such conditions or operations as will lead to its proof or disproof or to its acceptance or rejection.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the skin allergy test determines whether repeated exposure to cosmetic raw materials and/or risk substances can cause allergies and its extent.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^experiment^

<Type of relation> synonym

<Related words> ^allergy^, ^skin test^

<Type of relation> general

<Equivalence en-zh> Between the terms “test”, and “试验” exists complete conceptual equivalence.

<zh> 试验

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Lexica> 按 ^现代汉语词典, 2005^: 4256

<Definition> 为了察看某事的结果或某物的性能而从事某种活动。

<Source> ^化妆品安全评估技术导则, 2021^

<Context> 包括急性经口和/或经皮试验等。急性毒性试验可提供短时间毒性暴露对健康危害的信息。试验结果可作为化妆品原料和/或风险物质毒性分级以及确定重复剂量毒性试验和其他毒理学试验剂量的依据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

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<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> cause

<Morphosyntax> verb

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Lexica> Attested in ^Oxford Wordpower Dictionary^: 114

<Definition> A person or thing that acts, happens, or exists in such a way that some specific thing happens as a result, the producer of an effect.

<Source> ^Dictionary.com^

<Context> The terms refers to the skin allergy test that determines whether repeated exposure to cosmetic raw materials and/or risk substances can cause allergies and its extent.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<related words> ^skin test^

<Type of relation> general

<Equivalence en-zh> Between the terms “cause”, and “引起” exists complete conceptual equivalence.

<zh> 引起

<Morphosyntax> verb

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Lexica> 按 ^现代汉语词典,2005^: 5598

<Definition> 一种事情、现象、活动使另一种事情、现象、活动出现:他的反常举动~了大家的注意。

<Source> ^化妆品安全评估技术导则, 2021^

<Context> 皮肤变态反应试验确定重复接触化妆品原料和/或风险物质是否可引起变态反应及其程度。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.3

<Concept field> 评价化妆品原料和/或风险物质引起遗传毒性的可能性, 至少应包括一项基因突变试验和一项染色体畸变试验。

<Related words> ^皮肤^

<Type of relation> general

<Related words> ^使^, ^造成^, ^原因^

<Type of relation> synonym

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<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> ultraviolet radiation

<Morphosyntax> verb

<Standardisation> UNI EN ISO 17516:2015

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Lexica> Attested in ^Dictionary of Cancer Terms^

<Definition> Invisible rays that are part of the energy that comes from the sun. Ultraviolet radiation that reaches the Earth's surface is made up of two types of rays, called UVA and UVB. Ultraviolet radiation also comes from sun lamps and tanning beds. It can cause skin damage, premature aging, melanoma, and other types of skin cancer. It can also cause problems with the eyes and the immune system. Skin specialists recommend that people use sunscreens that protect the skin from both kinds of ultraviolet radiation. In medicine, ultraviolet radiation also comes from special lamps or a laser and is used to treat certain skin conditions such as psoriasis, vitiligo, and skin tumors of cutaneous T-cell lymphoma. Also called UV radiation.

<Source> ^Dictionary of Cancer Terms^

<Context> In order to observe the result of something or the performance of something to engage in a certain activity. For a new product, such as a component that can absorb ultraviolet light, the ultraviolet absorption wavelength and ultraviolet absorption spectrum of the compound (such as UV-VIS absorption spectrum) should be stated.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “Ultraviolet radiation”, and “紫外线” exists complete conceptual equivalence.

<zh> 紫外线

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Lexica> 按 ^Oxford Chinese Dictionary^:996

<Definition> 波长比可见光线短的射线,波长范围为 4—400 纳米,在光谱上位于紫色光的外侧。也叫“紫外光”。

<Source> ^ 汉典 2021 ^

<Context> 为了察看某事的结果或某物的性能而从事某种活动:~新 机如对于可吸收紫外线的成分,应说明化合物的紫外线吸收的波长及紫外线吸收光谱(如 UV-VIS 吸收光谱)。

<Source> ^ 化妆品安全评估技术导则, 2021 ^: art. 5.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> irradiate

<Morphosyntax> verb

<Source> ^ 化妆品安全评估技术导则, 2021 ^: art. 5.5

<Lexica> Attested in ^ Dictionary of Cancer Terms ^

<Definition> The use of high-energy radiation from x-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy or brachytherapy). Systemic irradiation uses a radioactive substance, such as a radiolabeled monoclonal antibody, that travels in the blood to tissues throughout the body. Also called radiation therapy and radiotherapy.

<Source> ^ Dictionary of Cancer Terms ^

<Context> The term refers to the process of irradiation applied during the evaluation test under ultra violet irradiation. The skin photoallergic test can evaluate the possibility of repeated exposure to cosmetic raw materials and/or risk substances and cause skin photoallergic reactions under irradiation.

<Source> ^ 化妆品安全评估技术导则, 2021 ^: art. 5.5

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^Ultraviolet radiation^

<Type or relation> general

<Equivalence en-zh> Between the terms “irradiate”, and “照射” exists complete conceptual equivalence.

<zh> 照射

<Morphosyntax> verb

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Lexica> 按 ^汉典 2021 ^

<Definition> 使暴露在射线(如 X 射线、镭辐射线或紫外线)下

<Source> ^汉典 2021 ^

<Context> 皮肤光变态反应试验可评估重复接触化妆品原料和/或风险物质, 并在紫外线照射下引起皮肤光变态反应的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.5

<Related words> ^紫外线^

<Type of relation> sub.

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

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<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> hereditary

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> Attested in ^Oxford Chinese Dictionary^: 885

<Definition> In medicine, describes the passing of genetic information from parent to child through the genes in sperm and egg cells. Also called inherited.

<Source> ^Dictionary of Cancer Terms^

<Context> A gene mutation test must be included to evaluate the possibility of cosmetic raw materials and/or risk substances causing gene toxicity.

<Source> 化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^gene^, ^chromosomal aberration^

<Type of relation> general

<Synonym> ^genetic^

<Equivalence en-zh> Between the terms “hereditary”, and “遗传” exists complete conceptual equivalence.

<zh> 遗传

<Morphosyntax> adj

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> 按 ^汉典 2021 ^

<Definition> 生物体的构造和生理机能等由上代传给下代。

<Source> ^汉典 2021 ^

<Context> 评价化妆品原料和/或风险物质引起遗传毒性的可能性, 至少应包括一项基因突变试验和一项染色体畸变试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Related words> ^染色体畸变^, ^基因^, ^突变^

<Type of relation> general

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

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<Subject> 化妆品/ cosmetic



<Subfield> 化妆品安全/ cosmetic safety

<en> chromosomal aberration

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> Attested in ^Dictionary.com^

<Definition> Any irregularity or abnormality of chromosome distribution, number, structure, or arrangement.

<Source> ^Dictionary.com^

<Context> The term refers to the evaluation of the possibility of cosmetic raw materials and/or risk substances causing genotoxicity. Therefore, at least one gene mutation test and one chromosome aberration test should be included.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “chromosomal aberration”, and “染色体畸变” exists complete conceptual equivalence.

<zh> 染色体畸变

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> 按 ^baidu.baikē^

<Definition> 染色体畸变是指生物细胞中染色体在数目和结构上发生的变化。每种生物的染色体数目与结构是相对恒定的，但在自然条件或人工因素的影响下，染色体可能发生数目与结构的变化，从而导致生物的变异。染色体畸变包括染色体数目变异和染色体结构变异。

<Source> ^ baidu.baikē^

<Context> 评价化妆品原料和/或风险物质引起遗传毒性的可能性，至少应包括一项基因突变试验和一项染色体畸变试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ cosmetic

<Subfield> 化妆品安全/ cosmetic safety

<en> gene

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> Attested in ^Dictionary of Cancer Terms^

<Definition> In medicine, describes the passing of genetic information from parent to child through the genes in sperm and egg cells. Also called inherited.

<Source> ^Dictionary of Cancer Terms^

<Context> The term refers to the gene mutation that has to be verified while executing the safety test.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^gene mutation^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “gene”, and “基因” exists complete conceptual equivalence.

<zh> 基因

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> 按 ^汉典 2021 ^

<Definition> 生物体遗传的基本单位，存在于细胞的染色体上，作线状排列。

<Source> ^汉典 2021 ^

<Context> 评价化妆品原料和/或风险物质引起遗传毒性的可能性，至少应包括一项基因突变试验和一项染色体畸变试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Related words> ^突变^

<Type of relation> sub.

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

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<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> mutation

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> the way in which genes change and produce permanent differences: it is well known that radiation can cause mutation.

<Source> ^Cambridge English Dictionary ^

<Context> The term refers to evaluation of the possibility of cosmetic raw materials and/or risk substances causing genotoxicity, gene mutation test and one chromosome aberration test should be included.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^gene^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “mutation”, and “突变” exists complete conceptual equivalence.

<zh> 突变

<Morphosyntax>

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Lexica> 按 ^汉典 2021 ^

<Definition> 生物体的基因型的突然变化,但并不由重组所产生,遗传物质可能在性质上和数量上发生变更或重排。

<Source> ^汉典 2021 ^

<Context> 评价化妆品原料和/或风险物质引起遗传毒性的可能性,至少应包括一项基因突变试验和一项染色体畸变试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.6

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^基因^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> duplicate

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Either of two things exactly alike and usually produced at the same time or by the same process.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the repeated dose toxicity that includes 28-days oral and/or dermal toxicity test, subchronic oral and/or dermal toxicity test.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^recur^, ^reappear^

<Type of relation> general

<Equivalence en-zh> Between the terms “duplicate”, and “重复” exists complete conceptual equivalence.

<zh> 重复

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^汉典 2021 ^

<Definition> 同样的东西再次出现;按原来的样子再次做。

<Source> ^汉典 2021 ^

<Context> 重复剂量毒性包括 28 天经口和/或经皮毒性试验、亚慢性经口和/或经皮毒性试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒性^, ^剂量^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> target organ

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Biology Dictionary^

<Definition> A tissue or organ upon which a hormone exerts its action; generally, a tissue or organ with appropriate receptors for a hormone.

<Source> ^Biology Dictionary^

<Context> The term refers to the repeated dose oral toxicity test, not only the health effects caused by repeated exposure to the test substance within a certain period of time, the target organs of the test substance and the accumulation in the test substance can be obtained, but also the level of no harmful effects of the exposure can be estimated. It can be used to select and determine the exposure level of chronic tests and to initially calculate the safety level of population exposure.

<Source> ^^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^target^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “target organ”, and “靶器官” exists complete conceptual equivalence.

<zh> 靶器官

<Morphosyntax> noun

<Usage label> main term

<Source> ^baidubaike^

<Lexica> 按 ^baidubaike^

<Definition> 靶器官是某种毒物在体内呈现毒作用，并引起典型病变的主要部位，这一部位如为器官称作靶器官，如为组织则称作靶组织。例如四氯化碳慢性中毒主要损害肝脏，肝脏即为四氯化碳的靶器官。

<Source> ^baidubaike^

<Context> 通过重复剂量经口毒性试验不仅可获得一定时期内反复接触受试物后引起的健康效应、受试物作用靶器官和受试物体内存积情况资料，还可估计接触的无有害作用水平，后者可用于选择和确定慢性试验的接触水平和初步计算人群接触的安全性水平。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> health

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> The condition of somebody's body or mind.

<Source> ^ Oxford Wordpower Dictionary ^: 349

<Context> The term refers to the health effects caused by repeated exposure to the test substance within a certain period of time, the target organs of the test substance and the accumulation in the test substance can be obtained, but also the level of no harmful effects of the exposure can be estimated.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^wellness^, ^hale^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “health”, and “健康” exists complete conceptual equivalence.

<zh> 健康

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^汉典 2021 ^

<Definition> 人的一切生理机能正常,没有疾病或缺陷。

<Source> ^汉典 2021 ^

<Context> 通过重复剂量经口毒性试验不仅可获得一定时期内反复接触受试物后引起的健康效应、受试物作用靶器官和受试物体内存积情况资料，还可估计接触的无有害作用水平，后者可用于选择和确定慢性试验的接触水平和初步计算人群接触的安全性水平。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^身体^, ^保健^, ^卫生^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> accumulate

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> To collect a number or quantity of something over a period of time.

<Source> ^Oxford Wordpower Dictionary^: 6

<Context> The term refers to the repeated dose oral toxicity test, not only the health effects caused by repeated exposure to the test substance within a certain period of time, the target organs of the test substance and the accumulation in the test substance can be obtained, but also the level of no harmful effects of the exposure can be estimated. It can be used to select and determine the exposure level of chronic tests and to initially calculate the safety level of population exposure.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^gather^, ^get together^, ^aggroup^

<Type of relation> synonym



<Equivalence en-zh> Between the terms “accumulate”, and “蓄积” exists complete conceptual equivalence.

<zh> 蓄积

<Morphosyntax>

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 积聚储存:水库可以~雨水。

<Source> ^现代汉语词典, 2005^: 5294

<Context> 通过重复剂量经口毒性试验不仅可获得一定时期内反复接触受试物后引起的健康效应、受试物作用靶器官和受试物体内存积情况资料, 还可估计接触的无有害作用水平, 后者可用于选择和确定慢性试验的接触水平和初步计算人群接触的安全性水平。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^积累^, ^聚敛^, ^累计^, ^蕴含^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> come into contact

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Oxford Chinese Dictionary^

<Definition> To approach or move toward someone or something.

<Source> ^Wordreference^

<Context> The term refers to the possibility while testing the safety of the cosmetic, to come in contact with a disease.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^exposure^

<Type of relation> general

<Equivalence en-zh> Between the terms “touch”, and “接触” exists complete conceptual equivalence.

<zh> 接触

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^汉典 2021 ^

<Definition> 皮肤和物体接触后产生的感觉就是触觉

<Source> ^汉典 2021 ^

<Context> 生殖发育毒性检测动物接触化妆品原料和/或风险物质后, 引起生殖功能、胚胎的初期发育(如致畸)、出生前后发育、母体机能以及胚胎和胎儿发育障碍的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^联络^, ^来往^, ^串联^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> preliminary

<Morphosyntax> adj  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7  
<Lexica> Attested in ^Cambridge English Dictionary^  
<Definition> Coming before a more important action or event, especially introducing or preparing for it.  
<Source> ^Cambridge English Dictionary^  
<Context> The term refers to the preliminary calculation of the exposure of the safety assessment.  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7  
<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment  
<Related words> ^preparatoy^, ^initial^  
<Type of relation> synonym  
<Equivalence en-zh> Between the terms “preliminary”, and “初步” exists complete conceptual equivalence.

<zh> 初步

<Morphosyntax> adj  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7  
<Lexica> 按 ^汉典 2021 ^  
<Definition> 属于或关于开始阶段的。  
<Source> ^汉典 2021 ^  
<Context> 后者可用于选择和确定慢性试验的接触水平和初步计算人群接触的安全性水平。  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7  
<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment  
<Related words> ^初赛^, ^预赛^, ^预审^  
<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> calculate

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Oxford Wordpower Dicitonary^

<Definition> To find something out by using mathematics.

<Source> ^Oxford Wordpower Dicitonary^: 101

<Context> The term refers to the calculation of the safety level of population exposure.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^count up^, ^enumerate^, ^figure^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “calculate”, and “计算” exists complete conceptual equivalence.

<zh> 计算

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 根据已知数通过数学方法求得未知数。

<Source> ^现代汉语词典, 2005^: 2246

<Context> 还可估计接触的无有害作用水平, 后者可用于选择和确定慢性试验的接触水平 and 初步计算人群接触的安全性水平。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^核算^, ^计量^, ^筹算^

<Type of relation> synonym

<Related words> ^安全^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> penetration

<Morphosyntax> verb

<Usage label> main term

<Standardisation> ISO 11140-3:2007

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A movement into or through something or someone.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the evaluation of the penetration of the test substance.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^skin test^

<Type of relation> sub.

<Related words> ^perforation^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “penetration”, and “渗透” exists complete conceptual equivalence.

<zh> 渗透

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Lexica> 按 ^hanyu.dict.cn^

<Definition> 两种气体或两种可以互相混合的液体；彼此通过多孔性的薄膜而混合。

<Source> ^hanyu.dict.cn^

<Context> 通过重复剂量经皮毒性试验不仅可获得在一定时期内反复接触受试物后可能引起的健康影响资料，而且为评价受试物经皮渗透性、作用靶器官和慢性皮肤毒性试验剂量选择提供依据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.7

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^纵深^, ^切入点^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> reproduction

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> Attested in ^Cambridge English Dictionary ^

<Definition> The process by which plants and animals give rise to offspring and which fundamentally consists of the segregation of a portion of the parental body by a sexual or an asexual process and its subsequent growth and differentiation into a new individual.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the reproduction of the toxicity; reproductive and developmental toxicity tests the possibility of animals' exposure to cosmetic raw materials and/or risk substances, which can cause reproductive function, early embryo development (such as

teratogenicity), development before and after birth, maternal function, and embryo and fetal development disorders

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^embryo^, ^toxicity^, ^risk^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “reproduction”, and “生殖” exists complete conceptual equivalence.

<zh> 生殖

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 生物产生幼小的个体以繁殖后代。分有性生殖和无性生殖两种。生殖是生命的基本特征之一。

<Source> ^现代汉语词典, 2005^: 4193

<Context> 生殖发育毒性检测动物接触化妆品原料和/或风险物质后, 引起生殖功能、胚胎的初期发育(如致畸)、出生前后发育、母体机能以及胚胎和胎儿发育障碍的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^翻拍^, ^再生产^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> embryo

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO 12890:1999

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> A baby, an animal, or a plant in the early stages of development before birth.

<Source> ^Oxford Wordpower Dictionary^: 243

<Context> The term refers to the reproductive and developmental toxicity tests the possibility of animal exposure to cosmetic raw materials and/or risk substances, which may cause reproductive function, early embryo development (such as teratogenicity), development before and after birth, maternal function, and developmental disorders of embryos and fetuses.

<Source> 化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^fetus^

<Type of relation> synonym

<Related words> ^disorders^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “embryo”, and “胚胎” exists complete conceptual equivalence.

<zh> 胚胎

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> 按 ^现代汉语词典, 2005^: 3540

<Definition> 在母体内初期发育的动物体, 由卵受精后发育而成。人的胚胎借脐带与胎盘相连, 通过胎盘从母体吸取营养。

<Source> ^现代汉语词典, 2005^: 3540



<Context> 生殖发育毒性检测动物接触化妆品原料和/或风险物质后，引起生殖功能、胚胎的初期发育（如致畸）、出生前后发育、母体机能以及胚胎和胎儿发育障碍的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^致畸^, ^生殖^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> teratogenic

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO 10993-6:2016

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Any agent that can disturb the development of an embryo or fetus. Teratogens may cause a birth defect in the child. Or a teratogen may halt the pregnancy outright. The classes of teratogens include radiation, maternal infections, chemicals, and drugs.

<Source> ^MedicineNet^

<Context> The term refers to the reproductive and developmental toxicity tests; the possibility of animal exposure to cosmetic raw materials and/or risk substances, which may cause reproductive function, early embryo development (such as teratogenicity), development before and after birth, maternal function, and developmental disorders of embryos and fetuses.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^malformation^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “teratogenic”, and “致畸” exists complete conceptual equivalence.

<zh> 致畸

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Lexica> 按 ^baidubaike^

<Definition> 环境污染等因素干扰胚胎正常发育, 导致先天性畸形的现象。

<Source> ^baidubaike^

<Context> 生殖发育毒性检测动物接触化妆品原料和/或风险物质后, 引起生殖功能、胚胎的初期发育 (如致畸)、出生前后发育、母体机能以及胚胎和胎儿发育障碍的可能性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.8

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^胚胎^, ^生殖^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> carcinogen

<Morphosyntax> adj

<Usage label> main term

<Standardisation> ISO 10993-3:2014

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Lexica> Attested in ^NIH^

<Definition> A carcinogen is an agent with the capacity to cause cancer in humans. Carcinogens may be natural, such as aflatoxin, which is produced by a fungus and sometimes

found on stored grains, or manmade, such as asbestos or tobacco smoke. Carcinogens work by interacting with a cell's DNA and inducing genetic mutations.

<Source> ^NIH^

<Context> The term refers to the prediction of having potential carcinogenicity, or the chemical structure about cosmetic is similar to a known carcinogen, therefore it needs to be further verified by carcinogen test.

<Source> 化妆品安全评估技术导则, 2021^: art. 5.9

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^cancer^, ^chemical structure^

<Type of relation> general

<Equivalence en-zh> Between the terms “carcinogen”, and “致癌” exists complete conceptual equivalence.

<zh> 致癌

<Morphosyntax> adj

<Usage label> main term

<Source> 化妆品安全评估技术导则, 2021^: art. 5.9

<Lexica> 按 ^baidubaike^

<Definition> 思是导致癌症大约有四大类致癌的原因：化学因素，物理因素，病毒，家族遗传。

<Source> ^baidubaike^

<Context> 预测具有潜在致癌性，或其化学结构与某种已知致癌剂相近时，需用致癌性试验进一步验证。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^癌症^, ^胃癌^, ^毒瘤^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> chronic

<Morphosyntax> adj.

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Continuing or occurring again and again for a long time.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to Chronic toxicity test is a test in which animals are exposed to the test substance in a certain way over a long period of time to cause a toxic reaction.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^toxicity^, ^test^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “chronic”, and “慢性” exists complete conceptual equivalence.

<zh> 慢性

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 发作得缓慢的;时间拖得长久的:~病|~中毒|~痢疾。

<Source> ^现代汉语词典, 2005^: 3180

<Context> 慢性毒性试验是使动物长期地以一定方式接触受试物而引起毒性反应的试验。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.9

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒性^,^试验^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> kinetics

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Merriam-Webster^

<Definition> a branch of science that deals with the effects of forces upon the motions of material bodies or with changes in a physical or chemical system.

<Source> ^Merriam-Webster^

<Context> The term refers to the toxicity kinetics test is to quantitatively study the absorption, distribution, metabolism, and excretion process and characteristics of raw materials and/or risk substances in animals at toxic doses, and then to explore the law of occurrence and development of their toxicity, and to understand their distribution in animals and its target organs.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^dynamics^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “kinetics”, and “动力学” exists complete conceptual equivalence.

<zh> 动力学

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^汉典 2021 ^

<Definition> 力学的一部分。研究物体机械运动状态变化与外力的关系。对宏观物体的低速运动，它的基本理论是牛顿运动理论；对宏观物体的近光速运动，要用相对论力学来研究；对微观粒子的运动，要用量子力学来研究。

<Source> ^汉典 2021 ^

<Context> 毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点，进而探讨其毒性的发生和发展的规律，了解其在动物体内的分布及其靶器官。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^毒代^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> in vitro

<Morphosyntax> adj

<Usage label> main term

<Standardisation> ISO 24442:2011

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Biologyonline^

<Definition> The term *in vitro* is associated with various biological processes that are made to occur outside the living organism. Etymologically, it is a Latin for *within a glassware* (i.e. *in-* pertains to within and *vitreus*, glassware). The term *in vitro* is typically written in italics.

<Source> ^Biologyonline^

<Context> The toxicokinetic test is to quantitatively study the absorption, distribution, metabolism, and excretion process and characteristics of raw materials and/or risk substances in animals at toxic doses, and then to explore the law of occurrence and development of their toxicity, and to understand their in vivo Distribution and its target organs.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^target organs^

<Type of relation> general

<Equivalence en-zh> Between the terms “in vitro”, and “体内” exists complete conceptual equivalence.

<zh> 体内

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^Hanyu.dict.cn^

<Definition> 位于或来源于生物体内部的。

<Source> ^Hanyu.dict.cn^

<Context> 毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点, 进而探讨其毒性的发生和发展的规律, 了解其在动物体内的分布及其靶器官。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^靶器官^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> absorption

<Morphosyntax> noun

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> The process by which a substance or object takes in a liquid, gas, waves, or chemical and makes it a part of itself.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the transdermal absorption test of raw materials and/or risk substances, the internationally accepted transdermal absorption test method can be used to obtain the corresponding data.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^transdermal^, ^substances^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “absorption”, and “吸收” exists complete conceptual equivalence.

<zh> 吸收

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 物体把外界的某些物质吸到内部, 如海绵吸收水, 木炭吸收气体等。特指机体把组织外部的物质吸到组织内部, 如肠黏膜吸收养分, 植物的根吸收水和无机盐等。

<Source> ^现代汉语词典, 2005^: 4985

<Context> 原料和/或风险物质的透皮吸收试验, 可采用国际通用的透皮吸收试验方法获取相应的数据。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^透皮^

<Type of relation> sub.



\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> metabolism

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> The chemical changes in living cells by which energy is provided for vital processes and activities and new material is assimilated.

<Source> ^Oxford Wordpower Dictionary^

<Context> The term refer to the toxicokinetic test is to quantitatively study the absorption, distribution, metabolism, and excretion process and characteristics of raw materials and/or risk substances in animals at toxic doses, and then to explore the law of occurrence and development of their toxicity, and to understand their in vivo Distribution and its target organs.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “metabolism”, and “代谢” exists complete conceptual equivalence.

<zh> 代谢

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^现代汉语词典, 2005^: 950

<Definition> 生物体内所进行的物质分解及与合成有关的化学变化。如：「新陈代谢」。

<Source> ^汉典 2021 ^

<Context> 毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点，进而探讨其毒性的发生和发展的规律，了解其在动物体内的分布及其靶器官。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> drain

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Cambridge English Dictionary ^

<Definition> If you drain something, you remove the liquid from it, usually by pouring it away or allowing it to flow away, and if something drains, liquid flows away or out of it.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the toxicology test; the test is to quantitatively study the absorption, distribution, metabolism and drain process characteristics or raw materials and/or risk substances in animals at toxic doses.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Equivalence en-zh> Between the terms “drain”, and “排泄” exists complete conceptual equivalence.

<zh> 排泄

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^汉典 2021 ^

<Definition> 使雨水、污水等流走。生物把体内新陈代谢产生的废物排出体外。如动物排尿、排汗, 植物把多余的水分和无机盐排出体外。

<Source> ^现代汉语词典, 2005^: 3508

<Context> 毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点, 进而探讨其毒性的发生和发展的规律, 了解其在动物体内的分布及其靶器官。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^过程^, ^特点^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> investigate

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition>

To examine a crime, problem, statement, carefully; especially to discover the truth.

<Source> ^Cambridge English Dictionary ^

<Context> The term refers to the toxicology test; it is needed to examine and investigate carefully the occurrence and development of the toxicity and its presence in animals.

<Source> > ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^examine^, ^discuss^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “investigate”, and “探讨” exists complete conceptual equivalence.

<zh> 探讨

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Lexica> 按 ^^现代汉语词典, 2005^

<Definition> 研究讨论:~哲学问题。

<Source> ^现代汉语词典, 2005^: 4547

<Context> 毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点, 进而探讨其毒性的发生和发展的规律, 了解其在动物体内的分布及其靶器官

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.10

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^评论^, ^说到^, ^洽谈^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> inhale

<Morphosyntax> verb

<Usage label> main term

<Standardisation> ISO 16900-9:2015

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.12

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To breathe air, smoke, or gas into your lungs.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the cosmetic raw materials that are used in products with risk of inhalation exposure, the possibility of inhalation exposure should be clearly mentioned, and the health hazard effects of inhalation exposure should be considered.

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.12

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^breathe^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “inhale”, and “吸入” exists complete conceptual equivalence.

<zh> 吸入

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.12

<Lexica> 按 ^汉典 2021 ^

<Definition> 特指把空气吸入肺里

<Source> ^汉典 2021 ^

<Context> 如果化妆品原料在有吸入暴露风险的产品中使用, 应该明确提及吸入暴露的可能, 并且应考虑吸入暴露的健康危害效应。

<Source> ^化妆品安全评估技术导则, 2021^: art. 5.12

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^暴露^, ^风险^, ^健康^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> population  
<Morphosyntax> noun  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^ : art. 5.13  
<Lexica> Attested in ^Merriam-Webster 2016^  
<Definition> A group of individual persons, objects, or items from which samples are taken for statistical measurement.  
<Source> ^Merriam-Webster 2016^  
<Context> The term refers to the products with high exposure and long contact time can be used for product evaluation with low exposure and short contact time. However, it is necessary to fully analyze the rationality of the target population, use location and use mode.  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.13  
<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment  
<Related words> ^target^, ^exposure^  
<Type of relation> general  
<Equivalence en-zh> Between the terms “population”, and “人群” exists complete conceptual equivalence.

<zh> 人群  
<Morphosyntax> noun  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^ : art. 5.13  
<Lexica> 按 ^现代汉语词典, 2005^  
<Definition> 成群的人:他在~里挤来挤去。  
<Source> ^现代汉语词典, 2005^: 3935  
<Context> 原料历史使用浓度可相互参考, 暴露量高和接触时间长的产品, 可用于暴露量低和接触时间短的产品评估, 但需要从目标人群、使用部位和使用方式等方面充分分析说明其合理性。  
<Source> ^化妆品安全评估技术导则, 2021^: art. 5.13

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^目标^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> register

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> A written record containing regular entries of items or details.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the domestic special products and imported products: the registration or filing formula (must be consistent with the formulation submitted at the time of declaration), product registration certificate or filing voucher, product listing certificate.

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^domestic products^, ^imported products^, ^formula^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “register”, and “注册” exists complete conceptual equivalence.

<zh> 注册

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.3

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 向有关机关、团体或学校登记备案:~商标|新生报到~从9月1日开始。2指计算机用户输入用户名和密码, 以取得计算机网络系统的认可。

<Source> ^现代汉语词典, 2005^: 6139

<Context> 国产特殊产品和进口产品: 注册或备案配方(须与申报时提交配方一致), 产品注册证书或备案凭证, 产品上市证明文件。

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^案配方^, ^产品^, ^文件^

<Type of relation> sub.

<Related words> ^登记^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> regulation

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO 22715:2006

<Source> ^化妆品注册备案资料管理规定^: art. 10.6

<Lexica> Attested in ^Cambridge English Dictionary ^

<Definition> Regulation is broadly defined as imposition of rules by government, backed by the use of penalties that are intended specifically to modify the economic behaviour of individuals and firms in the private sector. Various regulatory instruments or targets exist. Prices, output, rate of return (in the form of profits, margins or commissions), disclosure of information, standards and ownership ceilings are among those frequently used.

<Source> ^OECD^



<Context> When applying for cosmetics registration or filing within the territory of the People's Republic of China, materials shall be submitted in accordance with the requirements of these regulations.

<Source> ^化妆品注册备案资料管理规定^: art. 10.6

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^administration^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “regulation”, and “规定” exists complete conceptual equivalence.

<zh> 规定

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 10.6

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 对某一事物作出关于方式、方法或数量、质量的决定:~ 产品的质量标准| 不得超过~的日期。

<Source> ^现代汉语词典, 2005^: 1796

<Context> 在中华人民共和国境内申请化妆品注册或办理备案时, 应当按照本管理规定的要求提交资料。

<Source> ^化妆品注册备案资料管理规定^: art. 10.6

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^管理^

<Type of relation> sub.

\*\*

<Subject> 化妆品 / Cosmetics

<Subfield> 化妆品安全 / Cosmetics safety

<en> supervise  
<Morphosyntax> verb  
<Usage label> main term  
<Standardisation> ISO/TR 18811:2018  
<Source> ^化妆品注册备案资料管理规定^: 1  
<Lexica> Attested in ^Oxford Wordpower Dictionary^  
<Definition> To be in charge of somebody/something and make sure that everything is done correctly, safely, etc.  
<Source> ^Oxford Wordpower Dictionary^  
<Context> The term refers to overseas cosmetics registrants that when filing parties shall be supervised by the domestic responsible persons.  
<Source> ^化妆品注册备案资料管理规定^: 1  
<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials  
<Related words> ^管理^, ^境外^  
<Type of relation> general  
<Equivalence en-zh> Between the terms “supervise”, and “监督” exists complete conceptual equivalence.

<zh> 监督  
<Morphosyntax> verb  
<Usage label> main term  
<Source> ^化妆品注册备案资料管理规定^: 1  
<Lexica> 按 ^现代汉语词典, 2005^  
<Definition> 察看并督促:~执行|接受。  
<Source> ^现代汉语词典, 2005^: 2312  
<Context> 境外化妆品注册人、备案人应当对境内责任人的注册备案工作进行监督。  
<Source> ^化妆品注册备案资料管理规定^: 1  
<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials  
<Related words> ^境外^, ^化妆品^, ^管理^

<Type of relation> general

<Related words> ^督促^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> management

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 6

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> The act or skill of controlling and making decisions about a business, department, sports team, etc.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the certification materials of overseas production quality management regulations have a valid period, the certification materials shall be updated in time, and the maximum period shall not exceed 90 days after the expiration date; if there is no valid period, the latest version shall be submitted every five years.

<Source> ^化妆品注册备案资料管理规定^: 6

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^regulations^, ^register^, ^overseas^

<Type of relation> general

<Equivalence en-zh> Between the terms “management”, and “管理” exists complete conceptual equivalence.

<zh> 管理

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 6

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 负责某项工作使顺利进行:~财务|~国家大事。

<Source> ^现代汉语词典, 2005^: 1769

<Context> 境外生产质量管理规范证明资料有有效期限的, 应当及时更新证明资料, 最长不得超过有效期限截止后 90 日; 无有效期限的, 应当每五年提交最新版本。

<Source> ^化妆品注册备案资料管理规定^: 6

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^理规^, ^规定^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> regulation

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> A Regulation is an official rule. In the Government, certain administrative agencies have a narrow authority to control conduct, within their areas of responsibility. These agencies have been delegated legislative power to create and apply the rules, or “regulations”. Derived from “regulate”.

<Source> ^Cornell Law^

<Context> The term refers in order the management of cosmetics registration and filing, and to ensure the standardized submission of various materials for cosmetics registration and filing, these management regulations are formulated in accordance with the “Regulations on the Supervision and Administration of Cosmetics” and the “Administrative Measures for the Registration and Filing of Cosmetics” and other relevant laws and regulations.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^filing^, ^registration^, ^management^

<Type of relation> general

<Equivalence en-zh> Between the terms “regulation”, and “条例” exists complete conceptual equivalence.

<zh> 条例

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 由国家制定或批准的规定某些事项或某一机关的组织、职权等的法律文件, 也指团体制定的章程:奖惩~|治安管理~。

<Source> ^现代汉语词典, 2005^: 4640

<Context> 为规范化妆品注册备案管理工作, 保证化妆品注册、备案各项资料的规范提交, 依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求, 制定本管理规定。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^规定^, ^管理^, ^注册^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> file

<Morphosyntax> verb

<Usage label> main term

<Standardisation> ISO/TR 18811:2018

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> To place among official records as prescribed by law.

<Source> ^Merriam-Webster 2016^

<Context> In order to standardize the management of cosmetics registration and filing, and to ensure the standardized submission of various materials for cosmetics registration and filing, these management regulations are formulated in accordance with the “Regulations on the Supervision and Administration of Cosmetics” and the “Administrative Measures for the Registration and Filing of Cosmetics” and other relevant laws and regulations.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^management^, ^supervision^, ^record^

<Type of relation> general

<Equivalence en-zh> Between the terms “put on record”, and “备案” exists complete conceptual equivalence.

<zh> 备案

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典， 2005^

<Definition> 向主管机关报告事由存案以备查考:此事已报上级~。

<Source> ^现代汉语词典， 2005^: 246

<Context> 为规范化妆品注册备案管理工作，保证化妆品注册、备案各项资料的规范提交，依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求，制定本管理规定。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^注册^, ^管理^, ^规定^

<Type of relation> general

\*\*

<Subject> 化妆品 / Cosmetics

<Subfield> 化妆品安全 / Cosmetics safety

<en> method

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO/TR 14735:2013

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> A systematic plan followed in presenting material for instruction.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the measures for administration of the cosmetics register filing.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^measure^, ^means^, ^way^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “method”, and “办法” exists complete conceptual equivalence.

<zh> 办法

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 处理事情或解决问题的方法:好~|他不答应, 你也拿他没~。

<Source> ^现代汉语词典, 2005^: 171

<Context> 为规范化妆品注册备案管理工作, 保证化妆品注册、备案各项资料的规范提交, 依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求, 制定本管理规定。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^规定^, ^注册^, ^条例^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> law

<Morphosyntax> noun

<Usage label> main term

<Standardisation> ISO/TR 18811:2018

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A rule, usually made by a government, that is used to order the way in which a society behaves.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to all the cosmetic law that a company has to follow and respect in order to sell their own cosmetics products in the Chinese market, in particular on the management of cosmetics registration filing materials law.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^management^, ^cosmetics^, ^filing^

<Type of relation> general



<Equivalence en-zh> Between the terms “law”, and “法律” exists complete conceptual equivalence.

<zh> 法律

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 由立法机关或国家机关制定, 国家政权保证执行的行为规则的总和。包括宪法、基本法律、普通法律、行政法规和地方性法规等规范性文件。

<Source> ^现代汉语词典, 2005^: 1313

<Context> 为规范化妆品注册备案管理工作, 保证化妆品注册、备案各项资料的规范提交, 依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求, 制定本管理规定。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^化妆品^, ^管理^, ^条例^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> submit

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To formally send a document, plan, etc. to a person or group in authority so that they can make a decision about it.

<Source> ^Cambridge English Dictionary^

<Context> In order to standardize the management of cosmetics registration and filing, and to ensure the standardized submission of various materials for cosmetics registration and filing, these management regulations are formulated in accordance with the “Regulations on the Supervision and Administration of Cosmetics” and the “Administrative Measures for the Registration and Filing of Cosmetics” and other relevant laws and regulations.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^registration^, ^filing^, ^documents^

<Type of relation> general

<Equivalence en-zh> Between the terms “submit”, and “提交” exists complete conceptual equivalence.

<zh> 提交

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典， 2005^

<Definition> 把需要讨论、决定或处理的问题交有关机构或会议:~大会讨论。

<Source> ^现代汉语词典， 2005^: 4594

<Context> 为规范化妆品注册备案管理工作，保证化妆品注册、备案各项资料的规范提交，依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求，制定本管理规定。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^规范^, ^备案^, ^注册^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> data

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> Information, especially facts or numbers, collected to be examined and considered and used to help decision-making, or information in an electronic form that can be stored and used by a computer.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the materials that shall be submitted in accordance with the requirements of this management regulation.

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^material^, ^information^

<Type of relation> synonym

<Related words> ^submit^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “data”, and “资料” exists complete conceptual equivalence.

<zh> 资料

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: 1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 用作参考或依据的材料:收集~|参考~|统计~|谈笑的~。

<Source> ^现代汉语词典, 2005^: 6201

<Context> 应当按照本管理规定的要求提交资料。

<Source> ^化妆品注册备案资料管理规定^: 1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^提交^

<Type of relation> sub.

<Related words> ^料子^, ^物质^, ^器材^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> follow

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 2.2

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To obey or to act as ordered by someone.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the cosmetic safety assessment that should follow the principle of weight of evidence, based on existing scientific data and related information, and follow the principles of science, fairness, transparency, and case analysis. In the implementation process, the independence of the safety assessment should be ensured.

<Source> ^化妆品注册备案资料管理规定^: art. 2.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^comply^, ^obey^, ^abide by^

<Type of relation> synonym

<Related words> ^principle^, ^information^, ^cosmetic^, ^safety^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “follow”, and “遵循” exists complete conceptual equivalence.

<zh> 遵循

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 2.2

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 遵照:~原则|无所~, 碍难执行。

<Source> ^现代汉语词典, 2005^: 6280

<Context> 化妆品安全评估应遵循证据权重原则, 以现有科学数据和相关信息为基础, 遵循科学、公正、透明和个案分析的原则, 在实施过程中应保证安全评估工作的独立性。

<Source> ^化妆品注册备案资料管理规定^: art. 2.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^证据^, ^原则^

<Type of relation> sub.

<Related words> ^顺^, ^跟着^, ^伴随^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> risk  
<Morphosyntax> noun  
<Usage label> main term  
<Standardisation> ISO 29621:2017  
<Source> ^化妆品注册备案资料管理规定^: art. 2.3  
<Lexica> Attested in ^Merriam-Webster 2016^  
<Definition> Possibility of loss or injury.  
<Source> ^Merriam-Webster 2016^  
<Context> The term refers to the reference materials cited in the safety assessment of cosmetics should be full-text technical reports, announcements, professional books or academic papers, as well as data or risk assessment materials issued by international authoritative institutions.  
<Source> ^化妆品注册备案资料管理规定^: art. 2.3  
<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials  
<Related words> ^assessment^  
<Type of relation> sub.  
<Equivalence en-zh> Between the terms “risk”, and “风险” exists complete conceptual equivalence.

<zh> 风险  
<Morphosyntax> noun  
<Usage label> main term  
<Source> ^化妆品注册备案资料管理规定^: art. 2.3  
<Lexica> 按 ^现代汉语词典， 2005^  
<Definition> 可能发生的危险:担~|冒着~去搞试验。  
<Source> ^现代汉语词典， 2005^: 1440  
<Context> 化妆品安全评估引用的参考资料应为全文形式公开发表的技术报告、通告、专业书籍或学术论文，以及国际权威机构发布的数据或风险评估资料等。  
<Source> ^化妆品注册备案资料管理规定^: art. 2.3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^冒^,^卫星^

<Type of relation> synonym

<Related words> ^评估^,^估算^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> science

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Knowledge about or study of the natural world based on facts learned through experiments and observation.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the cosmetics registrant process that base on scientific resource and filing party shall follow the principles of risk management, and be responsible for the legality, authenticity, accuracy, completeness, and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^research^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “science”, and “科学” exists complete conceptual equivalence.

<zh> 科学

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 反映自然、社会、思维等的客观规律的分科的知识体系。

<Source> ^现代汉语词典, 2005^: 2684

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^研究^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> research

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^

<Lexica> Attested in ^化妆品注册备案资料管理规定^: art. 3

<Definition> A detailed study of a subject, especially in order to discover (new) information or reach a (new) understanding.

<Source> ^Cambridge English Dictionary^

<Context> Use Chinese consumers to carry out consumer test research or human efficacy test data in China.

<Source> ^化妆品注册备案资料管理规定^: art. 3



<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials  
<Related words> ^analysis^, ^investigation^, ^inquiry^  
<Type of relation> synonym  
<Equivalence en-zh> Between the terms “research”, and “研究” exists complete conceptual equivalence.

<zh> 研究

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 探求事物的真相、性质、规律等:~语言|学术~|调查~。

<Source> ^现代汉语词典, 2005^: 5386

<Context> 在中国境内选用中国消费者开展消费者测试研究或者人体功效试验资料。

<Source> ^化妆品注册备案资料管理规定^: art. 3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^剖析^, ^分许^, ^剖视^

<Type of relation> synonym

<Related words> ^科学^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> basic

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 7

<Lexica> Attested in ^Oxford English Dictionary^

<Definition> Forming the part of something that is most necessary and from which other things develop.

<Source> ^Oxford English Dictionary^

<Context> The term refers to the basic formula of the products. Different types or contents of colorants or fragrances, and all the products with the same content and type in the basic formula and the same series name can refer to the existing information and data to evaluate only the adjusted components and ensure product safety.

<Source> ^化妆品注册备案资料管理规定^: art. 7

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^formula^, ^safety^, ^fragrances^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “basic”, and “基础” exists complete conceptual equivalence.

<zh> 基础

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 7

<Lexica> 按 ^现代汉语词典， 2005^

<Definition> 事物发展的根本或起点:~知识|在原有的~上提高。

<Source> ^现代汉语词典， 2005^: 2204

<Context> 产品配方除着色剂或香料的种类或含量不同外，基础配方成分含量、种类相同，且系列名称相同的产品，可以参考已有的资料和数据，只对调整组分进行评估，并确保产品安全。

<Source> ^化妆品注册备案资料管理规定^: art. 7

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^配方^, ^含量^, ^种类^

<Type of relation> sub.

<Related words> ^基本^, ^基层^, ^根本^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> legal

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Having a formal status derived from law often without a basis in actual fact.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^authentic^, ^accuracy^, ^responsible^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “legal”, and “合法” exists complete conceptual equivalence.

<zh> 合法

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 符合法律规定:~权利|~地位|~斗争|这么做不~。

<Source> ^现代汉语词典, 2005^: 1914

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^真实^, ^准确^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> authentic

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Worthy of acceptance or belief as conforming to or based on fact.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^legal^, ^accurate^, ^complete^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “authentic”, and “真实性” exists complete conceptual equivalence.

<zh> 真实

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 跟客观事实相符合;不假:~情况|~的感情。

<Source> ^现代汉语词典, 2005^: 5958

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^准确^, ^完整^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> accurate

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> Correct and without any mistakes.

<Source> ^Oxford Wordpower Dictionary^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^legal^, ^authentic^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “accurate”, and “准确” exists complete conceptual equivalence.

<zh> 准确

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 6187

<Definition> 行动的结果完全符合实际或预期:~性|计算~~地击中目标。

<Source> ^现代汉语词典, 2005^: 6187

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^合法^, ^真实^, ^完整^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> complete

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3  
<Lexica> Attested in ^Cambridge English Dictionary^  
<Definition> To write all the details asked for on a form or other document.  
<Source> ^Cambridge English Dictionary^  
<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.  
<Source> ^化妆品安全评估技术导则, 2021^: art. 3  
<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment  
<Related words> ^accurate^, ^authentic^, ^legal^  
<Type of relation> sub.  
<Equivalence en-zh> Between the terms “complete”, and “完整” exists complete conceptual equivalence.

<zh> 完整

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 4808

<Definition> 具有或保持着应有的各部分;没有损坏或残缺:领土~|结构~|这套书是~的。

<Source> ^现代汉语词典, 2005^: 4808

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^真实^, ^合法^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> traceability

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Oxford Wordpower Dictionary^

<Definition> The ability to find or follow something.

<Source> ^Oxford Wordpower Dictionary^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^complete^, ^accurate^, ^legal^, ^authentic^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “traceability”, and “追溯” exists complete conceptual equivalence.

<zh> 追溯

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 6181

<Definition> 逆流而上, 向江河发源处走, 比喻探索事物的由来:两国交往的历史可以~到许多世纪以前。

<Source> ^现代汉语词典, 2005^: 6181



<Context> 化妆品注册人、备案人应当遵循风险管理的原则，以科学研究为基础，对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责，并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^真实^, ^合法^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> responsible

<Morphosyntax> adj

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To have control and authority over something or someone and the duty of taking care of it.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal responsibilities.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^authentic^, ^accurate^, ^legal^, ^traceability^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “responsible”, and “负责” exists complete conceptual equivalence.

<zh> 负责

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 1501

<Definition> 担负责任:~后勤工作|这里的事由你~。

<Source> ^现代汉语词典, 2005^: 1501

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^真实^, ^准确^, ^完整^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> commitment

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> An act of referring a matter to a legislative committee.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the cosmetics registrant and filing party shall follow the principles of risk management, based on scientific research, and be responsible for the

legality, authenticity, accuracy, completeness and traceability of the submitted registration filing materials, and bear corresponding legal commitment.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^legal^

<Type of relation> sub

<Related words> ^responsibility^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “commitment”, and “承担” exists complete conceptual equivalence.

<zh> 承担

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 649

<Definition> 担负;担当:~义务|~责任。

<Source> ^现代汉语词典, 2005^: 649

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^法律^, ^责任^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> correspond

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 2

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Corresponding quality control measures should be submitted according to the actual microbiological and physical and chemical indicators of the product.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the corresponding quality control measures should be submitted according to the actual microbiological and physical and chemical indicators of the product.

<Source> ^化妆品注册备案资料管理规定^: art. 2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^quality control^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “correspond”, and “相应” exists complete conceptual equivalence.

<zh> 相应

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 2

<Lexica> 按 ^现代汉语词典， 2005^: 5100

<Definition> 互相呼应或照应;相适应:这篇文章前后不~|环境改变了，工作方法也要~地改变。

<Source> ^现代汉语词典， 2005^: 5100

<Context> 应当根据产品实际控制的微生物和理化指标提交相应的质量控制措施。

<Source> ^化妆品注册备案资料管理规定^: art. 2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^控制^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> responsibility

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> Something that it is your job or duty to deal with.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the legal responsibilities that the submitted registration filing materials should corresponds.

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^complete^, ^accurate^, ^legal^, ^authentic^

<Type of relation>sub.

<Related words> ^duty^

<Type of relation> synonym

<Equivalence en-zh> Between the terms “responsibility”, and “责任” exists complete conceptual equivalence.

<zh> 责任

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Lexica> 按 ^现代汉语词典, 2005^: 5864

<Definition> 没有做好分内应做的事, 因而应当承担的过失:追究~。

<Source> ^现代汉语词典, 2005^: 5864

<Context> 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。

<Source> ^化妆品安全评估技术导则, 2021^: art. 3

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^完整^, ^真实^, ^准确^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> overseas

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 4

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> Beyond or across the sea.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the cosmetics registration filing materials shall use standardized Chinese characters promulgated by the state. Except for registered trademarks, website addresses, patent names, names and addresses of overseas companies, etc., other words must be used, or conventional professional terms (such as SPF, PFA, PA, UVA, UVB, vitamin C, etc.), all other words should be complete, translate into Chinese in a standardized manner, and attach the original text to the corresponding translation.

<Source> ^化妆品注册备案资料管理规定^: art. 4

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^company^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “overseas”, and “境外” exists complete conceptual equivalence.

<zh> 境外

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品注册备案资料管理规定^: art. 4

<Lexica> 按 ^baidu.baikē^

<Definition> 是指中国边境（国界）以外的所有国家与地区和中国以内政府尚未实施行政管辖的地域；境外范围包括：港澳台和其他外国国家和地区

<Source> ^baidu.baikē^

<Context> 化妆品注册备案资料应当使用国家公布的规范汉字。除注册商标、网址、专利名称、境外企业的名称和地址等必须使用其他文字的，或约定俗成的专业术语（如 SPF、PFA、PA、UVA、UVB、维生素 C 等），所有其他文字均应完整、规范地翻译为中文，并将原文附在相应的译文之后。

<Source> ^化妆品注册备案资料管理规定^: art. 4

<Concept field> 化妆品安全评估技术导则 / Technical Guidelines for Cosmetic Safety Assessment

<Related words> ^企业^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> determine

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.2.4

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To control or influence something directly, or to decide what will happen.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the content of the raw materials, the measurement method should be clarified, and the source of the analysis method and the measurement principle should be explained.

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.2.4

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^raw material^, ^measurement^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “determine”, and “测定” exists complete conceptual equivalence.

<zh> 测定

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.2.4

<Lexica> 按 ^现代汉语词典, 2005^: 6317

<Definition> 经测量后确定:~方向|~气温。

<Source> ^现代汉语词典, 2005^: 6317

<Context> 应明确原料的纯度/含量以及测定方法, 并说明分析方法的来源及测定原理。

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.2.4

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^来源^, ^原理^, ^原料^

<Type of relation> sub.

<Related words> ^鉴定^, ^判定^, ^测定^, ^决定^, ^确定^

<Type of relation> synonym

\*\*



<Subject> 化妆品/ Cosmetics  
<Subfield> 化妆品安全/ Cosmetics safety  
<en> raw material  
<Morphosyntax> noun  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^: art. 7.1.5  
<Lexica> Attested in ^Merriam-Webster 2016^  
<Definition> Crude or processed material that can be converted by manufacture, processing, or combination into a new and useful product.  
<Source> ^Merriam-Webster 2016^  
<Context> The term refers to the raw materials in the product formulation, the mechanism of their possible systemic toxicity is the same. If necessary, the cumulative exposure of the raw materials should be considered and case analysis should be carried out.  
<Source> ^化妆品安全评估技术导则, 2021^: art. 7.1.5  
<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials  
<Related words> ^formula^, ^product^, ^toxicity^  
<Type of relation> sub.  
<Equivalence en-zh> Between the terms “raw material”, and “原料” exists complete conceptual equivalence.

<zh> 原料  
<Morphosyntax> noun  
<Usage label> main term  
<Source> ^化妆品安全评估技术导则, 2021^: art. 7.1.5  
<Lexica> 按 ^现代汉语词典, 2005^: 5766  
<Definition> 指没有经过加工制造的材料, 如用来冶金的矿砂, 用来纺织的棉花。  
<Source> ^现代汉语词典, 2005^: 5766  
<Context> 如果产品配方中两种或两种以上的原料, 其可能产生系统毒性的作用机制相同, 必要时应考虑原料的累积暴露, 并进行个案分析。

<Source> ^化妆品安全评估技术导则, 2021^: art. 7.1.5

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^毒性^, ^品配方^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> substance

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.5

<Lexica> Attested in ^^

<Definition> A type of solid, liquid or gas that has particular qualities.

<Source> ^Oxford Wordpower Dictionary^

<Context> The term refers to the raw materials and/or risky substances that cannot be used with any of the above types of evidence, they shall be evaluated to prove their safety in accordance with the evaluation procedures required by this guideline.

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.5

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^raw material^, ^risky substance^, ^safety^

<Type of relation> general

<Equivalence en-zh> Between the terms “substance”, and “物质” exists complete conceptual equivalence.

<zh> 物质

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.5

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 独立存在于人的意识之外的客观实在。

<Source> ^现代汉语词典, 2005^: 4973

<Context> 对于无法使用上述任一证据类型的原料和/或风险物质, 应按照本导则要求的评估程序进行评估证明其安全性。

<Source> ^化妆品安全评估技术导则, 2021^: art. 9.1.5

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^或风^, ^安全性^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> characteristic

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A typical or noticeable quality of someone or something.

<Source> ^Cambridge English Dictionary^

<Context> The term refers on the results of toxicological tests, clinical studies, adverse reaction monitoring, and population epidemiological studies, the physical, chemical, and toxic effects of raw materials and/or risk substances characteristic are used to determine whether they are potentially harmful to human health.

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^health^, ^toxicological test^, ^reaction^, ^risk^

<Type of relation> general

<Equivalence en-zh> Between the terms “characteristic”, and “特征” exists complete conceptual equivalence.

<zh> 特征

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 可以作为人或事物特点的征象、标志等:艺术~|这个人的相貌有什么~?

<Source> ^现代汉语词典, 2005^: 4584

<Context> 基于毒理学试验、临床研究、不良反应监测和人群流行病学研究等的结果, 从原料和/或风险物质的物理、化学和毒作用特征来确定其是否对人体健康存在潜在危害。

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^风险^, ^结果^, ^安全^

<Type of relation> general

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> harm

<Morphosyntax> verb

<Usage label> main term

<Source> 化妆品安全评估技术导则, 2021^: art. 4.1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> Physical or other injury or damage.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the results of toxicological tests, clinical studies, adverse reaction monitoring, and population epidemiological studies, the physical, chemical, and toxic effects of raw materials and/or risk substances are used to determine whether they are potentially harmful to human health.

<Source> 化妆品安全评估技术导则, 2021<sup>^</sup>: art. 4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> <sup>^</sup>human<sup>^</sup>, <sup>^</sup>health<sup>^</sup>, <sup>^</sup>toxicological test<sup>^</sup>

<Type of relation> general

<Equivalence en-zh> Between the terms “characteristic”, and “危害” exists complete conceptual equivalence.

<zh> 危害

<Morphosyntax> verb

<Usage label> main term

<Source> <sup>^</sup>化妆品安全评估技术导则, 2021<sup>^</sup>: art. 4.1

<Lexica> 按 <sup>^</sup>现代汉语词典, 2005<sup>^</sup>

<Definition> 使受破坏;损害:~生命|~社会秩序。

<Source> <sup>^</sup>现代汉语词典, 2005<sup>^</sup>: 4843

<Context> 基于毒理学试验、临床研究、不良反应监测和人群流行病学研究等的结果, 从原料和/或风险物质的物理、化学和毒作用特征来确定其是否对人体健康存在潜在危害。

<Source> 化妆品安全评估技术导则, 2021<sup>^</sup>: art. 4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> <sup>^</sup>识别<sup>^</sup>, <sup>^</sup>临床研究<sup>^</sup>, <sup>^</sup>结果<sup>^</sup>

<Type of relation> general

<Related words> <sup>^</sup>危险<sup>^</sup>, <sup>^</sup>险恶<sup>^</sup>

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> distinguish

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.2

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> To separate into kinds, classes, or categories.

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the process of identifying hazards, the purity and stability of raw materials, their possible reactions with other raw materials in the product, and their ability to absorb through the skin, etc., should also be considered. At the same time, the risks unavoidable in the raw materials and the production process should also be considered.

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^hazards^, ^harm^, ^raw material^, ^product^

<Type of relation> general

<Equivalence en-zh> Between the terms “distinguish”, and “识别” exists complete conceptual equivalence.

<zh> 识别

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.2

<Lexica> 按 ^现代汉语词典, 2005^: 4244

<Definition> 辨别;辨认:~真伪。

<Source> ^现代汉语词典, 2005^: 4244

<Context> 在进行危害识别时，还应考虑原料的纯度和稳定性、其可能与产品中其他原料发生的反应以及透皮吸收的能力等，同时还应考虑到原料和生产过程中不可避免带入的风险物质的健康危害效应等。

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^区别^, ^鉴别^, ^辨别^

<Type of relation> synonym

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> technical

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> A statement of legal particulars (as of charges or of contract terms).

<Source> ^Merriam-Webster 2016^

<Context> The term refers to the raw materials in the list of restricted components, permitted preservatives, permitted sunscreens, permitted colorants and permitted hair dyes in the “Technical Specifications” shall meet the requirements of the “Technical Specifications”.

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^specification^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “technical”, and “技术” exists complete conceptual equivalence.

<zh> 技术

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 人类在认识自然和利用自然的过程中积累起来并在生产劳动中体现出来的经验和知识, 也泛指其他操作方面的技巧:钻研~|~先进。

<Source> ^现代汉语词典, 2005^: 2254

<Context> 使用《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料应满足《技术规范》要求。

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^规范^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> specification

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A detailed description of how something should be done, made.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the raw materials in the list of restricted components, permitted preservatives, permitted sunscreens, permitted colorants and permitted hair dyes in the “Technical Specifications” shall meet the requirements of the “Technical Specifications”.



<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^technical^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “specification”, and “规范” exists complete conceptual equivalence.

<zh> 规范

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 约定俗成或明文规定的标准:语音~|道德~。

<Source> ^现代汉语词典, 2005^: 1797

<Context> 使用《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料应满足《技术规范》要求。

<Source> ^化妆品安全评估技术导则, 2021^: art. 6.1.2

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^技术^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> develop

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> To grow or cause to grow or change into a more advanced form.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the ensure of the safety of cosmetics, standardize the safety assessment of cosmetics, guide the development of related work, and formulate this guideline.

<Source> ^化妆品安全评估技术导则, 2021^

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^work^, ^guide^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “develop”, and “开展” exists complete conceptual equivalence.

<zh> 开展

<Morphosyntax> verb

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 从小向大发展:植树造林活动已在全国~起来

<Source> ^现代汉语词典, 2005^: 2650

<Context> 为保障化妆品使用安全, 规范化妆品安全评估, 指导开展相关工作, 制定本导则。

<Source> ^化妆品安全评估技术导则, 2021^

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^指导^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> authority

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: 6.1.3

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A group of people with official responsibility for a particular area of activity.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the International authoritative Cosmetics Safety Assessment Agency who announced the assessment conclusion, the relevant assessment data shall be analyzed, and the relevant assessment conclusion may be adopted if it meets the requirements of the relevant cosmetics regulations in my country.

<Source> ^化妆品安全评估技术导则, 2021^: 6.1.3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^safety assessment^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “authority”, and “权威” exists complete conceptual equivalence.

<zh> 权威

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: 6.1.3

<Lexica> 按 ^现代汉语词典, 2005^: 3891

<Definition> 使人信服的力量和威望:~著作|维护政府~。

<Source> ^现代汉语词典, 2005^: 3891

<Context> 凡国际权威化妆品安全评估机构已公布评估结论的原料, 需对相关评估资料进行分析, 在符合我国化妆品相关法规要求的情况下, 可采用相关评估结论。

<Source> ^化妆品安全评估技术导则, 2021^: 6.1.3

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^化妆品安全^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> safety

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 7.4.1

<Lexica> Attested in ^Cambridge English Dictionary^

<Definition> A state in which or a place where you are safe and not in danger or at risk.

<Source> ^Cambridge English Dictionary^

<Context> The term refers to the monitor, record and archive the safety of products after the market. Including adverse reactions that occur during normal use, consumer complaints and follow-up follow-up, etc.

<Source> ^化妆品安全评估技术导则, 2021^: art. 7.4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^assessment^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “safety”, and “安全性” exists complete conceptual equivalence.

<zh> 安全性

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 7.4.1

<Lexica> 按 ^现代汉语词典, 2005^

<Definition> 没有危险;不受威胁;不出事故:~操作|~地带|注意交通~。

<Source> ^现代汉语词典, 2005^: 70

<Context> 对上市后产品的安全性进行监测、记录和归档。

<Source> ^化妆品安全评估技术导则, 2021^: art. 7.4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^性进^, ^监测^

<Type of relation> sub.

\*\*

<Subject> 化妆品/ Cosmetics

<Subfield> 化妆品安全/ Cosmetics safety

<en> epidemiology

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Lexica> Attested in ^Merriam-Webster 2016^

<Definition> A branch of medical science that deals with the incidence, distribution, and control of disease in a population.

<Source> ^Merriam-Webster 2016^

<Context>The term refers to the results of toxicological tests, clinical studies, adverse reaction monitoring, and population epidemiological studies, the physical, chemical, and toxic effects of raw materials and/or risk substances are used to determine whether they are potentially harmful to human health.

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Concept field> 化妆品注册备案资料管理规定/ Regulations on the management of cosmetics registration filing materials

<Related words> ^population^, ^disease^

<Type of relation> sub.

<Equivalence en-zh> Between the terms “epidemiology”, and “流行病学” exists complete conceptual equivalence.

<zh> 流行病学

<Morphosyntax> noun

<Usage label> main term

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Lexica> 按 ^汉典 2021 ^

<Definition> 研究疾病在人群中分布的现象及原因，并据此识别病因，采取预防措施的一门医学。

<Source> ^汉典 2021 ^

<Context> 基于毒理学试验、临床研究、不良反应监测和人群流行病学研究等的结果，从原料和/或风险物质的物理、化学和毒作用特征来确定其是否对人体健康存在潜在危害。

<Source> ^化妆品安全评估技术导则, 2021^: art. 4.1

<Concept field> 化妆品注册备案资料管理规定 / Regulations on the management of cosmetics registration filing materials

<Related words> ^人体健康^, ^毒作用特^

<Type of relation> sub.

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<source> ^EU1004/2014^

<Reference> Commission Regulation (EU) No 1004/2014, 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products Text with EEA relevance, available at: <https://op.europa.eu/en/publication-detail/-/publication/a22d3948-4545-11e4-a0cb-01aa75ed71a1/language-en>

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<source> ^化妆品注册备案资料管理规定^

<Reference> 《化妆品注册备案资料管理规定》政策解读, 2021, *Policy Interpretation of the “Regulations on the Administration of Cosmetics Registration and Filing Documents”*, NMPA, available at: <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/zhcjd/zhcjdhzhp/20210304172400137.html>

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## English – Chinese quick reference table

ENGLISH	Pinyin	中文
Analyse	Fēnxī	分析
Absorb	Xīshōu	吸收
Accumulate	Xùjī	蓄积
Accurate	Zhǔnquè	准确
Acute	Jíxìng	急性
Allergy	Biàntài fǎnyìng	变态反应
Authentic	Zhēnshí	真实
Authority	Quánwēi	权威
Basic	Jīchǔ	基础
Be responsible for	Fùzé	负责
Carcinogenic	Fùzé	致癌
Cause	Yīnqǐ	引起
Characteristic	Tèzhēng	特征
Chromosomal aberration	Rǎnsètǐ jībiàn	染色体畸变
Come into contact	Jiēchù	接触
Commitment	Chéngdān	承担
Complete	Wánzhěng	完整
Correspond	Xiāngyìng	相应
Corrosive	Fǔshíxìng	腐蚀性
Cosmetics	Huàzhuāngpǐn	化妆品
Count	Jìsuàn	计算
Cronic	Mǎnxìng	慢性
Crowd	Rénqún	人群
Data	Zīliào	资料
Determine	Cèdìng	测定
Develop	Kāizhǎn	开展

Distinguish	Shíbié	识别
Dose	Jiliàng	剂量
Drain	Páixiè	排泄
Duplicate	Chóngfù	重复
Embryo	Pēitāi	胚胎
Epidemiology	Liúxíng bìng xué	流行病学
Expose	Bàolù	暴露
Follow	Zūnxún	遵循
Gene	Jīyīn	基因
Harm	Wéihài	危害
Health	Jiànkāng	健康
Hereditary	Yíchuán	遗传
In vivo	Tǐnèi	体内
Inhale	Xīrù	吸入
Investigate	Tàntǎo	探讨
Irradiate	Zhàoshè	照射
Irritant	Cìjī xìng	刺激性
Issue	Fābù	发布
Law	Fǎlǜ	法律
Leading to genetic malformation	Zhì jī	致畸
Legal	Héfǎ	合法
Management	Guǎnlǐ	管理
Metabolism	Dàixiè	代谢
Method	Bànfǎ	办法
Mutation	Túbìàn	突变
Organization	Jīgòu	机构
Overseas	Jìngwài	境外
Penetration	Shèntòu xìng	渗透性
Preliminary	Chūbù	初步

Provisions on administration	Chūbù guǎnlǐ guīdìng	管理规定
Put on record	Bèi'àn	备案
Raw material	Yuánliào	原料
Register	Zhùcè	注册
Regulation	Tiáolì	条例
Reproduce	Shēngzhí	生殖
Research	Yánjiū	研究
Responsibility	Zérèn	责任
Risk	Fēngxiǎn	风险
Safety	Ānquán xìng	安全性
Science	Kēxué	科学
Short term	Duǎn shíjiān	短时间
Skin test	Pí shì	皮试
Skin	Pífū	皮肤
Source	Láiyuán	来源
Specification	Guīfàn	规范
Submit	Tíjiāo	提交
Substance	Wùzhì	物质
Supervisor	Jiāndū	监督
Target organ	Bǎ qìguān	靶器官
Technical	Jìshù	技术
Test	Shìyàn	试验
Toxicity	Dúxìng	毒性
Toxicokinetics	Dú dài dònglì xué	毒代动力学
Traceability	Zhuīsù	追溯
Ultraviolet radiation	Zǐwàixiàn	紫外线

## Chinese - English quick reference table

Pinyin	中文	ENGLISH
Ānquán xìng	安全性	Safety
Bǎ qìguān	靶器官	Target organ
Bànfǎ	办法	Method
Bàolù	暴露	Expose
Bèi'àn	备案	Put on record
Biàntài fǎnyìng	变态反应	Allergy
Cèdìng	测定	Determine
Chéngdān	承担	Commitment
Chóngfù	重复	Duplicate
Chūbù	初步	Preliminary
Chūbù guǎnlǐ guīdìng	管理规定	Provisions on administration
Cìjī xìng	刺激性	Irritant
Dàixiè	代谢	Metabolism
Dú dài dònglì xué	毒代动力学	Toxicokinetics
Duǎn shíjiān	短时间	Short term
Dúxìng	毒性	Toxicity
Fābù	发布	Issue
Fǎlǜ	法律	Law
Fēngxiǎn	风险	Risk
Fēnxī	分析	Analyse
Fǔshíxìng	腐蚀性	Corrosive
Fùzé	负责	Be responsible for
Fùzé	致癌	Carcinogenic
Guǎnlǐ	管理	Management
Guīfàn	规范	Specification
Héfǎ	合法	Legal

Huàzhuāngpǐn	化妆品	Cosmetics
Jiāndū	监督	Supervisor
Jiànkāng	健康	Health
Jīchǔ	基础	Basic
Jiēchù	接触	Come into contact
Jīgòu	机构	Organization
Jiliàng	剂量	Dose
Jìngwài	境外	Overseas
Jìshù	技术	Technical
Jìsuàn	计算	Count
Jíxìng	急性	Acute
Jīyīn	基因	Gene
Kāizhǎn	开展	Develop
Kēxué	科学	Science
Láiyuán	来源	Source
Liúxíng bìng xué	流行病学	Epidemiology
Mànxìng	慢性	Cronic
Páixiè	排泄	Drain
Pēitāi	胚胎	Embryo
Pí shì	皮试	Skin test
Pífū	皮肤	Skin
Quánwēi	权威	Authority
Rǎnsètǐ jībiàn	染色体畸变	Chromosomal aberration
Rénqún	人群	Crowd
Shēngzhí	生殖	Reproduce
Shèntòu xìng	渗透性	Penetration
Shìbié	识别	Distinguish
Shìyàn	试验	Test
Tàntǎo	探讨	Investigate



Tèzhēng	特征	Characteristic
Tiáolì	条例	Regulation
Tíjiāo	提交	Submit
Tǐnèi	体内	In vivo
Túbìàn	突变	Mutation
Wánzhěng	完整	Complete
Wéihài	危害	Harm
Wùzhì	物质	Substance
Xiāngyìng	相应	Correspond
Xīrù	吸入	Inhale
Xīshōu	吸收	Absorb
Xùjī	蓄积	Accumulate
Yánjiū	研究	Research
Yíchuán	遗传	Hereditary
Yīnqǐ	引起	Cause
Yuánliào	原料	Raw material
Zérèn	责任	Responsibility
Zhàoshè	照射	Irradiate
Zhēnshí	真实	Authentic
Zhì jī	致畸	Leading to genetic malformation
Zhùcè	注册	Register
Zhuīsù	追溯	Traceability
Zhǔnquè	准确	Accurate
Zīliào	资料	Data
Zǐwàixiàn	紫外线	Ultraviolet radiation
Zūnxún	遵循	Follow

## **Concluding remarks on the glossary**

The Chinese-English terminological records are based on the principal lexicon that belongs to the fields of cosmetic regulation in China. It is aimed at providing a comprehensive overview on the terminology of the analyzed field. The terms selected derive from the main Chinese regulation highlighted during the research. More specifically, the majority of the terminological records derive from the following regulations: Technical Guidelines for Cosmetic Safety Assessment (2021 edition) 化妆品安全评估技术导, 2021 年版 and *Policy Interpretation of the “Regulations on the Administration of Cosmetics Registration and Filing Documents”*, 化妆品注册备案资料管理规定》政策解读, 2021.

The terminological records gives an interesting examination of the terms encountered during the investigation and supports an international company interested in an investment in the Chinese great cosmetics market. As highlighted previously, expanding the business to China might not be straightforward due to the difficulty regarding the culture, regulations, and language. The language might be a substantial obstacle. The before-mentioned research could be the proper support that an international company might need to understand accurately how to proceed in such a market.

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## **APPENDIX**

## APPENDIX A

国家药监局关于发布《化妆品安全评估技术导则（2021年版）》的公告（2021）年第51号, Announcement No. 51 of the State Food and Drug Administration on the issuance of the “*Technical Guidelines for Cosmetic Safety Evaluation*”, 2021, NMPA.

化妆品安全评估技术导则

为保障化妆品使用安全，规范化妆品安全评估，指导开展相关工作，制定本导则。

适用范围

本导则适用于化妆品原料和产品的安全评估。

基本原则与要求

2.1 原料的安全性是化妆品产品安全的前提条件。化妆品原料的风险评估包括原料本身及可能带入的风险物质；化妆品产品一般可认为是各种原料的组合，应基于所有原料和风险物质进行评估，如果确认某些原料之间存在化学和/或生物学等相互作用的，应评估其产生的风险物质和/或相互作用产生的潜在安全风险。

2.2 化妆品安全评估应遵循证据权重原则，以现有科学数据和相关信息为基础，遵循科学、公正、透明和个案分析的原则，在实施过程中应保证安全评估工作的独立性。

2.3 化妆品安全评估引用的参考资料应为全文形式公开发表的技术报告、通告、专业书籍或学术论文，以及国际权威机构发布的数据或风险评估资料等；应用未公开发表的研究结果时，需经数据所有权方同意，并分析结果的科学性、准确性、真实性和可靠性等。

2.4 化妆品的安全评估工作应由具有相应能力的安全评估人员按照本导则的要求进行评估，并出具评估报告。

2.5 化妆品注册人、备案人应自行或委托专业机构开展安全评估，形成安全评估报告，并对其真实性、科学性负责。

2.6 化妆品的安全评估资料应当根据需要及时更新，保存期限不少于最后一批上市产品保质期结束以后10年。

2.7 化妆品安全评估人员开展安全评估时，以本导则作为参考依据，还应根据原料和产品的具体情况进行分析。

2.8 评估人员的简历应附在评估报告之后，简历内容应包括评估人员的教育经历、化妆品相关从业经历、专业培训经历等。

### 3. 化妆品安全评估人员的要求

化妆品安全评估人员应符合以下要求：

3.1 具有医学、药学、生物学、化学或毒理学等化妆品质量安全相关专业知识，了解化妆品成品或原料生产过程和质量安全控制要求，并具有5年以上相关专业从业经历。

3.2 能查阅和分析化学、毒理学等相关文献信息，分析、评估和解释相关数据。

3.3 能公平、客观地分析化妆品的安全性，在全面分析所有可获得的数据和暴露条件的基础上，开展安全评估工作，并对评估报告的科学性、准确性、真实性和可靠性负责。

3.4 能通过定期接受相应的专业培训等方式，学习安全评估的相关知识，了解和掌握新的安全评估理论、技术和方法，并用于实践。

### 4. 风险评估程序

化妆品原料和风险物质的风险评估程序分为以下四个步骤：

#### 4.1 危害识别

基于毒理学试验、临床研究、不良反应监测和人群流行病学研究等的结果，从原料和/或风险物质的物理、化学和毒作用特征来确定其是否对人体健康存在潜在危害。

##### 4.1.1 健康危害效应

根据产品的使用方法、暴露途径等，确认原料和/或风险物质可能存在的健康危害效应，主要包括：

(1) 急性毒性：包括经口和/或经皮接触后产生的急性毒性效应。

(2) 刺激性/腐蚀性：包括皮肤和/或眼刺激性/腐蚀性效应。

(3) 致敏性：主要为皮肤致敏性。

(4) 光毒性：紫外线照射后产生的光刺激性。

(5) 光变态反应：重复接触并在紫外线照射下引起的反应。

(6) 遗传毒性：包括基因突变和染色体畸变效应等。

(7) 重复剂量毒性：连续暴露后对组织和靶器官所产生的功能性和/或器质性改变。

(8) 生殖发育毒性：对亲代的生殖功能、妊娠母体机能、胚胎发育、胎儿出生前、围产期和出生后结构及功能的有害作用。

(9) 慢性毒性/致癌性：正常生命周期大部分时间暴露后所产生的毒性效应及引起肿瘤的可能性。

(10) 其他：有吸入暴露可能时，需考虑吸入暴露引起的健康危害效应。

##### 4.1.2 危害识别

(1) 按照《化妆品安全技术规范》（以下称《技术规范》）或国际上通用的毒理学试验结果的判定原则对化妆品原料和/或风险物质的急性毒性、皮肤刺激性/腐蚀性、眼刺激性/腐蚀性、致敏性、光毒性、光变态反应、遗传毒性、重复剂量毒性、生殖发育毒性、慢性毒性/致癌性等毒性特征进行判定，确定原料和/或风险物质的主要毒性特征及程度。

(2) 如有原料和/或风险物质的人群流行病学调查、人群监测以及不良反应事件报告等相关资料，应根据所提供的资料判定该原料和/或风险物质可能对人体产生的健康危害效应。

(3) 在进行危害识别时，还应考虑原料的纯度和稳定性、其可能与产品中其他原料发生的反应以及透皮吸收的能力等，同时还应考虑到原料和生产过程中不可避免带入的风险物质的健康危害效应等。

(4) 对可能有吸入暴露风险的产品，应评估其吸入暴露对人体可能产生的健康危害效应。

(5) 对于复配原料，应对复配原料本身和/或每种组分的危害效应进行识别。

#### 4.2 剂量反应关系评估

用于确定原料和/或风险物质的毒性反应与暴露剂量之间的关系。对有阈值的毒性效应，需获得未观察到有害作用的剂量（NOAEL）或基准剂量（BMD）。对于无阈值的致癌效应，用 25% 的实验动物的某部位有发生肿瘤的剂量（T<sub>25</sub>）或 BMD 来确定。对于具有致敏风险的原料和/或风险物质，还需通过预期无诱导致敏剂量（NESIL）来评估其致敏性。

4.2.1 对原料和/或风险物质的有阈值毒性效应的剂量反应关系评估，需确定原料的 NOAEL 或 BMD。

当选择 NOAEL 计算安全系数时，应选择来自系统毒性试验的数据，如亚慢性重复剂量毒性试验、慢性毒性/致癌试验、生殖发育毒性试验、致畸试验等，还应该考虑该值获得的试验条件与被评估物质使用条件和品种敏感度的相关性。如果选择 28 天重复剂量毒性试验数据时，应增加相应的不确定因子（UF，一般为 3 倍）。如果不能得到 NOAEL 或 BMD 的，则采用其观察到有害作用的最低剂量（LOAEL），但用 LOAEL 值计算安全边际值（MoS）时，应增加相应的不确定因子（UF，一般为 3 倍）。

4.2.2 对于原料和/或风险物质的无阈值致癌效应，可通过剂量描述参数 T<sub>25</sub> 或 BMD 等来进行剂量反应关系评估。

4.2.3 对于存在致敏风险的原料和/或风险物质，可通过 NESIL 进行剂量反应关系评估。

#### 4.3 暴露评估

指通过对化妆品原料和/或风险物质暴露于人体的部位、浓度、频率以及持续时间等的评估，确定其暴露水平。

4.3.1 进行暴露评估时，应考虑含该原料或风险物质产品的使用部位、使用量、浓度、使用频率以及持续时间等因素，具体包括：

- (1) 用于化妆品中的类别。
- (2) 暴露部位或途径：皮肤、粘膜暴露，以及可能的吞咽或吸入暴露。
- (3) 暴露频率：包括间隔使用或每天使用的次数等。
- (4) 暴露持续时间：包括驻留或用后清洗等。
- (5) 暴露量：包括每次使用量及每日使用总量等。
- (6) 浓度：在产品中的浓度。
- (7) 透皮吸收率。
- (8) 暴露对象的特殊性：如儿童、孕妇、哺乳期妇女等。

#### 4.3.2 全身暴露量 (SED) 的计算

(1) 如果暴露是以每次使用经皮吸收  $\mu\text{g}/\text{cm}^2$  时，根据使用面积，按以下公式计算：

$$SED = \frac{DA_a \times SSA \times F}{BW} \times 10^{-3}$$

其中：

SED：全身暴露量 ( $\text{mg}/\text{kg}\cdot\text{bw}/\text{day}$ )

DA<sub>a</sub>：经皮吸收量 ( $\mu\text{g}/\text{cm}^2$ )，每平方厘米所吸收的原料或风险物质的量，测试条件应该和产品的实际使用条件一致。

SSA：暴露于化妆品的皮肤表面积 ( $\text{cm}^2$ )

F：产品的日使用次数 ( $\text{day}^{-1}$ )

BW：默认的人体体重 (60kg)

(2) 如果经皮吸收率是以百分比形式给予时，根据使用量，按以下公式计算：

$$SED = A \times C \times DA_p$$

其中：

SED：全身暴露量 ( $\text{mg}/\text{kg}\cdot\text{bw}/\text{day}$ )

A：以单位体重计的化妆品每天使用量 ( $\text{mg}/\text{kg}\cdot\text{bw}/\text{day}$ )

C: 在产品中的浓度 (%)

DAp: 经皮吸收率 (%)。

暴露量计算时还应考虑其他暴露途径的可能性 (如吸入、吞入等); 必要时应考虑除化妆品外其他可能来源 (如: 食品和环境等) 的暴露情况。

#### 4.4 风险特征描述

指化妆品原料和/或风险物质对人体健康造成损害的可能性和损害程度的描述。可通过计算安全边际值、终生致癌风险 (LCR)、可接受暴露水平与实际暴露量的比较分别对化妆品原料和/或风险物质对人体引起有阈值毒性效应、无阈值致癌效应和致敏效应进行描述。

##### 4.4.1 原料和/或风险物质的有阈值毒性效应风险特征描述

对于化合物的有阈值毒性效应, 通常通过计算其安全边际值进行评估。计算公式为:

$$MoS = \frac{NOAEL(BMD)}{SED}$$

其中:

MoS: 安全边际值

NOAEL: 未观察到有害作用的剂量

BMD: 基准剂量

SED: 全身暴露量 (mg/kg·bw/day)

在通常情况下, 当  $MoS \geq 100$  时, 可以判定是安全的。

100 是由种间差异 10 和种内差异 10 相乘所得, 如有毒代动力学等数据, 应考虑进行调整。如果毒理学数据质量存在缺陷, MoS 值应适当增加。

如  $MoS < 100$ , 则认为其具有一定的风险性, 原则上不允许使用, 应结合毒代动力学数据进一步评估。对于特殊使用方式的原料如染发剂, 当 MoS 值小于 100 时, 需进一步进行评估。

##### 4.4.2 原料和/或风险物质无阈值致癌效应的风险特征描述

对于原料和/或风险物质的无阈值致癌效应, 可通过计算其终生致癌风险 (LCR) 进行风险评估。计算如下:

(1) 首先按照以下公式将动物试验获得的  $T_{25}$  转换成成人 ( $HT_{25}$ ):

$$HT_{25} = \frac{T_{25}}{(BW(人)/BW(动物))^{0.25}}$$

式中：

$T_{25}$ ：对自发肿瘤发生率进行校正后，25%的实验动物的某部位发生肿瘤的剂量。

$HT_{25}$ ：由动物试验获得的  $T_{25}$  转换的人  $T_{25}$

$BW(人)$ ：体重 kg（默认的成人体重为 60kg）。

$BW(动物)$ ：试验动物的体重 kg。

(2) 根据计算得出的  $HT_{25}$  以及暴露量按以下公式计算终生致癌风险：

$$LCR = \frac{SED}{4 \times HT_{25}}$$

式中：

$LCR$ ：终生致癌风险

$SED$ ：终生每日暴露平均剂量 (mg/kg·bw/day)

如果该原料或风险物质的终生致癌风险  $< 10^{-5}$ ，则认为其引起癌症的风险性较低，可以安全使用。

如果该原料或风险物质的终生致癌风险  $\geq 10^{-5}$ ，则认为其引起癌症的风险性较高，应对其使用的安全性予以关注。

#### 4.4.3 致敏性风险特征描述

对于潜在致敏风险的原料和/或风险物质，可按以下公式通过预期无诱导致敏剂量计算得出可接受暴露水平 (AEL)。

$$AEL = \frac{NESIL}{SAF}$$

式中：

$AEL$ ：可接受暴露水平 ( $\mu\text{g}/\text{cm}^2$ )

$NESIL$ ：预期无诱导致敏剂量 ( $\mu\text{g}/\text{cm}^2$ )

$SAF$ ：致敏评估因子，根据个体差异、产品类型、使用部位、使用频率/持续时间等，确定恰当的致敏评估因子。

当  $AEL$  低于全身暴露量时，认为其引起致敏性的风险较高，应对其使用的安全性予以关注。

毒理学研究

通过一系列毒理学研究，测定化妆品原料和/或风险物质的毒理学特征，将其作为危害识别的一部分，也是化妆品安全评估的基础。毒理学研究一般应当按照《技术规范》规定的毒理学试验方法开展。选用其他国内外权威机构发布的《技术规范》未收录的毒理学试验方法或标准时，应当在评估报告中载明方法的来源、识别毒理学危害的原理，并分析结果的科学性、准确性和可靠性。

#### 5.1 急性毒性

包括急性经口和/或经皮试验等。急性毒性试验可提供短时间毒性暴露对健康危害的信息。试验结果可作为化妆品原料和/或风险物质毒性分级以及确定重复剂量毒性试验和其他毒理学试验剂量的依据。

#### 5.2 刺激性/腐蚀性

包括皮肤和/或眼睛的刺激性/腐蚀性试验。确定和评价原料和/或风险物质对局部皮肤或眼睛是否有刺激作用或腐蚀作用及其程度。

#### 5.3 皮肤致敏性

皮肤变态反应试验确定重复接触化妆品原料和/或风险物质是否可引起变态反应及其程度。

#### 5.4 皮肤光毒性

皮肤光毒性试验评价化妆品原料和/或风险物质引起皮肤光毒性的可能性。

#### 5.5 皮肤光变态反应

皮肤光变态反应试验可评估重复接触化妆品原料和/或风险物质，并在紫外线照射下引起皮肤光变态反应的可能性。

#### 5.6 遗传毒性

评价化妆品原料和/或风险物质引起遗传毒性的可能性，至少应包括一项基因突变试验和一项染色体畸变试验。

#### 5.7 重复剂量毒性

包括 28 天经口和/或经皮毒性试验、亚慢性经口和/或经皮毒性试验。

通过重复剂量经口毒性试验不仅可获得一定时期内反复接触受试物后引起的健康效应、受试物作用靶器官和受试物体内存积情况资料，还可估计接触的无有害作用水平，后者可用于选择和确定慢性试验的接触水平和初步计算人群接触的安全性水平。



通过重复剂量经皮毒性试验不仅可获得在一定时期内反复接触受试物后可能引起的健康影响资料，而且为评价受试物经皮渗透性、作用靶器官和慢性皮肤毒性试验剂量选择提供依据。

#### 5.8 生殖发育毒性

生殖发育毒性检测动物接触化妆品原料和/或风险物质后，引起生殖功能、胚胎的初期发育（如致畸）、出生前后发育、母体机能以及胚胎和胎儿发育障碍的可能性。

#### 5.9 慢性毒性/致癌性

慢性毒性试验是使动物长期地以一定方式接触受试物而引起毒性反应的试验。当某种化学物质经短期筛选试验（如遗传毒性试验）预测具有潜在致癌性，或其化学结构与某种已知致癌剂相近时，需用致癌性试验进一步验证。

#### 5.10 毒代动力学

毒代动力学试验是定量地研究在毒性剂量下原料和/或风险物质在动物体内的吸收、分布、代谢、排泄过程和特点，进而探讨其毒性的发生和发展的规律，了解其在动物体内的分布及其靶器官。同时了解不同物种在动力学方面的差异可以为从动物实验结果外推到人时的不确定因子（UF）提供理论支持。

原料和/或风险物质经过皮肤吸收后，其代谢转化可能会对其潜在毒性、体内分布和排泄造成重要影响。因此，在特定情况下，需要实施体内或体外生物转化研究，以证明或排除某些不良反应。

#### 5.11 透皮吸收

原料和/或风险物质的透皮吸收试验，可采用国际通用的透皮吸收试验方法获取相应的数据。在无透皮吸收数据时，吸收率以 100%计；若满足以下部分条件：分子量 > 500 道尔顿，高度电离，脂水分配系数  $\text{Log Pow} \leq -1$  或  $\geq 4$ ，拓扑极性表面积  $> 120 \text{Å}^2$ ，熔点  $> 200^\circ\text{C}$ ，吸收率以 10%计；若化学合成的由一种或一种以上结构单元，通过共价键链接，平均相对分子质量大于 1000 道尔顿，且相对分子质量小于 1000 道尔顿的低聚体含量少于 10%，结构和性质稳定的聚合物（具有较高生物活性的原料除外），可不考虑透皮吸收。吸收率不以 100%计时，需提供有关情况说明。

#### 5.12 其他毒理学试验资料

有经呼吸道吸收可能时，需提供吸入毒性试验资料；必要时可提供其他有助于表明原料和/或风险物质毒性的毒理学试验资料。

#### 5.13 人群安全性试验资料

包括人体安全性试验资料 and 人群流行病学资料。

人群流行病学资料包括人群流行病学调查、人群监测以及临床不良事件报告、事故报告等。

原料的安全评估

## 6.1 安全评估原则

6.1.1 按照风险评估程序对化妆品原料和/或其可能存在的风险物质进行评估，保障原料使用的安全性。

6.1.2 使用《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料应满足《技术规范》要求。

6.1.3 凡国际权威化妆品安全评估机构已公布评估结论的原料，需对相关评估资料进行分析，在符合我国化妆品相关法规要求的情况下，可采用相关评估结论。不同的权威机构评估结果不一致时，根据数据的可靠性和相关性，科学合理地采用相关评估结论。

6.1.4 凡世界卫生组织（WHO）、联合国粮农组织（FAO）等权威机构已公布的安全限量或结论，如每日允许摄入量（ADI）、每日耐受剂量（TDI）、参考剂量（RfD）、一般认为安全物质（GRAS）、具有悠久食用历史的原料等，需对相关资料进行分析，在符合我国化妆品相关法规规定的情况下，可采用相关结论。如缺少局部毒性资料，需对其局部毒性另行开展评估。不同的权威机构评估结果不一致时，根据数据的可靠性和相关性，科学合理地采用相关评估结论。

6.1.5 如香精符合我国相关国家标准或国际日用香料协会（IFRA）标准，需对相关评估资料进行分析，在符合我国化妆品相关法规要求的情况下，可采用相关评估结论。

6.1.6 对于化学结构明确，且不包含严重致突变警告结构的原料或风险物质，含量较低且缺乏系统毒理学研究数据时，可参考使用毒理学关注阈值（TTC）方法进行评估，但该方法不适用于金属或金属化合物、强致癌物（如黄曲霉毒素、亚硝基化合物、联苯胺类和胍等）、蛋白质、类固醇、高分子质量的物质、有很强生物蓄积性物质以及放射性化学物质和化学结构未知的混合物等。

6.1.7 对于缺乏系统毒理学研究数据的非功效成分或风险物质，可参考使用分组/交叉参照（Grouping/Read Across）进行评估。所参照的化学物质与该原料或风险物质有相似的化学结构，相同的代谢途径和化学/生物反应性，其中结构相似性表现在：（1）各化学物质具有相同的官能团（如醛类、环氧化物、酯类、特殊金属离子物质）；（2）各化学物质具有相同的组分或被归为相同的危害级别，具有相似的碳链长度；（3）各化学

物质在结构上（如碳链长度）呈现递增或保持不变的特征，这种特征可以通过观察各化学物质的理化特性得到；（4）各化学物质由于结构的相似性，通过化学物质或生物作用后，具有相同的前驱体或降解产物可能性。

6.1.8 根据原物理化特性、定量构效关系、毒理学资料、使用历史、临床研究、人群流行病学调查以及类似化合物的毒性等资料情况，可增加或减免毒理学终点的评估。

## 6.2 化妆品原料的理化性质

原料的理化性质可用于预测特定的毒理学特性。一般包括以下内容：

### 6.2.1 原料的名称

包括标准中文名称、通用名称、商品名称、化学名称、INCI 名称、CAS 号、EINCES 号等。

### 6.2.2 物理状态

如固体、液体、挥发性气体等。

### 6.2.3 分子结构式和相对分子量

对于复配原料，必须说明每个组成成分的分子结构式和相对分子量。

### 6.2.4 化学特性和纯度

应说明表征化学特性时使用的技术条件（紫外光谱或红外光谱、核磁、质谱、元素分析等）以及检测结果等。

应明确原料的纯度/含量以及测定方法，并说明分析方法的来源及测定原理。

在理化试验和毒性试验中使用的原料必须与产品中使用的原料相当。确保理化试验和毒性试验中使用的原料更具有代表性，差异不会带来安全风险。

### 6.2.5 杂质/残留物

除了物质的纯度以外，还必须说明可能存在的杂质/残留物的浓度或含量。

### 6.2.6 溶解度

应说明原料在水中和/或任何其他相关有机溶剂的溶解度。对于其计算值，应说明计算方法。

### 6.2.7 分配系数（Log Pow）

如有，应说明分配系数。对于其计算值，应说明计算方法。

### 6.2.8 均质性和稳定性

应说明试验条件下检测原料时使用的试验溶液的均质性。

应说明试验条件下原料的稳定性和储存条件。

### 6.2.9 异构体组成

如果原料存在异构体，用作化妆品成分的相关异构体应进行安全评估。其他异构体作为杂质，应提供相关信息。

### 6.2.10 其他相关的理化指标

如对于可吸收紫外线的成分，应说明化合物的紫外线吸收的波长及紫外线吸收光谱（如 UV-VIS 吸收光谱）。

### 6.2.11 功能和用途

该原料拟用或已用于化妆品中的使用目的、化妆品中的最高浓度等。如果化妆品原料在有吸入暴露风险的产品中使用，应该明确提及吸入暴露的可能，并且应考虑吸入暴露的健康危害效应。

此外，此原料作为其他用途（例如消费产品，工业产品）时，所用浓度也应尽可能描述。

## 6.3 矿物、动物、植物、生物技术来源的原料

### 6.3.1 矿物来源的原料，一般包括以下内容：

- (1) 原料来源；
- (2) 制备工艺：物理加工、化学修饰、纯化方法及净化方法等；
- (3) 特征性组成要素：特征性成分（%）；
- (4) 组成成分的理化特性；
- (5) 微生物情况；
- (6) 防腐剂和/或其他添加剂。

### 6.3.2 动物来源的原料，一般包括以下内容：

- (1) 物种来源（牛、羊、甲壳动物等）、物种通用名称、拉丁名、种属名称包括物种、属、科及使用的器官组织（胎盘、血清、软骨等）；
- (2) 原产国（地区）等；
- (3) 制备过程：萃取条件、水解类型、纯化方法等；
- (4) 特征性成分含量；
- (5) 形态：粉末、溶液、悬浮液等；
- (6) 特征性组成要素：特征性的氨基酸、总氮、多糖等；
- (7) 理化特性；
- (8) 微生物情况（包括病毒性污染）；

(9) 防腐剂和/或其他添加剂。

6.3.3 植物来源的原料, 一般包括以下信息:

- (1) 植物的通用名称、拉丁名;
- (2) 种属名称包括物种、属、科;
- (3) 所用植物的部分;
- (4) 感官描述: 粉末、液态、色彩、气味等;
- (5) 形态解剖学描述;
- (6) 自然生态和地理分布;
- (7) 植物的来源包括地理来源以及是否栽培或野生;
- (8) 具体制备过程: 收集、洗涤、干燥、萃取等;
- (9) 储存条件;
- (10) 特征性组成要素: 特征性成分;
- (11) 理化特性;
- (12) 微生物情况包括真菌感染;
- (13) 农药、重金属残留等;
- (14) 防腐剂和/或其他添加剂;
- (15) 如果是含有溶剂的提取液, 应说明包含的溶剂和有效成分的含量。

6.3.4 生物技术来源的原料, 一般包括以下内容:

- (1) 制备过程;
- (2) 所用的生物描述: 供体生物、受体生物、经修饰的微生物等;
- (3) 生物技术的类型/方式;
- (4) 微生物致病性;
- (5) 毒性成分包括生物代谢物、产生的毒素等;
- (6) 理化特性;
- (7) 微生物质量控制措施;
- (8) 防腐剂和/或其他添加剂。

对于特殊生物技术来源的原料, 其中经修饰的对象(如微生物)或潜在的毒性物质不能彻底去除的, 需提供数据予以说明。

6.4 香精香料

香精香料应符合我国相关国家标准和/或国际日用香料协会（IFRA）修正案及其相关标准。

## 化妆品产品的安全评估

### 7.1 评估原则

7.1.1 化妆品产品的安全评估应以暴露为导向，结合产品的使用方式、使用部位、使用量、残留等暴露水平，对化妆品产品进行安全评估，以确保产品安全性。

7.1.2 按照风险评估程序对化妆品中的各原料和/或风险物质进行风险评估。使用《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料、有限制要求的风险物质应满足《技术规范》要求；国外权威机构已建立相关限量值或已有相关评估结论的原料和/或风险物质，可采用其风险评估结论，如不同的权威机构的限量值或评估结果不一致时，根据数据的可靠性和相关性，科学合理地采用相关评估结论。

7.1.3 完成化妆品产品的安全评估后，需要排除化妆品产品皮肤不良反应的，在满足伦理要求的前提下可以进行人体皮肤斑贴试验或人体试用试验。

7.1.4 产品配方除着色剂或香料的种类或含量不同外，基础配方成分含量、种类相同，且系列名称相同的产品，可以参考已有的资料和数据，只对调整组分进行评估，并确保产品安全。

7.1.5 如果产品配方中两种或两种以上的原料，其可能产生系统毒性的作用机制相同，必要时应考虑原料的累积暴露，并进行个案分析。

7.1.6 如果产品中所含原料存在于除该类化妆品外的其他产品的显著暴露来源时，如：其他化妆品、食品、环境等，在计算安全边际值时应考虑其他来源的暴露，并进行具体分析。

7.1.7 应针对每个产品编写安全评估报告，妥善保存，及时补充上市后的安全资料。

### 7.2 产品理化稳定性评价

7.2.1 应结合产品的具体情况评价相关理化指标以确定产品的稳定性，保障每批次上市化妆品的质量稳定，一般包括以下参数：

- (1) 物理状态；
- (2) 剂型（乳液、粉等）；
- (3) 感官特性（颜色、气味等）；
- (4) pH值（在何种温度条件下）；

(5) 粘度（在何种温度条件下）；

(6) 根据具体需要的其他方面。

7.2.2 确认原料之间是否存在化学和/或生物学相互作用，并考虑相互作用产生的潜在安全风险。如存在潜在安全风险的，应当结合相关文献研究资料或理化实验数据，进行评估。

7.2.3 对与内容物直接接触的容器或载体的理化稳定性及其与产品的相容性进行评估。可参考包装或载体供应商的安全资料或安全声明等资料，对容器的稳定性进行评估。

7.2.4 对配方体系近似、包装材质相同的化妆品，可根据已有的资料和实验数据对理化稳定性开展评估工作，但需阐明理由，说明情况。

### 7.3 产品微生物学评估

7.3.1 化妆品微生物污染通常来源于原料带入，产品配制和灌装过程，以及消费者使用环节。儿童化妆品、眼部/口唇化妆品，应当对微生物污染予以特别关注。

7.3.2 对处于研发阶段的化妆品，可参考国际通用的标准或方法对其防腐体系的有效性进行评价。

7.3.3 对于防腐体系相同且配方近似的产品，可参考已有的资料和实验数据进行产品安全性评价。根据产品特性，属于不易受微生物污染的产品，即非含水产品、有机溶剂为主的产品、含水产品中如水活度 $<0.7$ 、乙醇含量 $>20\%$ （体积）、高/低pH值（ $\geq 10$ 或 $\leq 3$ ）、灌装温度高于 $65^{\circ}\text{C}$ 的产品、一次性或包装不能开启等类型的产品等，可不进行防腐效能评价，但化妆品安全性评估人员应就相关情况予以说明。

### 7.4 产品上市后的安全监测

7.4.1 对上市后产品的安全性进行监测、记录和归档。包括正常使用时发生的不良反应，消费者投诉以及后续随访等。

7.4.2 如上市产品出现下列情况，需重新评估产品的安全性：

- (1) 上市产品所用原料在毒理学上有新的发现，且会影响现有评估结果的；
- (2) 上市产品的原料质量规格发生足以引起现有安全评估结果变化的；
- (3) 上市产品正常使用引起的不良反应率呈明显增加趋势，或正常使用产品导致严重不良反应的；
- (4) 其他影响产品质量安全的情况。

### 7.5 儿童化妆品评估要求

7.5.1 进行儿童化妆品评估时，在危害识别、暴露量计算等方面，应结合儿童生理特点。

7.5.2 应明确其配方设计的原则，并对配方使用原料的必要性进行说明，特别是香料、着色剂、防腐剂及表面活性剂等原料。

7.5.3 原则上不允许使用以祛斑美白、祛痘、脱毛、除臭、去屑、防脱发、染发、烫发为目的的原料，如因其他目的使用可能具有上述功效的原料时，需对使用的必要性及针对儿童化妆品使用的安全性进行评价。

7.5.4 应选用有较长期安全使用历史的化妆品原料，不鼓励使用基因技术、纳米技术等新技术制备的原料，如无替代原料必须使用时，需说明原因，并针对儿童化妆品使用的安全性进行评价。

## 8. 安全评估报告

### 8.1 化妆品原料的安全评估报告

化妆品原料的安全评估报告通常包括摘要、原物理化性质、评估过程、评估结果分析、风险控制措施或建议、安全评估结论、安全评估人员签名及简历、参考文献和附录等内容。

参考格式详见附录 1。

### 8.2 化妆品产品的安全评估报告

化妆品产品的安全评估报告通常包括摘要、产品简介、产品配方、配方设计原则（仅针对儿童化妆品）、配方中各成分的安全评估、可能存在的风险物质评估、风险控制措施或建议、安全评估结论、安全评估人员签名及简历、参考文献和附录等内容。

参考格式详见附录 2，化妆品产品安全评估报告（完整版）示例见附录 3，化妆品产品安全评估报告（简化版）示例见附录 4。

## 9. 说明

### 9.1 化妆品产品安全评估报告（简化版）可采用的证据

按照以下顺序依次选择至少一种证据进行评估以确定其安全性。

9.1.1 《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料，必须符合其使用要求；

9.1.2 国内外权威机构，如世界卫生组织（WHO）、联合国粮农组织（FAO）、欧盟消费者安全科学委员会（SCCS）、美国化妆品原料评价委员会（CIR）等已公布的安全限量或结论如化妆品安全使用结论、每日允许摄入量、每日耐受剂量、参考剂量、一般认为安全物质（GRAS）等，国际日用香料协会（IFRA）已发布的香料原料标准等，如有限制条件（如刺激性要求等），在符合其限制条件下，结合原料历史使用浓度、



产品或原料毒理学测试或人体临床测试结果，可采用其限量或结论；只有系统毒性评估结论的，结合原料历史使用浓度、产品或原料毒理学测试结果或人体临床测试结果，对产品刺激性等局部毒性进行评估后，可采用其限量或结论。

9.1.3 原料在本企业已上市（至少 3 年）的相同使用方法产品中的浓度（即：本企业的历史使用浓度）作为评估的证据。使用部位和使用方法相同产品配方中原料使用浓度原则上应不高于原料在本企业的历史使用浓度，如高于历史使用浓度，应按照本导则进行安全评估证明其安全性；原料历史使用浓度可相互参考，暴露量高和接触时间长的产品，可用于暴露量低和接触时间短的产品评估，但需要从目标人群、使用部位和使用方式等方面充分分析说明其合理性。

使用本企业的历史使用浓度应提供的证明文件包括以下内容：（1）国产特殊产品和进口产品：注册或备案配方（须与申报时提交配方一致），产品注册证书或备案凭证，产品上市证明文件；（2）国产普通产品：带原料含量或可计算原料含量的生产记录、工艺单、配料单，备案凭证，产品上市证明文件；（3）不良反应监测情况说明；（4）其他证明文件。

9.1.4 以上三种证据类型均不能评估时，化妆品监管部门公布的原料最高历史使用量可为评估提供参考。需评估产品中原料使用浓度原则上不应高于化妆品监管部门发布的原料最高历史使用量。

9.1.5 对于无法使用上述任一证据类型的原料和/或风险物质，应按照本导则要求的评估程序进行评估证明其安全性。

## 9.2 其他

本导则所列条款为化妆品安全评估中所涉及的全部内容，实际进行产品评估时，评估人员需按照本导则结合产品的具体情况进行评估。

### 术语和释义

下列术语和释义适用于本导则。

#### 10.1 危害（Hazard）

原料或风险物质在暴露情况下对人体产生不良效应的属性。

#### 10.2 风险（Risk）

暴露条件下，原料或风险物质对使用者产生有害作用的可能性及强度的定量或定性估计。

#### 10.3 风险物质（Risk Substance）

化妆品中可能存在的安全性风险物质是指由化妆品原料带入、生产过程中产生或带入的，可能对人体健康造成危害的物质。

#### 10.4 剂量 (Dose)

直接与机体的吸收部位（消化道、粘膜、皮肤等）接触，可供吸收的量，通常以 mg/kg·bw 表示。

#### 10.5 未观察到有害作用的剂量 (No Observed Adverse Effect Level, NOAEL)

在规定的试验条件下，用现有的技术手段或检测指标未观察到任何与受试物有关的毒性作用的最大剂量。

#### 10.6 观察到有害作用的最低剂量 (Lowest Observed Adverse Effect Level, LOAEL)

在规定的试验条件下，受试物引起实验动物组织形态、功能、生长发育等有害效应的最低剂量。

#### 10.7 基准剂量 (Benchmark Dose, BMD)

一种物质引起某种特定的、较低健康风险发生率（一般在 1%~10%之间）的剂量。

#### 10.8 有阈值毒性效应 (Threshold Effects)

必须在超过一定的剂量限值（阈剂量）之后，才会引起机体出现损伤的毒性效应。

#### 10.9 无阈值毒性效应 (Non-Threshold Effects)

多为遗传毒性和致癌性，是已知或假设其作用是无阈值的，即已知或假设大于零的所有剂量都可以诱导出有害作用的毒性效应。

#### 10.10 全身暴露量 (Systemic Exposure Dosage, SED)

通过各种暴露途径进入体循环的化学物质的预计量。通常以 mg/kg·bw/day 表示。

#### 10.11 安全边际值 (Margin of Safety, MoS)

NOAEL 或 BMD 与预期的全身暴露量之间的比值。

#### 10.12 不确定因子 (Uncertainty factor, UF)

即安全系数。为解决由动物实验资料外推至人的不确定因素及人群毒性资料本身所包含的不确定因素而设置的转换系数。不确定系数通常为 100，但可根据原料来源、理化性质、毒性大小、代谢特点、蓄积性、试验资料来源等因素综合考虑不确定系数的大小。

#### 10.13 可接受的致癌风险 (Acceptable Risk of Cancer)

能够为社会公认并能为公众接受的终生致癌风险概率，通常应小于  $10^{-5}$ ，可因时间、地点、条件和公众的接受能力而不同。

#### 10.14 T<sub>25</sub>

对自发肿瘤发生率进行校正后，引起 25% 的实验动物出现肿瘤的剂量。

#### 10.15 每日允许摄入量 (Acceptable Daily Intake, ADI)

是指人终生每日从食物或饮水中摄入某种化学物质，对健康无任何已知不良效应的剂量。

#### 10.16 每日耐受摄入量 (Tolerable Daily Intake, TDI)

是指人终生每日摄入某种物质，对健康无任何已知不良效应的剂量。

#### 10.17 参考剂量 (Reference Dose, RfD)

环境介质（空气、水、土壤、食品等）中化学物质的日平均接触剂量的估计值，人群（包括敏感亚群）在终生接触该剂量水平下，预期一生中发生非致癌或非致突变有害效应的危险度可接受或可忽略。

#### 10.18 预期无诱导皮肤过敏的剂量水平 (No Expected Sensitization Induction Level, NESIL)

不产生诱导致敏效应的最高剂量或浓度。

#### 10.19 毒理学关注阈值 (Threshold of Toxicological Concern, TTC)

化学品暴露阈值，在该暴露水平下，预计不存在危害人类健康的风险。

#### 10.20 分组/交叉参照 (Grouping/Read Across)

用一种/组化学物质的毒性终点信息预测另一种/组化学物质相同毒性终点的过程。目标化学物和源化学物被认为是“相似”的（通常基于结构相似性和/或相同的作用模式或机制）。

附录：1. 化妆品原料的安全评估报告

化妆品产品的安全评估报告

化妆品安全评估报告示例（完整版）

4. 化妆品安全评估报告示例（简化版）

## APPENDIX B

### 化妆品监督管理常见问题解答（一），Answers to frequently asked questions about cosmetics supervision and management (1), 2019, NMPA.

为进一步规范化妆品监督管理工作，引导消费者科学理性消费，国家药监局化妆品监管司整理了化妆品监督管理中常见问题，并依据我国现行化妆品法规规定和有关技术规范，逐一进行了解答。具体如下：

**问：为何经常听说国外有所谓的“化妆品”，而我国化妆品法规中并没有“化妆品”的概念？**

答：需要明确指出的是，不但是我国，世界大多数的国家在法规层面均不存在“化妆品”的概念。避免化妆品和药品概念的混淆，是世界各国（地区）化妆品监管部门的普遍共识。部分国家的药品或医药部外品类别中，有些产品同时具有化妆品的使用目的，但这类产品应符合药品或医药部外品的监管法规要求，不存在单纯依照化妆品管理的“化妆品”。

我国现行《化妆品卫生监督条例》中第十二条、第十四条规定，化妆品标签、小包装或者说明书上不得注有适应症，不得宣传疗效，不得使用医疗术语，广告宣传中不得宣传医疗作用。对于以化妆品名义注册或备案的产品，宣称“药妆”“医学护肤品”等“化妆品”概念的，属于违法行为。

**问：寡肽-1 和表皮生长因子（EGF）有何区别？EGF 可否作为化妆品原料使用？**

答：寡肽-1 和人寡肽 1（表皮生长因子，EGF）非同一种物质。寡肽-1 为甘氨酸、组氨酸和赖氨酸等 3 种氨基酸组成的合成肽。而人寡肽-1 又名表皮生长因子（Epidermal Growth Factor, EGF），是由 53 个氨基酸组成的“53 肽”，分子量为 6200 道尔顿。

寡肽-1 收录于我国《已使用化妆品原料名称目录》（2015 年版），一般作为皮肤调理剂使用。而人寡肽-1 未被收录于该目录，一般在医学领域使用较多，临床适应症为外用治疗烧伤、创伤及外科伤口愈合，加速移植的表皮生长。由于分子量较大，EGF 在正常皮肤屏障条件下较难被吸收，一旦皮肤屏障功能不全，可能会引发其它潜在安全性问题。基于有效性及安全性方面的考虑，EGF 不得作为化妆品原料使用。

综上，不同于寡肽-1，人寡肽-1（EGF）不得作为化妆品原料使用。在配方中添加或者产品宣称含有人寡肽-1 或 EGF 的，均属于违法产品。

**问：化妆品原料中添加的如稳定剂等保护原料的成分，是否应当在产品标签上进行标注？**

答：根据国家标准《消费品使用说明 化妆品通用标签》（GB5296.3-2008），化妆品销售包装的可视面上应真实地标注化妆品全部成分的名称。

化妆品成分是指生产过程中有目的地添加到产品配方中，并在最终产品中起到一定作用的成分。为了保证化妆品原料质量而在原料中添加的微量稳定剂、防腐剂、抗氧化剂等成分，虽然在产品配方中应当进行填报，但不属于化妆品成分的范畴，可以在产品标签上进行标注。

**问：进口非特殊用途化妆品备案境内责任人与原行政许可在华申报责任单位有何区别？**

答：进口非特殊用途化妆品备案境内责任人与原行政许可在华申报责任单位主要有以下两点区别：

一是授权的范围和承担的责任不同。境内责任人根据境外化妆品生产企业授权，负责产品的进口和经营，并依法承担相应的产品质量安全责任；在华申报责任单位负责代理化妆品行政许可申报有关事宜，对行政许可申报材料负责并承担相应的法律责任。

二是境外化妆品生产企业可以授权的数量不同。境外化妆品生产企业可以根据经营活动的需要，授权多个境内责任人，但授权范围不得重复，同一产品不得授权多个境内责任人；同一家进口化妆品生产企业只能授权一家在华责任申报单位。

**问：进口非特殊用途化妆品备案境内责任人如何变更？**

答：境外化妆品企业根据需要，可以变更境内责任人及其授权产品范围。变更境内责任人的，新的境内责任人应当按要求进行网上备案系统的用户名称注册；仅变更授权产品范围的，境内责任人应当通过网上备案平台重新上传授权书。

变更境内责任人涉及已备案产品的，变更前后的境内责任人应就前期已经进口和销售的产品责任归属问题协商一致后，由拟变更后的境内责任人通过网上备案系统平台提出变更，同时提交原境内责任人签署的知情同意书，变更经原境内责任人通过网上备案系统平台进行确认后完成。

**问：全面实施备案管理之前申报行政许可未获批准的进口非特殊用途化妆品，后续可否进行备案？**

答：2018年11月10日前已受理进口非特殊用途化妆品行政许可未获批准的产品，不批准理由涉及产品安全性原因的，后续不得办理备案；不涉及安全性原因的，后续可以由境内责任人办理备案。备案时应当同时提交《不批准决定书》并说明重新申报的理由。原行政许可申报资料中的产品检验报告、安全性评估资料以及相关证明性文件等可作为备案资料提交，相关资料原件已随原行政许可申请提交无法获取的，可提供复印件并加盖境内责任人的公章，同时提交相关情况说明。

**问：全面实施备案管理之前已获行政许可的进口非特殊用途化妆品，后续可否进行备案？**

答：2018年11月10日前已获行政许可的产品，许可有效期结束后仍需继续进口的，或者有效期结束前原行政许可事项发生变更的，应当在有效期届满5个工作日前，或变更产品上市之前，按照要求办理备案，备案完成后原纸质版凭证自动失效。境内责任人与原在华申报责任单位为不同的企业法人时，还应当同时提交原在华申报责任单位签署的知情同意书。原行政许可申报资料中的产品检验报告、安全性评估资料以及相关证明性文件等可作为备案资料提交，相关资料原件已随原行政许可申请提交无法获取的，可提供复印件并加盖境内责任人的公章，同时提交相关情况说明。

**问：此前在自贸试验区已完成备案的进口非特殊用途化妆品，后续如何开展事中事后监管？**

答：2018年11月10日前，在天津、辽宁、上海、浙江、福建、河南、湖北、广东、重庆、四川、陕西等自贸试验区试点实施进口非特殊用途化妆品备案管理的省份，已经按照试点备案管理要求完成备案的进口产品，其产品的事中事后监管措施、进口省份管理等，与《关于在全国范围实施进口非特殊用途化妆品备案管理有关事宜的公告》（2018年第88号）提出的备案管理要求一致。

**问：能否在提交进口非特殊用途化妆品备案时，一并选择多个进口省份？**

答：系统默认境内责任人所在省份即为进口省份，后续境内责任人需要从其它省份进口时，境内责任人在备案系统中增加填报进口省份及收货人信息后，系统将自动在原备案凭证的“进口省份”栏目中增加载明新增省份名称。该项操作无须人工审查，但境内责任人应根据实际情况如实填写。监管部门后续开展监督检查时，发现境内责

任人并未从所填报省份进口的，将按提交虚假备案资料进行调查处理，一经查实将对该境内责任人按照异常用户予以冻结。

**问：进口非特殊用途化妆品备案电子信息凭证的有效期如何设定？**

答：进口非特殊用途化妆品调整为备案管理以后，对备案产品的备案电子信息凭证不再设定有效期。境内责任人应当每年定期通过网上备案系统平台向化妆品监督管理部门报送已备案产品上一年度的生产或进口、上市销售、不良反应监测以及接受行政处罚等有关情况。

**【相关链接】**

图解政策：化妆品监督管理常见问题解答（一） 2019-02-13

## APPENDIX C

《化妆品注册备案资料管理规定》政策解读, Policy Interpretation of the “*Regulations on the Administration of Cosmetics Registration and Filing Documents*”, 2021, NMPA.

### 第一章 总 则

第一条 为规范化妆品注册备案管理工作, 保证化妆品注册、备案各项资料的规范提交, 依据《化妆品监督管理条例》《化妆品注册备案管理办法》等有关法律法规要求, 制定本管理规定。

第二条 在中华人民共和国境内申请化妆品注册或办理备案时, 应当按照本管理规定的要求提交资料。

第三条 化妆品注册人、备案人应当遵循风险管理的原则, 以科学研究为基础, 对提交的注册备案资料的合法性、真实性、准确性、完整性和可追溯性负责, 并且承担相应的法律责任。境外化妆品注册人、备案人应当对境内责任人的注册备案工作进行监督。

第四条 化妆品注册备案资料应当使用国家公布的规范汉字。除注册商标、网址、专利名称、境外企业的名称和地址等必须使用其他文字的, 或约定俗成的专业术语(如 SPF、PFA、PA、UVA、UVB、维生素 C 等), 所有其他文字均应完整、规范地翻译为中文, 并将原文附在相应的译文之后。

第五条 化妆品注册备案资料应当符合国家有关用章规定, 签章齐全, 具有法律效力。境外企业及其他组织不使用公章的, 应当由法定代表人或者企业(其他组织)负责人签字。除用户信息相关资料外, 产品的注册备案资料中如需境外化妆品注册人、备案人签章的, 其法定代表人或者负责人可授权该注册人、备案人或者境内责任人的签字人签字。授权委托签字的, 应当提交授权委托书原件及其公证书原件, 授权委托书中应当写明授权签字的事项和范围。

除政府主管部门或者有关机构、注册和备案检验机构、公证机关等出具的资料原件外, 化妆品注册备案资料均应由境内注册人、备案人或者境内责任人逐页加盖公章。使用带有电子加密证书的公章的, 可直接在电子资料上加盖电子公章。

第六条 化妆品注册备案资料中应当使用我国法定计量单位, 使用其他计量单位时, 应当折算为我国法定计量单位; 应当准确引用参考文献, 标明出处, 确保有效溯源; 应当规范使用标点符号、图表、术语等, 保证资料内容准确规范。



第七条 化妆品注册备案资料中，出现的同项内容应当保持前后一致；有相关证明文件的，应当与证明文件中所载内容一致。

第八条 化妆品注册备案的文本资料中主体文字颜色应当为黑色，内容易于辨认，设置合适的行间距和页面边距，确保在打印或者装订中不丢失文本信息。

第九条 化妆品注册备案的纸质资料应当使用国际标准 A4 型规格纸张，内容完整清晰，不得涂改。化妆品的包装展开图片等确需更大尺寸纸张的，可使用其他规格纸张，确保妥善置于 A4 规格资料内。纸质文件资料的载体和书写材料应当符合耐久性的要求。

## 第二章 用户信息相关资料要求

### 第一节 资料项目及要求

第十条 首次申请特殊化妆品注册或者办理普通化妆品备案时，境内的注册申请人、备案人和境内责任人应当提交以下用户信息相关资料：

- (一) 注册人备案人信息表（附 1）及质量安全负责人简历；
- (二) 注册人备案人质量管理体系概述（附 2）；
- (三) 注册人备案人不良反应监测和评价体系概述（附 3）；
- (四) 境外注册人、备案人应当提交境内责任人信息表（附 4）；
- (五) 境内责任人授权书原件（式样见附 5）及其公证书原件；
- (六) 注册人、备案人有自行生产或者委托境外生产企业生产的，应当提交生产企业信息表（附 6）和质量安全负责人信息，一次性填报已有生产企业及其信息。生产企业为境外的，应当提交境外生产规范证明资料原件。

第十一条 我国境内仅从事受托生产的企业，应当提交第十条第（六）项中的生产企业信息表，以便关联确认委托生产关系。

第十二条 具有境内注册人或者备案人、境内责任人、生产企业等多重身份的，或者同一境内责任人对应多个境外注册人、备案人的，可以一次性提交全部相关资料，取得相应的用户权限。已有用户可以根据情况补充提供相关资料，增加用户权限。

第十三条 质量安全负责人的简历应当包括与其要求相关的教育背景、工作经历以及其他内容。

第十四条 质量管理体系概述是对注册人、备案人质量管理控制能力和过程的总结描述，应当如实客观地反映实际情况，包括供应商遴选、原料验收、生产及质量控制、产品

留样等管理制度。语言应当简明扼要，体现出质量控制关键点设置和日常执行管理要求。

注册人、备案人同时存在自行生产和委托生产的，应当分别提交相应版本的质量管理体系概述。

第十五条 不良反应监测和评价体系概述是对注册人、备案人和境内责任人不良反应监测评价能力和过程的总结描述，应当如实客观地反映实际情况。语言应当简明扼要，体现出不良反应监测关键点、各环节设置和日常执行管理要求。

第十六条 境内责任人授权书应当至少明确体现以下内容和信息：注册人、备案人和境内责任人名称，授权和被授权关系，授权范围，授权期限。同一产品不得授权多个境内责任人，境内责任人应当在授权范围内开展注册备案工作。

第十七条 境外生产企业应当提交生产企业符合质量管理体系或者生产质量管理规范的资质证书、文件等证明资料，证明资料应当由所在国（地区）政府主管部门、认证机构或者具有所在国（地区）认证认可资质的第三方出具或者认可，载明生产企业名称和实际生产地址信息。

无法提供证明资料原件的，应当提供由中国公证机关公证的或由我国使（领）馆确认的复印件。

## 第二节 用户信息和资料更新

第十八条 用户信息或者相关资料发生变化时，应当及时进行更新，确保注册备案信息服务平台中的用户信息和相关资料真实准确。

更新方式主要包括自行更新、一般审核更新、生产场地更新以及其他各具体规定情形的审核更新。属于审核更新的，经药品监督管理部门审核后，完成相关信息和资料的更新。

第十九条 用户权限相关资料中，可自行更新的内容包括法定代表人信息、质量安全负责人信息、联系信息。

以上信息发生变化时，用户应当及时自行更新。

第二十条 用户权限相关资料中，可进行一般审核更新的内容包括基本信息、质量管理体系概述、不良反应监测和评价体系概述、境内责任人的授权范围和授权期限。

一般审核更新时，应当提交一般审核更新信息表（附7），同时一并提交符合要求的相关资料。其中，境外注册人、备案人名称发生变化的，应当提供由所在国（地区）政府主管部门或者有关机构出具的主体未发生变化的相关证明文件原件，无法提交原件

的，应当提供由中国公证机关公证的或者由我国使（领）馆确认的复印件；境外生产企业生产场地仅地址文字改变的，应当提供由所在国（地区）政府主管部门或者有关机构出具的生产现场未改变的证明文件原件，无法提交原件的，应当提供由中国公证机关公证的或者由我国使（领）馆确认的复印件；境内责任人授权范围改变的，新授权范围应当包括原授权范围。

第二十一条 用户权限相关资料中，可进行生产场地更新的内容为生产企业的生产场地信息。具体情形包括：生产场地搬迁、生产场地增加、生产场地减少、仅生产规范证明文件更新。

进行生产场地更新时，应当提交生产场地更新信息表（附8）。其中，境外生产企业的生产场地搬迁或者增加，或生产质量管理规范证明文件进行更新的，应当按要求提供境外生产质量管理规范证明相关资料。

第二十二条 根据实际生产经营情况，如需增加自行生产或者委托境外生产企业的，可提交相关资料增加生产企业信息，必要时还需补充提交相应的质量管理体系概述。

第二十三条 在进行用户信息更新时，企业应当首先对照用户名下全部信息自行检查。如有多个信息同时发生变化的，应同时更新，一并提交相关资料。

第二十四条 境内责任人授权书所载授权期限到期后，应当重新提交更新的授权书，延长授权期限。逾期未重新提交的，境内责任人将无法继续为对应的境外注册人、备案人办理新增的注册或者备案事项，名下已开展的注册或者备案事项可继续办理完毕。

境外生产质量管理规范证明资料有有效期限的，应当及时更新证明资料，最长不得超过有效期限截止后90日；无有效期限的，应当每五年提交最新版本。

第二十五条 根据实际生产经营情况，需对用户权限进行注销的，应当在相关产品全部完成注销或变更后，提交用户权限注销信息表（附9），进行用户权限注销。

### 第三章 注册与备案资料要求

第二十六条 注册人、备案人办理注册或者备案时，应当提交以下资料：

- （一）《化妆品注册备案信息表》及相关资料；
- （二）产品名称信息；
- （三）产品配方；
- （四）产品执行的标准；
- （五）产品标签样稿；

(六) 产品检验报告；

(七) 产品安全评估资料。

第二十七条 注册人、备案人应当逐项填写《化妆品注册备案信息表》（附 10），并提交相关资料。

(一) 产品名称包括中文名称和进口产品的外文名称，产品中文名称应当符合化妆品标签管理相关规定。

(二) 注册人、备案人应当按照《化妆品监督管理条例》和化妆品分类规则与分类目录的规定，确定产品类别以及相应的产品分类编码，涉及特殊化妆品功效宣称的，应当按照特殊化妆品申报。

(三) 委托境内企业生产的化妆品，注册人、备案人或者境内责任人应当选择已开通用户权限的生产企业进行关联，经生产企业确认后提交注册申请或者办理备案。

委托境外企业生产的化妆品，注册人、备案人或者境内责任人应当提交委托关系文件。委托关系文件应当至少载明产品名称、委托方、受托生产企业名称、生产地址、本产品接受委托的日期、受托生产企业法人或者法人授权人的签章。注册人、备案人与受托生产企业属于同一集团公司的，可提交属于同一集团公司的证明资料以及企业集团出具的产品质量保证文件以确认委托关系。

(四) 进口产品应当提供由化妆品注册人、备案人所在国或生产国（地区）政府主管部门或者行业协会等机构出具的已上市销售证明文件，境内注册人、备案人委托境外生产企业生产的和产品配方专为中国市场设计的除外。已上市销售证明文件应当至少载明注册人、备案人或者生产企业的名称、产品名称、出具文件的机构名称以及文件出具日期，并由机构签章确认。

1. 组合包装产品同时存在进口部分和国产部分的，仅提交进口部分的已上市销售证明文件。

2. 专为中国市场设计销售包装的，应当提交该产品在化妆品注册人、备案人所在国或生产国（地区）的已上市销售证明文件，同时提交产品配方、生产工艺与化妆品注册人、备案人所在国或者生产国（地区）产品一致的说明资料。

(五) 产品配方专为中国市场设计的进口产品（境内委托境外生产的除外），应当提交以下资料：

1. 针对中国消费者的肤质类型、消费需求等进行配方设计的说明资料；

2. 在中国境内选用中国消费者开展消费者测试研究或者人体功效试验资料。

(六) 进口产品的已上市销售证明文件、委托关系文件或者属于一个集团公司的证明资料等文件可同时列明多个产品。这些产品申请注册或者办理备案时，其中一个产品可使用原件，其他产品可使用复印件，并说明原件所在的产品名称以及相关受理编号、注册证号或者备案编号等信息。

第二十八条 注册人、备案人应当提交产品名称命名依据，产品名称命名依据中应当指明商标名、通用名、属性名，并分别说明其具体含义。进口产品应当对外文名称和中文名称分别进行说明，并说明中文名称与外文名称的对应关系（专为中国市场设计无外文名称的除外）。

产品中文名称中商标名使用字母、汉语拼音、数字、符号等的，应当提供商标注册证。

第二十九条 产品配方为生产投料配方，应当符合以下要求：

(一) 配方表要求。产品配方表应当包括原料序号、原料名称、百分含量、使用目的等内容（附 11）。

1.原料名称。产品配方应当提供全部原料的名称，原料名称包括标准中文名称、国际化化妆品原料名称（简称 INCI 名称）或者英文名称。配方成分的原料名称应当使用已使用的化妆品原料目录中载明的标准中文名称、INCI 名称或者英文名称；配方中含有尚在安全监测中化妆品新原料的，应当使用已注册或者备案的原料名称；进口产品原包装标注成分的 INCI 名称与配方成分名称不一致的，应当予以说明。

使用来源于石油、煤焦油的碳氢化合物（单一组分除外）的，应当在产品配方表备注栏中标明相关原料的化学文摘索引号（简称 CAS 号）；使用着色剂的，应当在产品配方原料名称栏中标明《化妆品安全技术规范》载明的着色剂索引号（简称 CI 号），无 CI 号的除外；使用着色剂为色淀的，应当在着色剂后标注“（色淀）”，并在配方备注栏中说明所用色淀的种类；含有与产品内容物直接接触的推进剂的，应当在配方备注栏中标明推进剂的种类、添加量等；使用纳米原料的，应当在此类成分名称后标注“（纳米级）”。

2.百分含量。产品配方应当提供全部原料的含量，含量以质量百分比计，全部原料应当按含量递减顺序排列；含两种或者两种以上成分的原料（香精除外）应当列明组成成分及相应含量。

3.使用目的。应当根据原料在产品中的实际作用标注主要使用目的；申请祛斑美白、防晒、染发、烫发、防脱发的产品，应当在配方表使用目的栏中标注相应的功效成分，如果功效原料不是单一成分的，应当在配方表使用目的栏中明确其具体的功效成分。

4.备注栏。以下情形应当在备注栏中说明：使用变性乙醇的，应当说明变性剂的名称及用量；使用类别原料的，应当说明具体的原料名称；直接来源于植物的，应当说明原植物的具体使用部位。

（二）注册人、备案人或者境内责任人应当填写产品所使用原料的生产商信息并上传由原料生产商出具的原料安全信息文件。原料生产商已根据《化妆品原料安全相关信息报送指南》（附12以及附13）报送原料安全相关信息（附14）的，注册人、备案人或者境内责任人可填写原料报送码关联原料安全信息文件。

（三）使用了尚在安全监测中化妆品新原料的，注册人、备案人或者境内责任人应当经新原料注册人、备案人确认后，方可提交注册申请或者办理备案。

（四）产品配方香精可按两种方式填写，分别提交以下资料：

1.产品配方表中仅填写“香精”原料的，无须提交香精中具体香料组分的种类和含量；产品标签标识香精中的具体香料组分的，以及进口产品原包装标签标识含具体香料组分的，应当在配方表备注栏中说明。

2.产品配方表中同时填写“香精”及香精中的具体香料组分的，应当提交香精原料生产商出具的关于该香精所含全部香料组分种类及含量的资料。

（五）使用贴、膜类载体材料的，应当在备注栏内注明主要载体材料的材质组成，同时提供其来源、制备工艺、质量控制指标等资料。

（六）产品配方中使用动物脏器组织及血液制品提取物作为原料的，应当提供其来源、组成以及制备工艺，并提供原料生产国允许使用的相关文件。

第三十条 产品执行的标准包括全成分、生产工艺简述、感官指标、微生物和理化指标及其质量控制措施、使用方法、贮存条件、使用期限等内容，应当符合国家有关法律法规、强制性国家标准和技术规范的要求（式样及编制说明见附15，样例见附16）。

（一）产品名称。包括中文名称和进口产品的外文名称。

（二）全成分。包括生产该产品所使用的全部原料的序号、原料名称和使用目的，所有原料应当按含量递减顺序排列。

（三）生产工艺简述。

1.应当简要描述实际生产过程的主要步骤，包括投料、混合、灌装等。配方表2个以上原料的预混合、灌装等生产步骤在不同生产企业配合完成的，应当予以注明。

2.应当体现主要生产工艺参数范围，全部原料应当在生产步骤中明确列出，所用原料名称或者序号应当与产品配方中所列原料一致；若同一原料在不同步骤阶段中使用，应

当予以区分；若生产过程中需使用但在后续生产步骤中去除的水、挥发性溶剂等助剂，应当予以注明。

（四）感官指标。应当分别描述产品内容物的颜色、性状、气味等指标。套装产品应当分别说明各部分的感官指标，使用贴、膜类载体材料的产品应当分别描述贴、膜类材料以及浸液的颜色、性状等。

1.颜色是指产品内容物的客观色泽。同一产品具有可区分的多种颜色，应当逐一描述；难以区分颜色的，可描述产品目视呈现或者使用时的主要色泽，也可描述颜色范围。

2.性状是指产品内容物的形态。

3.气味是指产品内容物是否有气味。

（五）微生物和理化指标及质量控制措施。

1.应当提交对产品实际控制的微生物和理化指标，微生物和理化指标应当符合《化妆品安全技术规范》《化妆品注册和备案检验工作规范》的要求。

2.应当根据产品实际控制的微生物和理化指标提交相应的质量控制措施。

3.采用检验方式作为质量控制措施的，应当注明检验频次，所用方法与《化妆品安全技术规范》所载方法完全一致的，应当填写《化妆品安全技术规范》的检验方法名称；与《化妆品安全技术规范》所载方法不一致的，应当填写检验方法名称，说明该方法是否与《化妆品安全技术规范》所载方法开展过验证，完整的检验方法和方法验证资料留档备查。

4.采用非检验方式作为质量控制措施的，应当明确具体的实施方案，对质量控制措施的合理性进行说明，以确保产品符合《化妆品安全技术规范》要求。

（六）使用方法。应当阐述化妆品的使用方法，对使用人群和使用部位有特殊要求的，应当予以说明；安全警示用语应当符合化妆品标签管理规定和《化妆品安全技术规范》等相关法规的要求。

（七）贮存条件。应当根据产品包装及产品自身稳定性等特点设定产品贮存条件。

（八）使用期限。应当根据产品包装、产品自身稳定性或者相关实验结果，设定产品的使用期限。

第三十一条 注册人、备案人或者境内责任人应当逐项填写《产品标签样稿》（附17），填写的使用方法、安全警示用语、贮存条件、使用期限等内容应当符合产品执行的标准。

进口化妆品应当提交生产国（地区）产品的销售包装（含说明书），以及外文标签的中文翻译件。

第三十二条 普通化妆品办理备案时、特殊化妆品上市前，注册人、备案人或者境内责任人应当上传产品销售包装的标签图片，图片应当符合以下要求：

（一）图片包括全部包装可视面的平面图和可体现产品外观的立体展示图，图片应当完整、清晰。平面图应当容易辨别所有标注内容；无法清晰显示所有标注内容的，还应当提交局部放大图或者产品包装设计图；

（二）使用电子标签的，应当提交电子标签内容，销售包装上的图码应当是注册备案信息服务平台生成的预置图码；

（三）上传图片的标签内容和说明书内容不得超出产品标签样稿载明的内容；

（四）存在多种销售包装的，应当提交所有的销售包装的标签图片。符合以下一种或多种情形的，提交其中一种销售包装的标签图片，其他销售包装的标签图片可不重复上传：

- 1.仅净含量规格不同的；
- 2.仅在已上传销售包装上附加标注销售渠道、促销、节日专款、赠品等信息的；
- 3.仅销售包装颜色存在差异的；
- 4.已注册或者备案产品以套盒、礼盒等形式组合销售，组合过程不接触产品内容物，除增加组合包装产品名称外，其他标注的内容未超出每个产品标签内容的；
- 5.通过文字描述能够清楚反映与已上传销售包装差异，并已备注说明的。

第三十三条 注册或者备案产品的产品检验报告，由化妆品注册和备案检验机构出具，应当符合《化妆品安全技术规范》《化妆品注册和备案检验工作规范》等相关法规的规定。

（一）产品检验报告包括微生物与理化检验、毒理学试验、人体安全性试验报告和人体功效试验报告等。

- 1.产品检验报告的受检样品应当为同一产品名称、同一批号的产品。
- 2.产品检验报告中载明的产品信息应当与注册或者备案产品相关信息保持一致。由于更名等原因，导致检验报告中产品名称、企业名称等不影响检验结果的信息与注册备案信息不一致的，应当予以说明，并提交检验报告变更申请表和检验检测机构出具的补充检验报告或者更正函。



- 3.多个生产企业生产同一产品的，应当提供其中一个生产企业样品完整的产品检验报告，并提交其他生产企业样品的微生物与理化检验报告。
- 4.多色号系列普通化妆品按《化妆品注册和备案检验工作规范》抽样进行毒理学试验的，可作为一组产品进行备案，每个产品均应附上系列产品的名单、基础配方和着色剂一览表以及抽检产品名单。
- 5.宣称新功效的化妆品，按照《化妆品注册和备案检验工作规范》以及相关技术法规文件开展检验。

(二) 普通化妆品的生产企业已取得所在国（地区）政府主管部门出具的生产质量管理体系相关资质认证，且产品安全风险评估结果能够充分确认产品安全性的，可免于提交该产品的毒理学试验报告，有下列情形的除外：

- 1.产品宣称婴幼儿和儿童使用的；
  - 2.产品使用尚在安全监测中化妆品新原料的；
  - 3.根据量化分级评分结果，备案人、境内责任人、生产企业被列为重点监管对象的。
- 有多个生产企业生产的，所有生产企业均已取得所在国（地区）政府主管部门出具的生产质量管理体系相关资质认证的，方可免于提交毒理学试验报告。

(三) 申请特殊化妆品注册时应当提交符合化妆品功效宣称评价相关规定的人体功效试验报告。

- 1.特殊化妆品宣称的功效试验报告应当由化妆品注册和备案检验机构出具。
- 2.多色号系列防晒化妆品按《化妆品注册和备案检验工作规范》抽样进行人体功效试验的，可作为一组产品同时申请注册，每个产品资料中均应附上系列产品的名单、基础配方和着色剂一览表以及抽检产品名单。

第三十四条 注册人、备案人应当按照化妆品安全评估相关技术指南的要求开展产品安全评估，形成产品安全评估报告。

必须配合仪器或者工具（仅辅助涂擦的毛刷、气垫、烫发工具等除外）使用的化妆品，应当评估配合仪器或者工具使用条件下的安全性；并应当提供在产品使用过程中仪器或者工具是否具有化妆品功能，是否参与化妆品的再生产过程，是否改变产品与皮肤的作用机理等情况的说明资料。

第三十五条 包含两个或者两个以上必须配合使用或者包装容器不可拆分的独立配方的化妆品，应当分别填写配方，按一个产品申请注册或者办理备案。

其中一个（剂）或者多个（剂）产品为特殊化妆品的，应当按照特殊化妆品申请注册；其中一个（剂）或者多个（剂）产品在境外生产的，应当按照进口化妆品申请注册或者办理备案。

第三十六条 化妆品注册人备案人应当留存每一批生产的化妆品样品备查，留存样品数量应当能够满足开展注册备案检验所需。同时，特殊化妆品应当留存由首家注册和备案检验机构封样的1件样品；进口特殊化妆品在产品注册检验时提交试制样品的，应当同时留存经检验机构封样的试制样品和未启封的市售产品各1件；普通化妆品应当由境内备案人或者境内责任人留存1件市售产品备查；专为中国市场设计销售包装的进口普通产品，应当由境内责任人留存1件原产国市售产品备查。

第三十七条 仅供出口的特殊化妆品和普通化妆品，应当在注册备案信息服务平台进行备案，由生产企业提交以下资料：

- 1.产品名称；
- 2.拟出口国家（地区）；
- 3.产品标签图片，包括产品销售包装正面立体图、产品包装平面图和产品说明书（如有）。

#### 第四章 变更事项要求

第三十八条 已注册产品的注册事项发生变更的，应当在拟变更产品生产或者进口前提交相应资料，完成相应的变更之后，方可生产或者进口。

已备案产品的备案事项发生变更的，应当在拟变更产品上市或者进口前提交相应资料，完成相应的变更之后，方可上市或者进口。

变更前已生产、上市或者进口的产品可以销售至保质期结束。

第三十九条 已注册或者备案产品的注册人、备案人、境内责任人或者生产企业的名称、住所等发生变化的（生产场地未改变），应当按照本管理规定第二章第二节相关要求完成信息更新后，对涉及的特殊化妆品注册证或者普通化妆品备案信息以及产品标签样稿的上述相关信息分别进行一次性变更。

第四十条 已注册或者备案产品的产品名称发生变化的，应当合理说明理由并提交以下资料：

- （一）特殊化妆品变更申请表（附18）或者普通化妆品变更信息表（附19）；
- （二）按照本管理规定第二十八条要求提交产品名称相关资料。

第四十一条 生产场地改变或者增加的，应当提交以下资料：

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表；
- (二) 拟变更场地生产产品的微生物和理化检验报告；
- (三) 拟变更备案产品仅通过产品安全评估方式评价产品安全，且拟增加的生产企业不能提供其所在国（地区）政府主管部门出具的生产质量管理体系相关资质认证文件的，应当提交该产品的相关毒理学试验资料；
- (四) 拟变更产品委托生产关系发生改变的，国产产品应当按照本管理规定第二十七条（三）的要求，对变化的委托生产关系进行确认；进口产品应当提交委托关系文件或者属于同一集团公司的证明资料以及企业集团出具的产品质量保证文件。

第四十二条 已注册或者备案产品所使用原料的生产商、原料质量规格增加或者改变的，所使用的原料在配方中的含量以及原料中具体成分的种类、比例均未发生变化的，应当通过注册备案信息平台对原料生产商信息和原料安全信息进行更新维护。涉及产品安全评估资料发生变化的，还应当进行产品安全评估资料变更。

已注册或者备案产品所使用原料的生产商、原料质量规格增加或者改变的，原料在配方中的含量和原料中主要功能成分含量及溶剂未发生变化，为了保证原料质量而添加的微量稳定剂、抗氧化剂、防腐剂等成分发生种类或者含量变化的，应当提交以下资料：

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表；
- (二) 产品配方；
- (三) 发生变更的情况说明，包括变更的原因，变化的成分在原料中的使用目的等；
- (四) 拟变更产品的产品安全评估资料；
- (五) 涉及产品执行的标准发生变化的，应当提交拟变更产品执行的标准；
- (六) 拟变更事项涉及产品标签样稿中的全成分标注、安全警示用语等发生变化的，应当提交拟变更产品的产品标签样稿。

第四十三条 产品执行的标准中生产工艺简述、微生物和理化指标及质量控制措施、使用方法、安全警示用语、贮存条件、使用期限等发生变化的，应当提交以下资料：

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表；
- (二) 拟变更产品执行的标准；
- (三) 涉及生产工艺简述变化的，应当提交发生变更的情况说明，并提交拟变更产品的微生物和理化检验报告；

- (四) 涉及产品使用方法变更的, 应当提交拟变更产品的产品安全评估资料;
- (五) 涉及产品使用期限延长的, 应当提交拟变更产品的稳定性研究资料;
- (六) 涉及产品安全评估资料内容发生变化的, 应当提交产品安全评估资料;
- (七) 涉及进口产品原销售包装和标签变化的, 应当提交拟变更产品的原销售包装(含说明书)和外文标签的中文翻译件;
- (八) 涉及产品标签样稿变化的, 还应当按照第四十四条要求进行产品标签样稿变更。

第四十四条 产品标签样稿内容发生变化的, 应当提交以下资料:

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表;
- (二) 拟变更的产品标签样稿;
- (三) 防晒类化妆品增加 PA、广谱防晒或者浴后 SPF 等标识的, 应当提交拟变更产品相应的功效试验报告;
- (四) 祛斑美白类化妆品增加祛斑或者美白功效宣称的, 应当提交拟变更产品相应的人体功效试验报告;
- (五) 涉及进口产品原销售包装和标签变化的, 应当提交拟变更产品的原销售包装(含说明书)和外文标签的中文翻译件。

第四十五条 产品安全评估资料内容发生变化的, 应当提交以下资料:

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表;
- (二) 拟变更的产品安全评估资料;
- (三) 化妆品安全评估人员发生变化的, 应当提交拟变更化妆品安全评估人员的相关信息。

第四十六条 产品分类发生变化的, 应当提交以下资料:

- (一) 特殊化妆品变更申请表或者普通化妆品变更信息表;
- (二) 按照拟变更产品分类的要求补充或者更新资料;
- (三) 涉及已注册特殊化妆品拟增加染发、烫发、祛斑美白、防晒、防脱发功效或者新功效的, 应当按照第三章的要求补充提交资料。

第四十七条 注册人因公司吸收合并、新设合并、分立等原因发生改变的, 由新的境内注册人或者具有新的境外注册人相应用户权限的境内责任人提交以下资料, 对涉及的特殊化妆品注册证进行一次性变更:

- (一) 公司合并注销、分立、成立全资子公司或者由同一集团内不同子公司运营的声明及相关文件;

(二) 利益相关方(如原注册人,新注册人,境内责任人等)及其法定代表人对特殊化妆品注册证所有权归属无异议的声明及其公证文件原件。

第四十八条 变更境内责任人的,应当提交以下资料:

(一) 拟变更境内责任人的产品清单;

(二) 原境内责任人盖章同意更换境内责任人的知情同意书,或者能够证明境内责任人发生变更生效的判决文书;

(三) 拟变更境内责任人承担产品(含变更前已上市的产品)原境内责任人相关各项责任的承诺书。

第四十九条 涉及其他事项变更的,应当提交拟变更事项的情况说明,并根据具体情况提交相关资料。

第五十条 已注册或者备案产品的销售包装发生变化的,按照第三十二条原则,在新销售包装产品上市前,重新上传产品销售包装的标签图片或者对拟变更部分予以备注说明。

第五十一条 已注册特殊化妆品完成变更之后,领取变更后纸质产品注册证时,应当交还原产品注册证。

## 第五章 延续、注销等事项要求

第五十二条 申请特殊化妆品注册证有效期延续的,应当提交以下资料:

(一) 注册延续申请表(附20);

(二) 产品自查情况说明(式样见附21),主要包括:

- 1.生产(进口)销售证明材料(限上一注册周期);
- 2.监督抽检、查处、召回情况(限上一注册周期);
- 3.该产品不良反应统计分析情况及采取措施;
- 4.其他需要说明的内容。

(三) 根据现行法规、标准调整情况,应当提交相应的产品检验报告。

第五十三条 普通化妆品年度报告应当包括以下内容:

(一) 产品的生产、进口概况,以及期间产品的停产情况;

(二) 产品符合法规、强制性国家标准、技术规范自查情况。

第五十四条 申请补发产品注册证的,应当提交以下资料:

(一) 补发申请表(附22);

(二) 因产品注册证原件破损申请补发的, 领取新产品注册证时, 应当交还原产品注册证;

(三) 因产品注册证遗失申请补发的, 应当提交承诺书。

第五十五条 注册人申请撤回注册申请的, 应当提交撤回申请表(附 23)。

第五十六条 注册人申请注销已注册特殊产品注册证的, 应当提交注销申请表(附 24)。

第五十七条 已备案普通产品因备案人、境内责任人地址变化导致备案管理部门改变, 备案人主动注销原备案信息后重新办理备案的, 可使用原备案资料。

第五十八条 对于非安全性原因不予注册的特殊产品再次申请注册时, 可使用原注册资料的复印件, 同时提交不予注册未涉及安全性的说明, 包括对不予注册原因的解释。

第五十九条 普通产品注销后再次备案时, 应当提交情况说明。对于非安全性原因注销的, 再次申请备案时可使用原备案资料的复印件。