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The Chinese cosmetics industry and legal requirements on cosmetics:

is China going to align with European regulations?

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List of abbreviations

AQSIQ – General Administration of People's Republic of China for Quality Supervision & Inspection and Quarantine

CAGR – Compound Annual Growth Rate

CCARE – Chinese Center for Alternatives Research &Evaluation

CFDA – China Food and Drug Administration

CHSR – Cosmetics Hygiene Supervision Regulation

CIQ – China Inspection and Quarantine Bureau

CMR – Carcinogenic, mutagenic, or toxic for reproduction

CPNP – Cosmetic Product Notification Portal

CSAR – Cosmetic Supervision and Administration Regulation

ECVAM – European Center for Validation of Alternative Methods

EPAA – European Partnership for Alternative approaches to Animal testing

FDA – Food and Drug Administration

GAC – General Administration of Customs

GMP – Good Manufacturing Practices

ICCR – International Cooperation on Cosmetics Regulation

IECIC – Inventory of Existing Cosmetic Ingredients in China

INC – International Cosmetic Ingredient Nomenclature Committee

INCI – International Nomenclature of Cosmetic Ingredients

NMPA – National Medical Product Administration

OECD – Organization for Economic Cooperation and Development

PaO – Period after Opening

PCPC – Personal Care Products Council

PEMSAC – Platform of European Market Surveillance Authorities for Cosmetics

PIF – Product Information File

SAMR – State Administration for Market Regulation

SCCS – Scientific Committee on Consumer Safety

SFDA – State Food and Drug Administration

SUE – Serious Undesirable Effect

WTO – World Trade Organization

前言

近年来，中国化妆品市场有了前所未有的发展，如今已成为世界第二大化妆品市场。中国人对化妆品的消费需求不断增长，所以许多外国公司开始把它们的化妆品出口到中国市场。因为以前中国市场上没有关于化妆品的单行条例，也没有主管机关对进入中国市场的化妆品进行监督，所以众多外国公司开始大量出口到中国，或把它们的生产线迁移到中国。在中国市场上最成功的企业主要是来自欧盟或美国的。因为这些企业有良好的品牌形象，它们的产品在国际上非常著名，并且它们的产品质量优良，也比较安全，所以欧盟和美国企业在中国市场上取得了圆满成功，迅速占据了最大的市场份额。

因为中国经济迅速发展，中国消费者的购买力增加了，并且消费者提高了他们的生活水平，所以消费升级了，外国化妆品的销售额大幅增长了。中国消费者更愿意购买外国化妆品的原因是他们认为外国产品比中国产品的质量良好、安全，并且还认为这些产品是社会经济地位较高的标志。

与此同时，中国化妆品公司没有先进技术，没有技术知识，也没大量财源，所以它们没有竞争力，不能与外国对手竞争。

另外，中国科技环境与西方国家的没有那么发达， 导致外国企业在中国市场上占据最大的市场份额。不发达的中国科技环境败坏了中国在国际上的名誉，因为中国产品被认为对消费者的身体不安全，所以不能在国际市场上与其他国家的产品竞争。

但是，近年来，中国政府正在加强中国法律体制，并修正过时的法律和条例，尤其是对于化妆品的条例和相关法律规定。这样做，中国一方面可以控制针对中国市场的外国进口，一方面可以保证在国内市场上的产品质量良好、安全性强。

严峻的法律条件和复杂的化妆品注册手续使外国企业经历艰难困苦。对许多外国企业来说，中国对于化妆品的条例和法律条件是贸易壁垒。

为了提高国内企业的竞争力、国内市场上的技术水平， 中国政府对关于化妆品的条例和法律条件进行了调整，这样表现它更加关注在国内市场上的化妆品质量和安全性。另外，中国实施的新条例和法律条件还出现了与其他国家的条例接轨的趋势，尤其是与欧盟法规的。但是，为什么中国决定对化妆品条例和法律条件进行调整？中国打算实施与欧盟法规完全一致的条例和法律条件吗？

本论文的目标就是试图回答上述说的问题，探讨对于中国化妆品条例的最新变化，并且研究这些变化对中国市场上的外国企业有什么影响，尤其是对欧盟企业的影响。

本论文是由五章组成的。第一章中，我们先介绍一些关于化妆品历史的重点，以便解释为什么世界上所有国家都需要日益控制并规定化妆品的质量和安全性。然后，我们提出在不同国家条例中“化妆品”词语的定义。最后，这章中我们介绍国际化妆品市场的现状，重点是国际化妆品市场发展，国际上化妆品的销售额，最新国际市场趋势，化妆品市场增长潜力。

第二章专注于中国化妆品市场的分析。第二章中，我们讨论中国化妆品市场的巨大发展潜力和中国市场在国际上越来越大的影响。我们首先解释中国化妆品市场发展，它怎么从 1980 年代初期不受监管的、不发达的市场变成了强大而发达的市场，并且为什么目前在中国市场上国外和国内公司之间的竞争日益激烈。其次，我们对目前中国化妆品市场情况进行分析，重点是市场规模及增长率，中国消费者对化妆品的需求，主要销售渠道以及最近市场趋势。

第三章中，我们主要讨论三个方面：第一个方面是中国化妆品法律体制的发展如何；第二个是新的《化妆品监督管理条例》（CSAR）以及与化妆品有关的其他法规和法律条件的变化；第三个方面是上述所说的变化对中国市场上的外国企业有什么影响，尤其是对欧盟企业的。本章中,我们强调下列方面：一方面中国提高了与欧盟法规的一致性，这样促进外国企业向中国市场的出口额；另一方面还有中国条例和欧盟法规之间的还有巨大区别，这些区别对外国企业来说是庞大的贸易壁垒。

第四章中，为了更好地了解中国化妆品条例和法律条件最近变化的原因，我们对中国《化妆品监督管理条例》和欧盟化妆品法规进行了比较。由于别的国家化妆品法规都是以欧盟法规为基础的，并且欧洲企业占据中国化妆品市场的最大份额，欧盟法规和中国条例之间的比较是至关重要的。通过这个比较，我们也可以更好地了解欧盟和中国之间的异同怎么影响在中国市场上做生意的欧洲企业。这种比较进一步支持了前几章中已经讨论过的内容：中国条例与欧盟法规日益一致，但是在关键方面上存在重大差异。

我们就此提出了一些关键问题：中国条例会不会与欧盟法规未来完全一致？中国对化妆品条例和法律条件进行调整的原因是什么？

本论文的最后一部分试图得出结论，回答论文中提出的问题，并对中国的真实意图给出个人解释。事实上，第五章中回答了论文中的两个主要问题：

- 中国的真实意图是什么？促进国际贸易还是保护国内市场？
- 中国化妆品条例和法律条件会不会完全符合欧盟法规？国际上不同国家的化妆品法规之间的协调是不是可以实现的目标？

此外，我们显示了为什么欧盟和中国在化妆品法规方面的日益协调可以使双方都受益。中国条例和欧盟法规之间的协调不仅有利于欧盟企业和其他进入中国市场的外国公司，而且主要有利于中国公司和消费者，以及整个中国化妆品行业和中国经济发展。

Introduction

In the last few decades, the Chinese cosmetic market has experienced an unprecedented growth, so that nowadays it is the second largest cosmetics market in the world.

Increased consumption of cosmetics and sophistication of consumer demand made China the most sought-after market for many Western companies that started to import their products and establish production subsidiaries in China, taking advantage of an initial lack of regulations and controls on the market. As a result, foreign enterprises, especially European and American ones, easily ended up conquering major market shares thanks to their strong brand image and their reputation for safe and high-quality products.

The increasing purchasing power of consumers and their growing desire to improve their living standards further pushed the consumption of foreign cosmetics since these goods were regarded as essential daily-use products not only to enhance one's well-being, but also to show off one's social status.

While the Chinese cosmetic market grew together with foreign import into the country, Chinese domestic companies were left behind because they lacked the technology and resources to compete with experienced foreign companies. At the same time, the technological and regulatory environment on the Chinese market was really underdeveloped compared to Western countries. Lack of proper regulations, on one hand, allowed foreign companies to conquer the market, and, on the other hand, undermined Chinese reputation on the international market. Chinese products were regarded as unsafe and of poor quality, and the Chinese cosmetic market was deeply underdeveloped in terms of innovation and technology, therefore China was not able to compete with other world economic powers at the international level.

However, in the last few years, China has been strengthening its regulation and legal requirements on cosmetics in order to control the import of foreign products and to ensure safety and quality of cosmetics on its domestic market.

Increased requirements on cosmetics and complex procedures for importation and registration of cosmetics let foreign cosmetic companies experience major difficulties and they became real barriers to entry for many small and medium enterprises that intended to enter the Chinese market. Moreover, in order to be able to compete at the international level, recent developments in Chinese regulations and legal requirements on cosmetics showed a greater attention from the Chinese part toward safety and quality of cosmetic products and a tendency to align its requirements with international ones, especially with European ones. But what are the real reasons behind these recent developments? Is China going to completely align its regulation to the European one?

The aim of this thesis is investigating the latest developments in Chinese regulations, their impact

on foreign import of cosmetic products in the Chinese market, and the current state of Chinese regulatory framework on cosmetics in order to answer the above-mentioned questions.

The first part of this thesis introduces a general framework about the state of cosmetics at the international level, followed by a general overview on the Chinese cosmetic market based on the analysis of its state of development and its major characteristics.

In particular, Chapter 1 provides an introduction highlighting crucial aspects of the history of cosmetics and the reasons behind an increasing need for regulations worldwide. Then, it presents a definition of the term "cosmetics" among different regulations stressing that, on one hand, there is an increasing regulatory convergence between countries, but, on the other hand, some differences remain. Finally, this chapter provides a general overview over the current state of the international cosmetic market.

Chapter 2 focuses on the introduction and analysis of the Chinese cosmetic market highlighting its huge potential for growth and its increasing economic influence at the international level. In this chapter, first we explain the development of the Chinese cosmetic market from an unregulated and underdeveloped market in the early 1980s to a strong and developed one, characterized by increasing competition between foreign and domestic companies. Then, we analyze the current state of the Chinese cosmetic market from four important points of view: market size and growth rate, consumer demand, main sales channels, and new trends on the market.

The central part of this thesis is devoted to the recent developments and the current state of regulations and legal requirements on cosmetics in China, which represent significant trade barriers for foreign companies, and it ends up with a comparison between Chinese and European regulations which shows how differences have an impact on foreign cosmetic companies that operate on the Chinese market.

Specifically, Chapter 3 provides an in-depth analysis on the Chinese regulation and legal requirements on cosmetics explaining why they represent such significant trade barriers for foreign companies that operate or aim at the Chinese market. Firstly, we introduce the development of the Chinese regulatory framework highlighting a stronger attention toward safety and increasing strictness of legal requirements, especially for foreign products. Secondly, we go on analyzing the new *Cosmetic Supervision and Administration Regulation* (CSAR), the new Chinese regulation on cosmetics which entered into force in January 2021 bringing revolutionary changes into the whole Chinese regulatory framework. One major example is the important change in animal testing requirements.

Lastly, we underline the impact of the new regulatory changes on foreign companies and foreign import highlighting, on one hand, an increasing alignment with EU regulations which facilitate

foreign import and, on the other hand, major critical points and regulatory differences that represent significant barriers to foreign entry in the Chinese market.

In order to better understand the reasons behind the latest developments in Chinese regulations on cosmetics and why they are trade barriers for foreign companies, we provide a comparison between the Chinese and the EU regulatory framework on cosmetics in Chapter 4.

Since the EU has provided the basis for cosmetic regulations worldwide and European companies have the biggest share of the Chinese cosmetic market, it is particularly relevant to investigate similarities and differences between the EU and the Chinese legal requirements on cosmetics and their impact on European companies working on the Chinese market.

This comparison further reinforces our perspective on what has already been discussed in the previous chapter: an increasing regulatory alignment with the EU but major differences on crucial regulatory aspects. At this point, we raise some key questions: will China increasingly get in line with international standards and requirements, especially with the EU? What are the real intentions behind China's regulatory developments? Does it want to foster international trade? Or it is just another way to protect its domestic market from a "foreign invasion" while hiding behind the goodwill to improve its regulations in line with other countries?

Finally, the last part of this thesis attempts to draw conclusions, answer to the questions raised throughout this thesis and give a personal interpretation of the implied intentions of China.

Indeed, Chapter 5 provides answers to the two main questions of our thesis:

- What are China's real intentions? Foster international trade or protect its domestic market?
- Is China going to completely align with the EU regulations? Is international regulatory harmonization an achievable goal?

Moreover, we demonstrate why increasing harmonization between the EU and the Chinese regulations and legal requirements on cosmetics can benefit all parties involved, not only European companies and foreign import into the Chinese market, but also Chinese companies and consumers, the whole Chinese cosmetics industry and China's own economic development and growth.

1. The cosmetics industry: general framework

1.1 Brief history of cosmetics: the need for regulation

Cosmetics and personal-care products have a thousand-year history that traces back to Greek and Egyptian age. The first cosmetics derived from natural ingredients easily found in nature, for example plants, flowers, minerals, and they were linked to religious and cultural beliefs.[1]
Throughout time, from a symbol of beauty and social status, cosmetic products have become daily used and widely commercialized, including a wide range of products, from high-end lipsticks to common soaps.
As cosmetics industry grew, so did the number and types of ingredients used for cosmetic production. As a result, from natural organic cosmetics in ancient times, producers started to gradually implement synthetic ingredients in cosmetic formulas. With the use of new unregulated ingredients, concerns about their impact on people's heath and on the environment arose. Therefore, countries all over the world felt the need to regulate cosmetic production in terms of formulations and ingredients, and to clearly establish methods for testing and safety assessment of products in order to protect their domestic market, consumer's health and the environment.
The above-mentioned development of cosmetic industry throughout history has been largely described and debated in literature.
Ancient Egyptian are considered the pioneer of cosmetics; however, beauty practices already existed several thousand years before. For instance, in China the first findings about the use of cosmetics date back to the 3000 B.C. when Chinese people used to paint their fingernails with gum Arabic, gelatin, beeswax and egg white[2], and aristocrats used lead powder to whiten their skin[3], a trend which still influences Chinese beauty nowadays.
Romans and Greeks also had a long tradition of beauty practices that deeply influenced Western cosmetic industry.[4]
By the first century A.D., from a symbol of beauty, cosmetics began to be suspected of containing toxic compounds and of posing a danger to people's health but, only one thousand years later, a Spanish Moor wrote the first medical encyclopedia to include one section about cosmetics.[5] This

[1] Geoffrey Jones, *Beauty Imagined: A History of the Global Beauty Business*, New York, Oxford University Press, 2010, p.1
[2] Beautifully invisible, "A History of Nail Lacquer: Blood Red Nails On Your Fingertips", on "beautifully-invisible.com", May 27, 2011, http://www.beautifully-invisible.com/2011/05/nail-lacquer-blood-red-nails-fingertips-history-nailpolish.html (18/03/21)
[3] Cao Chen, "How cosmetics were created in ancient China", *China Daily USA*, 2018, https://www.chinadaily.com.cn/a/201804/21/WS5ada295aa3105cdcf6519a30.html (18/03/21)
[4] For example, Romans used herbs for hot baths and massages and red clay as lipstick, and Greeks scrubbed with goat's soap and bathed with olive oil and embellished their faces with lead and chalk powder. (Ibidem)
[5] The Editorial Team, "Muslim Contribution to Cosmetics", on "muslimheritage.com", May 20, 2003, https://muslimheritage.com/muslim-contribution-to-cosmetics/ (19/03/21)

was the first time that cosmetics were considered from a scientific point of view, and this approach was adopted later in the twentieth century with the rise of anti-aging products.

For several centuries, cosmetics had both a positive and a negative reputation. On one hand, they were mainly used by rich women, since certain types of cosmetics or combinations of colors specifically represented a social status and could only be worn by members of the upper class. On the other hand, cosmetics were also associated with prostitutes, and, during the Middle Ages, it was even thought sinful and immoral to wear makeup.

Cosmetic products were revaluated only several centuries later thanks to the upper-class endorsement.[6]

Even at that time, there were concerns about possible threats posed by cosmetics to people's health, especially after the first scandals and deaths due to the widespread and thoughtless use of toxic ingredients.[7]

During the two decades prior to the First World War, the cosmetic industry experienced an unprecedented growth thanks to a great number of innovative products that transformed the whole beauty industry.[8] The rise of advertisement helped these products to become popular all over the world and, from that moment on, the types of cosmetic products multiplied and grew constantly.[9]

International cosmetics industry grew exponentially, and cosmetic products became widely commercialized and strongly demanded by consumers all over the world thanks to the growing popularity of Hollywood actresses wearing make-up.

During the 1920s the cosmetics industry further expanded with the wide use of preservatives and other synthetic substances in cosmetics and personal-care products. The use of artificial ingredients made cosmetic products cheaper and more accessible to a wider public but, as stated by Epstein, "as use of synthetic chemicals grew, the impacts on human health became impossible to ignore".[10]

Several warning signs emerged from the market, for example, a skin cream called Koremlu caused several cases of paralysis, abdominal pain, blindness, and other severe symptoms in 1930.

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[6] An emblematic example was Queen Elizabeth I, who set a new beauty trend among the upper class with the practice of wearing lead to whiten her face. (Oumeish Youssef Oumeish, "The Cultural and Philosophical Concepts of Cosmetics in Beauty and Art Through the Medical History of Mankind", *Clinics in Dermatology*, *19*, 4, 2001, p.380)

[7] A popular accident happened in Italy where Signora Toffana invented a popular product for the skin made from arsenic. Several thousand husbands died by kissing their wives' cheeks before the cosmetic product was withdrawn from the market. (Ivi, p.381)

[8] Some examples were the first deodorant called Mum, the first hair dye known as Aureole, and the first synthetic mascara that later gave its name to the well-known brand Maybelline. (Samuel Epstein, Randall Fitzgerald, *Toxic Beauty: How Cosmetics and Personal-Care Products Endanger Your Health... and What You Can Do About It*, Dallas, BenBella Books, 2009, p.30)

[9] For example, Hans Schwarzkopf launched the first shampoo in 1903, and Eugene Schueller, founder of L'Oréal, invented the first safe synthetic hair-color formula in 1907. (Sources: Geoffrey Jones, *Beauty Imagined…*, p.48-49; Maggie Angeloglou, *A history of makeup*, London, Studio vista Ltd., 1970, p.115)

[10] Samuel Epstein, Randall Fitzgerald, *Toxic Beauty: How Cosmetics and Personal-Care Products Endanger Your Health... and What You Can Do About It*, Dallas, BenBella Books, 2009, p.30

The need for regulating and controlling the production and circulation of cosmetics resulted in the *Food, Drug, and Cosmetic Act* implemented by the US Food and Drugs Administration (FDA) in 1938, it was the first regulation of its kind to define and control cosmetics on the market.
"During the boom years of the 1950s and 1960s," writes Riordan in her book, "industry was transmuting oil into a motherlode of new wonder synthetics. Researchers broke down natural petroleum into its constituent parts and put them back together in sophisticated new combinations".[11] With the spread of cosmetics popularity and the development of the chemical industry, from the 1950s onwards, there was a definitive shift from natural formulations to synthetic ones thanks to the invention of silicone polymers, which made the skin feel soft and smooth and allowed the production of many products such as gloss lipsticks and long-lasting make-up.[12]
During this period, several improvements in cosmetics regulations took place and influenced the regulatory framework that is currently in force in many countries. Some milestones were the *Fair Packaging and Labeling Act* of the US Congress in 1966 that required consumer products to be properly labeled and the ban of six carcinogenic color additives from cosmetics by the FDA in 1977.
In the 1990s, further steps in the regulation of cosmetics were taken by the European Union, pushing for the establishment of a legal "precautionary principle" based on the idea that manufacturers have to prove the safety of their product ingredients before marketing them to consumers.[13]
In 2000, EU countries banned several ingredients from all cosmetics and personal-care products sold on their markets because they were suspected of being a threat to consumers' health.
The most important European initiative was the *European Union's Seventh Amendment* of 2005, the first attempt to completely ensure the safety of cosmetics and personal-care products sold in the EU countries. It definitely divided ingredients into categories and clearly regulated toxic substances.
It deeply influenced the industry because it marked a shift of consumers demand toward natural cosmetics and the consequent rejection of synthetic ingredients. It also affected big multinational companies working at the international level, for example, L'Oréal had to reformulate its products to comply with the Amendment.[14]
However, regulations are far to be exhaustive and further steps need to be taken in order to improve legislation and standards in the international cosmetics industry. Many countries do not apply in-

[11] Teresa Riordan, *Inventing beauty: A history of the innovations that have made us beautiful*, New York, Broadway Books, 2004, p.30
[12] Imelda Burke, *The Nature of Beauty: Organic Skincare, Botanical Beauty Rituals and Clean Cosmetics*, London, Ebury publishing, 2016, p.332-333
[13] Samuel Epstein, Randall Fitzgerald, *Toxic Beauty...*, p.35
[14] Ivi, p.217

depth examination of cosmetics. For example, although the American FDA regulates ingredients that can be used in cosmetics, it does not pre-approve or review cosmetics before launching them on the US market. Moreover, US cosmetic companies are not required to report injuries caused by the use of their products, but they only need to comply with FDA instructions on labeling and product registration.[15]

The EU countries seem to be the only countries to implement and abide to consistent and detailed regulations and standards at the international level. Therefore, the EU is trying to leverage its strong position to influence other countries in improving their regulations.

In recent years, new developments in regulations have affected the cosmetic industry in several countries due to global pressures. Many countries are implementing new regulations, safety assessment requirements and testing methods to ensure quality and safety of cosmetic products on their domestic market.

In a globalized era, as the one in which we are living in, countries influence each other through their regulations and standards, so no one can be exempted from adapting to the latest developments occurring on the market in order to stay competitive at the international level. As a result, different national regulations are gradually converging causing the rise of a worldwide harmonization trend. One major example is provided by China who, as we will further discuss in this paper, is gradually updating its regulations and implementing changes in line with other countries, especially in line with the EU.

1.2 Definition of the term "cosmetics" according to different legislations

The term "cosmetics" comes from the Greek *kosmētikos,* which means "skilled in adornment", and from *kosmos,* which means "order".

Cosmetics can be defined as "something that is cosmetic", that is to say something "of, relating to, or making for beauty especially of the complexion", or "done or made for the sake of appearance".[16]

There are several definitions of the term "cosmetics" provided by countries and national authorities all over the world. Each country provides its own definition of the term through its laws and regulations but, even though there are small differences among definitions, they all provide more or less the same concept of what can be defined as "cosmetics".

By looking more in depth among the most important definitions at the international level, we will provide a definition of the term based on the regulations on cosmetic products issued by the Food

[15] For further information: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law#Assuring_Ingredient_and_Product_Safety (21/03/21)

[16] Merriam-Webster Dictionary, "cosmetic", https://www.merriam-webster.com/dictionary/cosmetic (21/03/21)

and Drug Administration (FDA)[17], the European Union (EU) and the National Medical Products Administration (NMPA)[18].

According to the FDA,

> products commonly referred to as 'personal care products' are cosmetics. These include, for example, skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants.[19]

A more detailed definition is provided by the European Commission in *Regulation (EC) No. 1223/2009 of 30 November 2009 on cosmetic products* which defines this kind of products as

> 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.[20]

This definition implies that cosmetic products cannot be objects or other physical items so, for example, hair extensions or applications for nail art do not fall under this category.

Moreover, according to the EU Regulation, cosmetics are products that can be applied on the face and on the surface of body parts, and they do not include products that can be inhaled, ingested, or injected under the skin. Their core function is to clean, perfume, protect, correct, and change the appearance of body parts, therefore, other products that aim at treating or healing specific diseases or conditions are not considered cosmetics.[21]

In the EU, cosmetic products may include a wide range of products, for example, creams, emulsions, lotions, gels and oils for the skin, beauty masks, foundations, face powders, talcum powder for body care, beauty soaps, perfumes, toilet waters and cologne, preparations for baths and showers, hair removal products, deodorants and antiperspirants, hair dyes, products for waving, straightening and fixing, hair cleansing products, hair styling products, products for shaving, make-up products, products intended to be applied on the lips, products for hygiene of the teeth and

[17] Food and Drug Administration (FDA) is the US federal agency that is responsible for protecting and promoting the public health by ensuring the safety and the supervision of food, tobacco, pharmaceutical drugs, vaccines, veterinary products, and cosmetics. (Further information at: https://www.fda.gov)

[18] The National Medical Products Administration (NMPA), or 国家药品监督管理局(*guojia yaopin jiandu guanliju*) in Chinese, is the Chinese government's administrative body responsible for regulating pharmaceuticals, medical devices, and cosmetics in China. (Further information at: https://www.nmpa.gov.cn)

[19] Food and Drug Administration (FDA), "Are all personal care products regulated as cosmetics?", on "fda.gov", https://www.fda.gov/industry/fda-basics-industry/are-all-personal-care-products-regulated-cosmetics (21/03/21)

[20] European Commission, *Regulation (EC) No 1223/2009 on cosmetic products*, November 30, 2009, art.2, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (21/03/21)

[21] ABC cosmetici, "Cos'è un cosmetico", on "abc-cosmetici.it", http://www.abc-cosmetici.it/conoscere-i-cosmetici/cose-un-cosmetico/cose-un-cosmetico/ (22/03/21)

mouth, products for the nailcare and nail lacquers, products for external intimate hygiene, solar products, self-tanning products, skin lightening products and anti-wrinkle products.[22]

The FDA and the EU Regulation provide similar definitions and, by looking at the Chinese regulation, we can see that the definition given by the NMPA shares some similarities with the previous ones.

The official definition provided by the NMPA states that

> Cosmetics are daily used industrial chemicals which can be spread on the outer surface of human body (e.g., skin, hairs, nails. lips etc.) for the purpose of cleaning, deodorizing, providing skin care, beauty and make–up, by way of smearing, spraying or other similar means.[23]

Similarly to Western regulations, in China cosmetic products refer to chemical products for daily use intended to be applied on any external part of the human body (such as skin, hair, nails, lips, etc.) by spreading, spraying or in other similar ways to keep the body clean, eliminate unpleasant odors, protect the skin, improve appearance and enhance beauty.[24]

However, some products that generally fall under the scope of "cosmetics" in some legislations do not follow the same classification in China.

In order to determine whether a product is included in the category of cosmetics in China, we can take into consideration three aspects of the product: its usage, the body parts for its application, its function and purpose.

[22] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, 30 November 2009, art.2, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (22/03/21)

[23] Chemical Inspection & Regulation Service (CIRS), "Cosmetic regulation in China", on "cirs-reach-com", http://www.cirs-reach.com/Cosmetics_Registration/China_cosmetics_regulations_registration.html (22/03/21)

[24] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation#C4 (22/03/21)

On the ChemLinked website[25], there is a table that clearly shows this distinction:

Aspects	**Yes**	**No**
Usage	Smearing, spraying or other similar ways like rubbing	Oral administration or injection
Applied body parts	Any external part of the human body, such as skin, hair, nails, lips	Teeth or oral mucosa
Functions and purposes of use	Skin care, to make the body hygienic, to eliminate undesirable odors, to enhance the beauty of the appearance	Prevent and treat diseases

Table 1: Table to determine whether a product falls under the Chinese definition of "cosmetics" (cosmetic.chemlinked.com)

By looking at the above table, it is evident that products that are usually applied in the oral cavity and whose main function is to clean and protect teeth, such as toothpastes, are not considered cosmetics in China, unlike other countries.[26]

Definition is a fundamental aspect when it comes to international trade since different definitions across countries mean that the same product will have to follow different approval procedures before being placed on the market. Nowadays many countries have adopted the same definition of "cosmetics", often in line with the EU. However, different interpretations and approaches to the management of cosmetics continue to exist causing the emergence of trade barriers between countries.[27]

[25] ChemLinked is a leading provider of Asia-Pacific regulatory information and market intelligence across chemical, food, cosmetic and agrochemical industries. (Further information at: https://cosmetic.chemlinked.com)
[26] However, the new Chinese Cosmetic Supervision and Administration Regulation (CSAR) have introduced some changes in the definition and in other requirements on cosmetics, showing an increasing alignment with other regulations at the international level. This point will be discussed in detail in Chapters 3 and 4 of this thesis.
[27] This point will be discussed in more detail in the following chapters, especially focusing on trade barriers between China and the EU (Chapter 3) and similarities and differences between the EU and the Chinese regulatory framework on cosmetics (Chapter 4).

1.3 Common characteristics of cosmetics on the international market

Product categories

The globalization phenomenon has facilitated international trade between different countries all around the world. International commercial exchanges have experienced an unprecedented growth thanks to the development of new media, the improvement of transport facilities and the strengthening of diplomatic relations between countries.

As a result, products that are manufactured in one country can be exchanged between different locations and can enter other countries' market in order to meet and satisfy consumer demand worldwide. Many products have made their appearance on the international market, therefore, nowadays it is easier to find more or less the same brands and product categories all around the world, no matter where we are located.

This is due to the fact that several consumers in different countries seem to show the same consumer behavior and share the same preferences and needs. Many scholars[28] have theorized the existence of "global consumer segments", groups of consumers across different countries that share some similarities in their consumer behavior despite economic, social, and cultural differences.[29] Indeed, one of the consequences of globalization is the so-called "homogenization" which is the spread of the same values, symbols, and attitudes across people of different ethnicity and nationality. This "homogenization" also resulted in the rise of similar consumer behaviors around the world. This is the reason why we can notice that different markets are characterized by the same product categories.

Even though these products show some differences in terms of product characteristics or packaging, they are present in several markets at the same time, and they register comparable sale volumes in different locations. On the international level, we can find different brands and product characteristics in line with national taste, but the main product categories are basically the same around the world. This is also true for the cosmetics market.

[28] Cfr. Hassan and Katsanis (1994), Mahajan and Muller (1994), Alden, Steenkamp, and Batra (1999), Levitt (1983), Yip (1995), Jeannet and Hennessey (1998).

[29] However, the debate between global market orientation and local market orientation, which is an approach that recognizes differences between countries and stresses the limits of the global approach in overcoming deep-rooted cultural differences among consumers, still remains an unsolved issue (cfr. Horn and Shy, 1996).

Cosmetics on the international market mainly comprise the following product categories:

- Make-up products that are applied mainly on the face, skin, eyes, lips, and eyebrows with a decorative function. They include a wide range of products such as foundation, concealers, blushes, bronzers, highlighters, eyeshadows, eyeliners, mascaras, lipsticks and so on.
- Skincare products that are used in order to preserve, nurture and take care of the natural skin condition. There is a wide range of skincare products: moisturizing creams, cleansers, facial masks, toners, serums, sunscreens, etc.
- Fragrances or perfumes.
- Other personal care products that are used to take care of personal hygiene and body wellbeing, for example shampoos, bath foams, soaps, deodorants, baby powders, etc.

According to the data collected by Statista, the above-mentioned product categories represent a global beauty and personal care market that generated a total revenue of 504.5 billion US dollars in 2019.[30]

In particular, make-up products[31] occupy the 18% of total worldwide revenue, while skincare products represent the 27%, fragrances are the 10% and the biggest share is represented by personal care products with the 45% of worldwide revenue share.

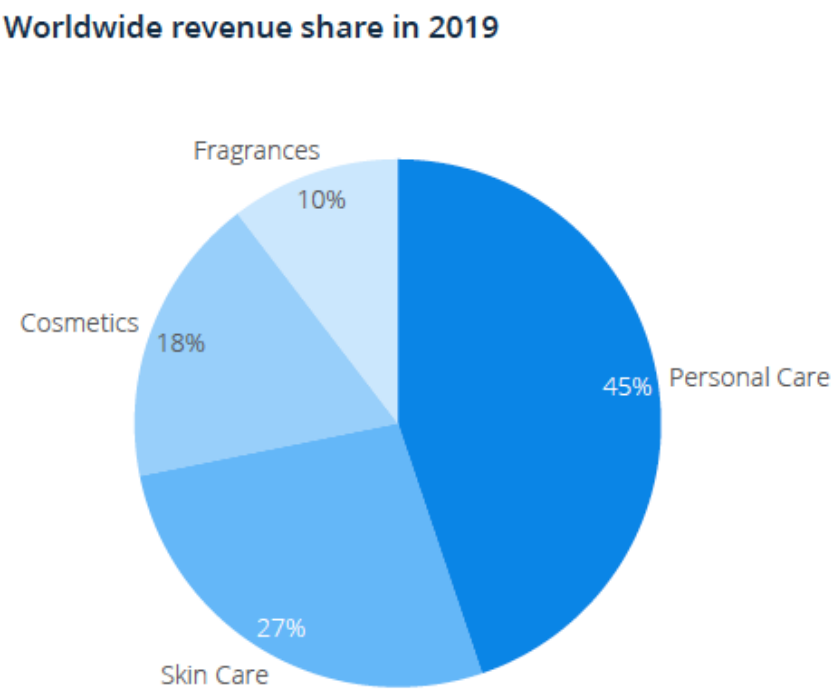

Figure 1: Worldwide revenue share of the Beauty and personal care market in 2019 (Statista, 2020)

[30] Statista Consumer Market Outlook, *Cosmetics report 2020*, November 2020, p.4
[31] In Statista's report make-up products are referred to as "cosmetics".

Cosmetic ingredients

As we have already discussed in the first paragraph of this chapter, the first cosmetic products were made of natural ingredients easily found in nature, such as plants, flowers, minerals, oils, and so on. Starting from the twentieth century, companies that manufactured this kind of products, started to add synthetic ingredients into their cosmetic formulas. The search for the best balance between effectiveness and profitability led companies to employ ingredients that eventually turned out to be dangerous to people's health, carcinogenic, toxic, or even deadly only after several accidents and tests run on cosmetics years later.

After several cases of reported allergic reactions and permanent damages, countries started to regulate the use of certain ingredients. Some ingredients were banned, while others were required to be explicitly stated on product labels or were limited in their use.

Nowadays, there is not a uniform regulatory framework concerning cosmetics at the international level, and each country has its own regulation, mandatory certificates and standards for product labels and packaging.

However, many efforts have been made in order to create and promote a uniform system of nomenclature for ingredient lists to be displayed on products. This led the Personal Care Products Council (PCPC)[32] to promote the development and implementation of the International Nomenclature of Cosmetic Ingredients (INCI) through the institution of the International Cosmetic Ingredient Nomenclature Committee (INC).[33]

The INCI has been adopted by the majority of countries as the official mandatory way of listing product ingredients and, in many cases, it is explicitly required by national regulations in terms of labeling and packaging, as in the case of the EU and the USA.

As stated by the PCPC, "INCI names are systematic names internationally recognized to identify cosmetic ingredients".[34]

The main aim of the INCI adoption is to ensure an "orderly dissemination of scientific

[32] The Personal Care Products Council (PCPC) is the leading national trade association representing 600 global cosmetics and personal care products companies. (For further information: https://www.personalcarecouncil.org)

[33] It is a body composed by scientists and experts from the industry, scholars, regulatory authorities, and associations who voluntarily devote their time to serve the global cosmetic industry community. The INC is charged with the responsibility of designating INCI names. Members of the INC gather approximately five times a year for 2-day sessions to review applications for new INCI names, and petitions for INCI name changes. (For further information: https://www.personalcarecouncil.org/resources/inci/background-information/international-cosmetic-ingredient-nomenclature-committee-inc/)

[34] Personal Care Products Committee (PCPC), "The INCI", on "personalcarecouncil.org", https://www.personalcarecouncil.org/resources/inci/ (25/03/21)

information"[35] in order to "avoid confusion, misidentification, or the loss of essential information"[36] due to uneven nomenclature employed by scientists and experts in the field.

Moreover,

> It also enables the cosmetic industry to track the safety and the regulatory status of ingredients efficiently on a global basis, enhancing its ability to market safe products in compliance with various national regulations. And finally, transparency is provided to consumers as ingredients are identified by a single labeling name regardless of the national origin of the product.[37]

According to the general conventions established by the INC, ingredients names are expressed in Latin and

> Nomenclature assignments are based on the chemical composition of the intended product, and simple chemical names are used when possible. The assigned names are generally based on an ingredient's final composition and purity irrespective of the type of manufacturing process (e.g., chemical synthesis, biotechnology, etc.).[38]

The ingredients are listed in order of quantity or percentage inside the product. The first names to appear in the ingredient list represent the bigger part of the product formulation, and the first ingredient is usually distilled water (aqua).

By reading ingredient lists based on the INCI, it is possible to clearly understand the ingredients employed and their quantity, as a result labels are more transparent. INCI names let consumers clearly understand if the product is more or less natural or organic and allow them to avoid possible allergic reactions. Moreover, the adoption of the INCI has forced companies to disclose the substances employed in cosmetic manufacturing and to stop employing toxic and dangerous chemical ingredients improving the safety and quality of cosmetics on the international market.

Ingredient nomenclature together with the definition of "cosmetics" are two important regulatory issues in the cosmetic industry. At the international level, different national regulations are increasingly aligning on these two aspects and on many other regulatory aspects in order to both strengthen product safety and to facilitate international trade of cosmetics.[39]

1.4 International cosmetic market

The cosmetics industry has the most promising and thriving market worldwide, particularly driven by a growing interest of consumers toward make-up and skincare products, especially among a new generation of young consumers.

In the last decade, this industry has witnessed a steady annual growth, between 3% and 5% on each

[35] Ibidem
[36] Ibidem
[37] Ibidem
[38] Personal Care Products Committee (PCPC), "INCI nomenclature conventions", on "personalcarecouncil.org", March 2021, p.3, https://www.personalcarecouncil.org/wp-content/uploads/2021/03/Conventions2021_v2.pdf (24/03/21)
[39] This point will be further discussed in the following chapters of this thesis.

year (apart from the period of global crisis between 2008 and 2009 when its growth slowed down to 2-1%), as shown in the chart below.[40]

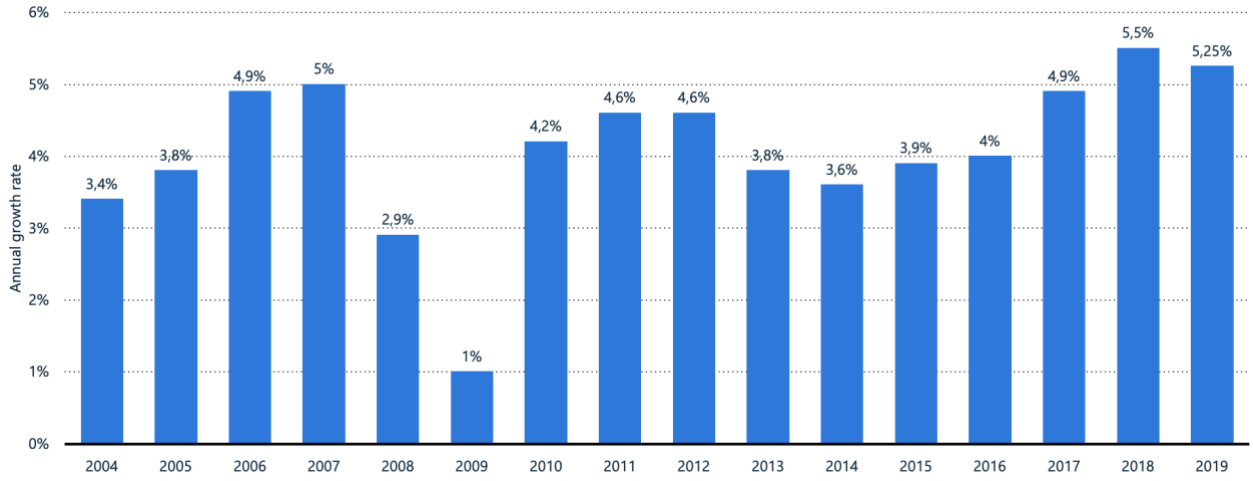

Figure 2: Growth rate of the global cosmetic market 2004-2019 (Statista, 2020)

According to a report made by Statista, "the global beauty and personal care market was estimated to value at about 500 billion U.S. dollars in 2019".[41]

In 2019, "the Beauty & Personal Care market generated a total revenue of US$504.5 billion worldwide"[42] and it was expected to keep increasing in terms of value in the following years, maintaining a growth rate of 3.4%, according to a forecast made by Statista.

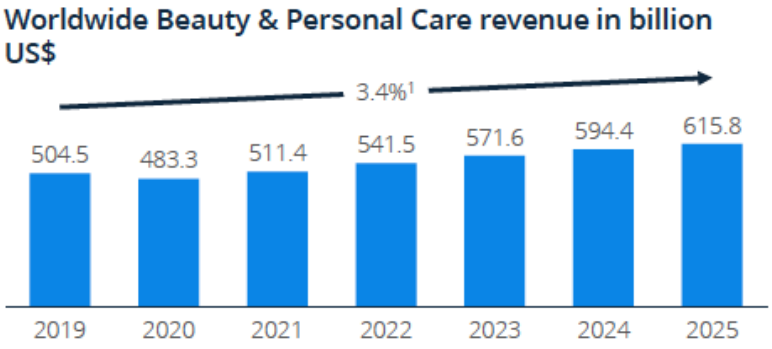

Figure 3: Worldwide Beauty & Personal Care revenue in US$ (Statista, 2020)

However, due to recent events linked to the Covid-19 pandemics, "the Beauty & Personal Care market is expected to witness a […] decline of 7%".[43]

The cosmetic market has always shown a growth trend but, as many other markets, it has been negatively affected by a series of national lockdowns and restrictive measures adopted by several

[40] Statista, *Cosmetic industry worldwide*, 2020, p.4
[41] Ivi, p.33
[42] Statista Consumer Market Outlook, *Personal Care Report 2020*, November 2020, p.4
[43] Statista Consumer Market Outlook, *Beauty & Personal Care Report*, December 2020, p.11

countries during the last year. International trade has been slowing down together with consumer demand and worldwide consumption which also declined because of the shutdown of shops, the temporary stop of manufacturing production and the closing of country borders.
At the moment, it is difficult to envision future developments in a post-pandemic scenario since they will depend on several variables such as the effectiveness of the vaccination campaigns, the efficacy of economic policies implemented by countries and the market response.
Nonetheless, by looking at the current state of the cosmetic market, we can make a market analysis identifying five homogenous segments, namely cosmetics, skincare, fragrances and personal care or hygiene products. These segments can be found in different markets worldwide.
According to Statista's data, in 2019 personal care was the largest segment with the 45% of market share and a revenue of 226 billion US dollars, followed by the skincare segment with 27% and a 136 billion US dollars revenue. The cosmetics segment occupied the 18% of the worldwide market and fragrances only the 10%, with the smallest revenue equal to 53 billion US dollars.[44]
Each segment can be further subdivided into different subsegments, each one corresponds to a different kind of products that can be identified within each product category. These subsegments and their percentages are explained in a more detailed way in the following chart.

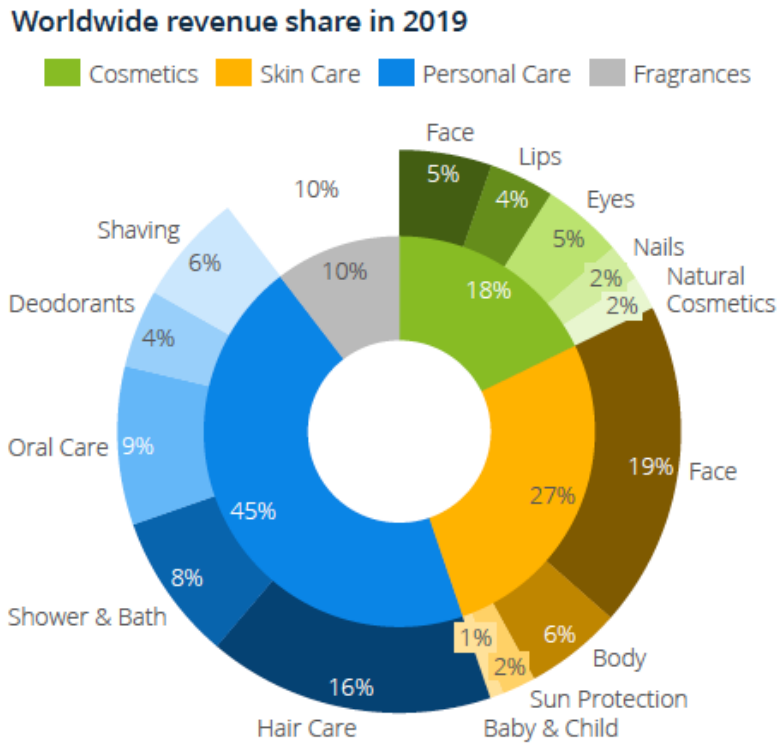

Figure 4: Worldwide revenue share in 2019 (Statista, 2020)

[44] Ivi, p.6

The segments with the highest potential for growth are cosmetics and skincare. The growth experienced by these segments can be explained by looking at the latest trends on the international market. Their sales were mostly driven by an increment in online sales and by the renewed interest of young people toward these kinds of products due to the influence of social media trends and beauty influencers online.

As a matter of fact, the cosmetics segment is expected to witness a growth of 32% in terms of revenue, while the skincare one will increase of 24.3%, according to forecasts made by Statista.[45]

In terms of geographical segmentation[46], the countries where the cosmetics industry is more developed and where consumers are more willing to spend money on cosmetic products are mostly developed countries in North America and Europe. In 2019, the country that spent more on beauty and personal care products was Iceland with a per-capita revenue of 301 US dollars, followed by Japan and the US. Other flourishing markets are Canada, Australia, and other countries in Northern Europe.

Nowadays, the most promising markets for the cosmetics industry are Asian countries, particularly China that, in 2019 "was the country with the highest revenue in the cosmetic segment" in Asia and, according to Statista's forecasts, it "is expected to increase the most, with a CAGR[47] of 6.9%".[48]

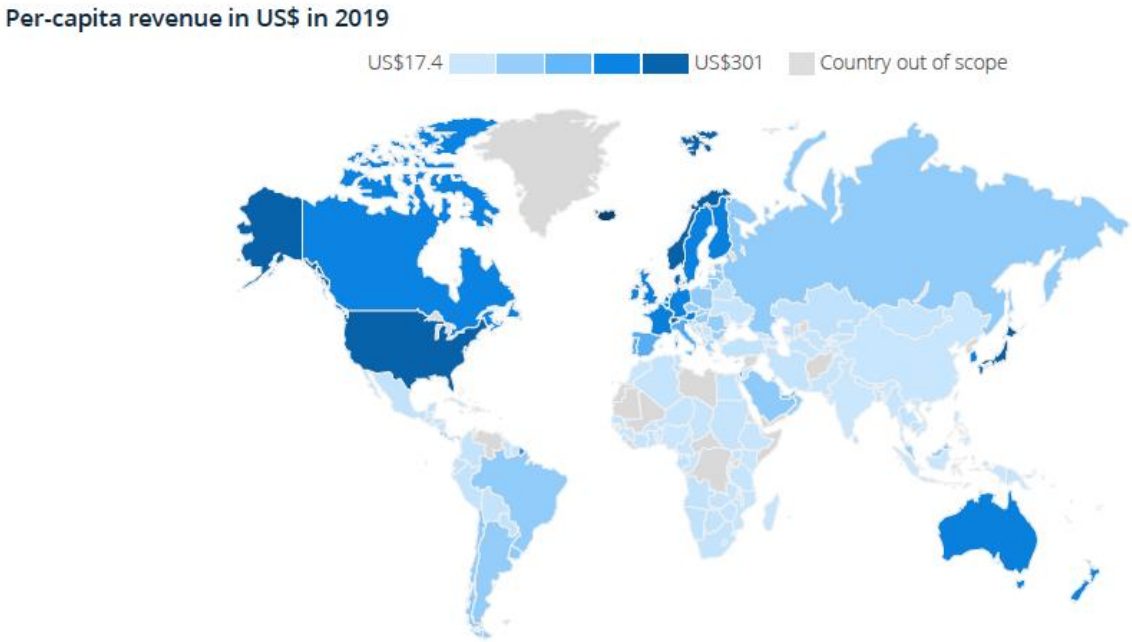

Figure 5: Per-capita revenue of the worldwide cosmetic market in 2019 (Statista, 2020)

[45] Ivi, p.8
[46] Geographical segmentation is the division of a market into segments based on geographical areas. By taking into account the international cosmetics market, the segmentation criteria are based on individual countries.
[47] Compound Annual Growth Rate (CAGR)
[48] Ivi, p.10

In the last years, competition on the cosmetic market has been increasing as more companies are entering the market and developing new products and brands.

By now, the key players on the international cosmetic market are overall European and US companies, indeed, the current major competitor is L'Oréal which, only in 2019, registered 29 billion US dollars of sales. Other important cosmetic multinationals are Unilever (with 21 billion US dollars in sales), Procter & Gamble (with 13 billion) and Colgate Palmolive (with 13.2 billion).[49]

These key players are now facing the challenge of new emerging companies coming from Asian countries, such as South Korea, Japan, and China.

According to Statista, the Japanese "Shiseido is showing high growth potential especially in the prestige and fragrances segments".[50]

Also Chinese companies have a high potential for growth, and they are acquiring a larger share of their domestic market aiming at expanding globally in the following years. One example of a "Chinese company with global ambitions" is Perfect Diary (完美日记 *wanmei riji*), which has confessed that it intends to fight against the success of Japanese and Korean beauty at the international level.[51]

As regards market trends, sales on the international cosmetic market have been characterized by the rise of e-commerce as one of the main sales channels, pushed also by the pandemic situation. Nowadays, "51% of the world's population shop online regularly"[52], this has caused a radical change in the purchasing behavior and consumption patterns showed by consumers worldwide.

The online shopping trend had a huge impact also on the cosmetic market, which is currently characterized by a well-developed online market "with a current online share of 14% of revenues in 2019 in Europe and 19% in Asia".[53] Moreover, its market share "is expected to grow by 8% annually".[54]

Another important trend at the international level is the rise of the Japanese beauty (or J-beauty) which is now threatening the well-established position on the market of Korean beauty (or K-beauty).

J-beauty includes multi-purpose products and skin-supporting foods with natural ingredients, such

[49] Ivi, p.30
[50] Ivi, p.34
[51] Marie-Hélène Corbin, "Perfect Diary, the Chinese unicorn with global ambitions", on "premiumbeautynews.com", October 13, 2020, https://www.premiumbeautynews.com/en/perfect-diary-the-chinese-unicorn,17360 (02/04/21)
[52] Ivi, p.26
[53] Ibidem
[54] Ivi, p.28

as seaweed, green tea, and rice[55] in line with a greater attention of consumers toward natural, organic, and sustainable products. In fact, another important trend that has been ruling the international market for a few years is sustainability.

Sustainability has fostered a distrust for synthetic cosmetic ingredients and a continuous search for more natural ingredients to improve cosmetic formulas with benefits for both environment and people's health.

A "growing concern about environmental issues" and an "increased awareness of pollution and related issues", such as animal testing, has given rise to a new group of so-called "green-consumers" and the appearance of "cruelty free consumer products" all over the world.[56]

International pressures for increasing environmentalism, improvement of cosmetic formulations, spread of new natural ingredients, stronger protection of animal rights and concerns for product safety assessment are highlighting the need for global regulatory changes.[57]

Therefore, countries are gradually updating their regulations on cosmetics pushing toward a convergence with requirements of other countries, not only to facilitate international trade, but also to increase product safety and to better satisfy an increasing consumer demand for natural and cruelty-free products.[58] Nevertheless, an international regulatory framework and uniform safety assessment methods worldwide do not exist yet.[59]

[55] Ivi, p.37

[56] Sameer Kumar, "Exploratory analysis of global cosmetic industry: major players, technology and market trends", *Technovation*, 25, 11, 2005, p.1268

[57] Ivi, p.1265

[58] The same phenomenon has been registered also in China in the past few years. The increasing alignment of Chinese regulation and legal requirements on cosmetics with other countries, especially with the EU, will be discussed in Chapters 3 and 4 of this thesis.

[59] The issue of international regulatory harmonization will be addressed in detail in Chapter 5 of this thesis.

2. The cosmetics industry in China

2.1 Development of the Chinese cosmetics industry

The Chinese cosmetic market has experienced an unprecedented growth in the last forty years, considering that, at the end of the Mao Zedong era, China was an underdeveloped country and many market sectors barely existed, including the cosmetic one.

How has China become the second country in the world in terms of cosmetic market size after the US?[1]

As we have seen in the previous chapter, cosmetics in China have an ancient history, however, it was not until 1980s that the Chinese cosmetics industry actually started to take off.

As a matter of fact, in the period of Mao's government and especially during the Cultural Revolution (1966-1976), the use of cosmetics, like many other goods intended for individual use, was strongly discouraged by authorities because they were considered a symbol of "bourgeois lifestyle"[2] in contrast with the Communist ideals of humility and equality.

During this period, the display of femininity and any other sign of individual distinctiveness were rejected because individuality had to be subjected to the collective wellbeing. As a result, the consumption of beauty and personal care products was limited to basic soaps produced by state factories.[3]

The situation drastically changed when Mao died in 1976 and Deng Xiaoping launched a period of reforms in 1979, known as *gaige kaifang* (改革开放). Deng's reforms influenced both ideology and economics because they promoted productivity and consumption giving a new impulse to the economic growth of China.

This ideological shift of the Communist party caused an increase in the consumption of goods, including cosmetics. During the 1980s, women began to spend more on beauty products in order to display their femininity and reclaim their personal identity after several years of restrictions.[4]

Moreover, small-scale free enterprise was encouraged causing a high-speed development of the industry, and the production of consumer goods was strongly promoted turning China into the so-called "world's factory".

Consequently, China showed an impressive economic growth, "incomes […] rose and by 1981, over 30 million Chinese were earning more than 8 times the national average income".[5]

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[1] In 2020, China has ranked second after the US in terms of beauty and personal care market size, estimated 70.9 billion US dollars. (Statista, *Cosmetic industry worldwide*, 2020, p.3)

[2] Barbara E. Hopkins, "Western cosmetics in the gendered development of consumer culture in China", *Feminist Economics, 13*, 3-4, 2007, p.289

[3] Ibidem

[4] Ibidem

[5] Russell W. Belk, Nan Zhou, "Learning to want things", *Advances in Consumer Research, 14*, 1987, p.478

The growing purchasing power of consumers and the increasing accessibility to consumer goods made the demand and consumption of several products rise. Many products became a symbol of social status and success, especially foreign products that were associated with the idea of wealth and modernity. As a consequence, consumers interest for foreign cosmetics, as means for expressing one's individuality and socio-economic status, also grew and consumption of foreign products and luxury items skyrocketed.

In fact, "sales of cosmetics grew from less than 500 million yuan per year before 1980 to 4 billion yuan in 1990, and they continued to grow in the 1990s and early 2000s"[6], especially in bigger cities and areas open to Western investments.[7]

During the 1980s, many Western companies came to China in order to invest on the market because of the profitable and unregulated investment environment and the low manufacturing costs.

The Japanese firm Shiseido was the first foreign company to enter the Chinese market in 1981, followed by the US company Avon in 1990.[8]

At that time, the Chinese cosmetics industry was at the early stages of its development. "In 1982, the total market was only about 200 million RMB"[9], there were only few Chinese cosmetic companies and competition was not strong, so Western companies took advantage of the absence of proper regulations and lower costs in order to acquire big market shares. However, foreign companies still had to face trade barriers such as expensive tariffs and difficult bureaucratic procedures to get a market license.

Only after China's entry into the World Trade Organization (WTO) in 2001, the Chinese cosmetic market rapidly prospered.

The membership of WTO was a milestone in the Chinese history because it marked the opening of China to international trade and its official recognition as a nation by the world's most powerful countries. In order to join the WTO, China agreed to lower its tariffs on several products including cosmetics. Indeed, import tariffs on cosmetics were lowered from 55% to 20-28% in 2001 and, in the following years, these tariffs continued to be further reduced reaching 10% in 2005.[10]

Lower tariffs encouraged Western companies to import greater amounts of products in China and many of these companies decided to establish their production facilities on the Chinese territory

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[6] Barbara E. Hopkins, "Western cosmetics in…", cit., p.290

[7] The economic reforms promoted by Deng included the establishment of Special Economic Zones (经济特区 *jinji tequ*), opened to Western investments and characterized by a favorable investment environment. In these Special Economic Zones, the Chinese government provided economic incentives for foreign companies willing to invest in China.

[8] Ivi, p.293

[9] Lei Tang, *The Chinese consumer market: opportunities and risks*, Oxford, Chandos Publishing, 2009, Chap.3 "The cosmetic sector in China", p.47

[10] Ivi, p.294

because of lower manufacturing costs.

Under WTO's pressures, China agreed to further lift restrictions on wholesale and retail in 2006 and to open its advertising industry to foreign investments.[11] Consequently, Western multinationals, such as L'Oréal, got greater access to the Chinese mass market and expended not only to big metropolis but also to smaller cities, acquiring the majority of cosmetic market shares.

After the Chinese entry into the WTO, foreign cosmetics have gradually dominated the Chinese market so that, in 2003, 32% of the cosmetic companies in China were foreign-owned and the 68% of the whole Chinese cosmetic market was occupied by foreign imported products or cosmetics produced by foreign firms located in China.[12]

Increasing competition on the market, together with rapid economic growth and improved living conditions of Chinese consumers, fostered a fast-growing development of the Chinese cosmetic market, which grew more than two hundred times since the early 1980s, reaching 62 billion RMB of annual sales in 2006.[13]

Even though import tariffs were gradually lifted, there were other non-tariff barriers such as strict regulations in terms of product testing, labeling and registration. These regulations were implemented by China in order to protect its domestic cosmetic market and prevent big foreign enterprises from establish a monopoly. Indeed, in 1990 the Ministry of Health (MoH) had already formulated and implemented the *Cosmetics Hygiene Supervision Regulation* (CHSR)[14] in order to strengthen the supervision over cosmetic products on the Chinese market, to ensure quality and safety of products and to protect consumer's health. In particular,

> it stipulates that the state shall exercise hygiene supervision over enterprises engaged in production of cosmetics by means of hygiene license system and the use of new cosmetic raw ingredients, special cosmetics and cosmetics imported into China for the first time must get approval from the health administrative department under the State Council.[15]

It also forbade the sale of certain types of products and the use of specific contents in cosmetic advertising.

In the following years, the above-mentioned regulation was followed by the implementation of other requirements on cosmetics such as the *Requirements for Application and Acceptance of*

[11] Ivi, p.296
[12] Ivi, p.297
[13] Lei Tang, *The Chinese consumer market…*, cit., p.47
[14] This was the first attempt to regulate cosmetic production and trade on the Chinese market. CHSR was gradually changed during the years resulting in a complex fragmentated regulatory framework that was not able to ensure proper product safety and posed significant trade barriers for foreign companies. In 2013, a process of revision and update of the CHSR started, ending up in 2021 with the entry into force of the new *Cosmetic Supervision and Administration Regulation* (CSAR). CSAR has introduced revolutionary changes in the Chinese regulatory framework, as we will discuss in Chapter 3 of this thesis.
[15] ChemLinked, "Regulations concerning the Hygiene Supervision over Cosmetics", on "cosmetic.chemlinked.com", https://cosmetic.chemlinked.com/database/view/768 (06/04/21)

Administrative Licensing for Cosmetics released by the State Food and Drug Administration (SFDA) in 2009 with more details and higher demands in terms of documents and duties to fulfill in order to get a cosmetic production license.[16]

Other legal provisions were the *Administrative Provisions on Cosmetics Labeling* (2008)[17], the *INCI Chinese version for the denomination of cosmetic ingredients* (2010)[18], the *Guidelines for Risk Assessment of Cosmetic Raw Materials* (2011)[19] and other safety and technical standards.

These regulations and provisions have been revised in recent times or they are about to be updated in order to better suit the new conditions on the Chinese cosmetic market.

Latest developments are demonstrating an interest on part of the Chinese government to foster cosmetics trade on its domestic market through the revision of its legal requirements in line with other international regulations.[20]

To sum up, the development of the cosmetic market in China can be divided into 4 stages:[21]

- A "starting stage" from the beginning of 1980s, when the cosmetic market was underdeveloped and mainly dominated by few small domestic companies in Shanghai which produced a small range of products mainly targeted at the low-end market.
- A "competitive stage" from 1982 to 1996, when China's economic reforms made the Chinese market open up to international cosmetic companies. Foreign companies subtracted huge market shares from local Chinese cosmetic companies and started to import know-how and high-end products fostering the development of the Chinese cosmetics industry.
- A "developing stage" from 1996 to 2002, in which the Chinese cosmetic market arrived at a mature stage with a developed competitive environment and a wide variety of well-targeted products to satisfy the increasing consumer demand.
- A "growing stage" from 2002 up to now, in which international companies are conducting product development strategies to enter lower levels of the Chinese market thanks to their strong brand image. Meanwhile, new Chinese local cosmetic companies are emerging, and they are trying to carve out a space on the domestic market through new media and new distribution channels. Their aim is to build their brand image and grow on the domestic market in order to be able to compete with foreign firms.

[16] ChemLinked, "Provisions for Application and Acceptance of Administrative Licensing for Cosmetics", on "cosmetic.chemlinked.com", https://cosmetic.chemlinked.com/database/view/770 (06/04/21)
[17] Full text available at: http://www.lawinfochina.com/display.aspx?id=6384&lib=law (06/04/21)
[18] Full text available at: http://law.foodmate.net/show-172248.html (06/04/21)
[19] Further information: https://cosmetic.chemlinked.com/database/view/1005 (06/04/21)
[20] This tendency to align Chinese regulations with international ones will be discussed in the next chapters of this thesis.
[21] Yong Fu, *Potential of the Chinese cosmetic market*, Oulu University of Applied Sciences, 2013, p.16, https://www.theseus.fi/bitstream/handle/10024/63667/Fu_Yong.pdf?sequence=1 (07/04/21)

With the development of the Chinese cosmetic market, there was an increasing need to formulate and implement specific regulations and provisions on cosmetics approval, registration, labeling and testing, first of all, with the aim of protecting the domestic market from the "Western colonization". Then, these requirements have been constantly revised with more attention toward cosmetics safety and facilitation of cosmetics trade both inside and outside of China.

2.2 Analysis of the Chinese cosmetic market

2.2.1 Market size and growth rate

As we have mentioned in the previous paragraph, the Chinese cosmetic market is the second largest market worldwide and it has a huge growth potential.

According to Euromonitor's data, the cosmetic market in China was worth 410.48 billion RMB (almost 60 billion USD) in 2019. And it is expected to grow more than 100 billion USD by 2024.[22] Due to recent events linked to the spread of the Coronavirus, in 2020 the domestic cosmetic market grew at the lowest rate ever registered in the last five years, estimated at -3.0% compared to previous years.[23]

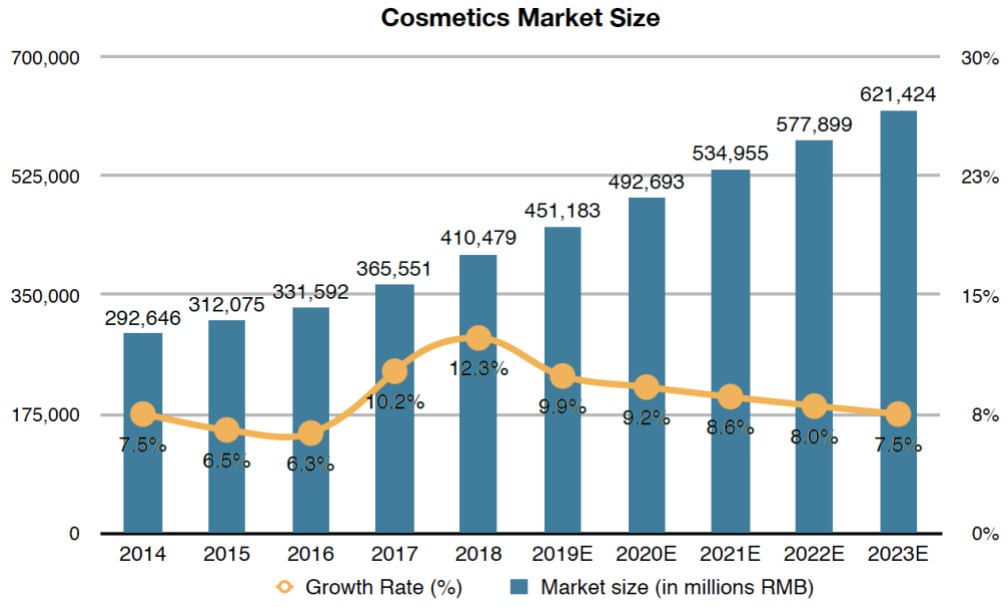

Figure 6: Chinese cosmetics market size (Euromonitor, 2020)

Even though forecasts have been adjusted downward compared to original predictions made before the outbreak of Covid-19, the cosmetic market size is supposed to keep on expanding even with an overall declining growth rate on previous years.

[22] TMO Group, *China cosmetics industry report*, October 2020, p.5
[23] Zhao Yongjie, "Analysis on development of China's cosmetics industry from 2019 to 2020", *China Detergent & Cosmetics*, *5*, 3, 2020, p.54

As a matter of fact, the Chinese cosmetic market was severely affected by the pandemic during the first half of 2020, but it started to bounce back in April and quickly got back to grow in the following months. In October, its total retail sales increased by 18.3%, and in November, total retail sales even grew by 32.3% due to the Double 11[24] shopping festival.[25]

Skincare and makeup products are the two biggest categories of cosmetics on the Chinese market, they respectively occupy the 53.5% and the 9.9% of market shares.[26]

Skincare products alone constitute more than half of the entire Chinese cosmetic market with a year-on-year compound growth rate of 6.23% between 2015 and 2019.[27]

Skincare market value was estimated at 233.71 million RMB in 2019 with a growth rate of 10.1% on 2018, but three points of percentage lower compared to the growth rate registered in previous years.[28]

Its growth rate is expected to slow down during the next years because of the recent recession that has affected different sectors after the pandemic outbreak. Another cause behind the declining year-on-year growth rate is the reached maturity of the skincare market. Indeed, skincare products have already achieved a penetration rate close to 100% among Chinese consumers.[29]

The make-up segment accounts for 9.9% of the total cosmetic market in China with a market value of 43.39 million RMB. Even if its growth rate is expected to slow down in the immediate future, according to forecasts made by Euromonitor, its market size will continue to constantly grow since "cosmetics brands traditionally more interested in skincare products [are showing a] shift […] of their focus to concentrate more on makeup products than in previous years".[30]

The biggest share of the entire make-up segment is represented by lipsticks that occupy the 39%[31], and they are expected to reach 33.4 billion USD of sales by 2023.[32]

The remaining cosmetics market share is mainly constituted by fragrances and personal care products like shampoo and soaps, as shown by the following chart based on Euromonitor's data.

[24] Double 11 or Single's Day (双十一 *shuangshiyi* or 光棍节 *guanggunjie* in Chinese) is a Chinese unofficial festival celebrated the 11th of November. During this day, there are several sale discounts online so Chinese consumers tend to spend more and online platform register record-breaking sale volumes each year.
[25] ChemLinked, "China Beauty & Care Market 2021: 10 trends to watch", on "chemlinked.com", December 17, 2020, https://cosmetic.chemlinked.com/report/china-beauty-care-market-2021-10-trends-to-watch (08/04/21)
[26] TMO Group, *China cosmetics industry report*, October 2020, p.5
[27] Zhao Yongjie, "Analysis on development of China's cosmetics industry from 2019 to 2020", *China Detergent & Cosmetics*, *5*, 3, 2020, p.54
[28] TMO Group, *China cosmetics industry report*, October 2020, p.7
[29] Ivi, p.5
[30] Ivi, p.9
[31] Statista, *Cosmetics market in China*, 2020, p.33
[32] TMO Group, *China cosmetics industry report*, October 2020, p.10

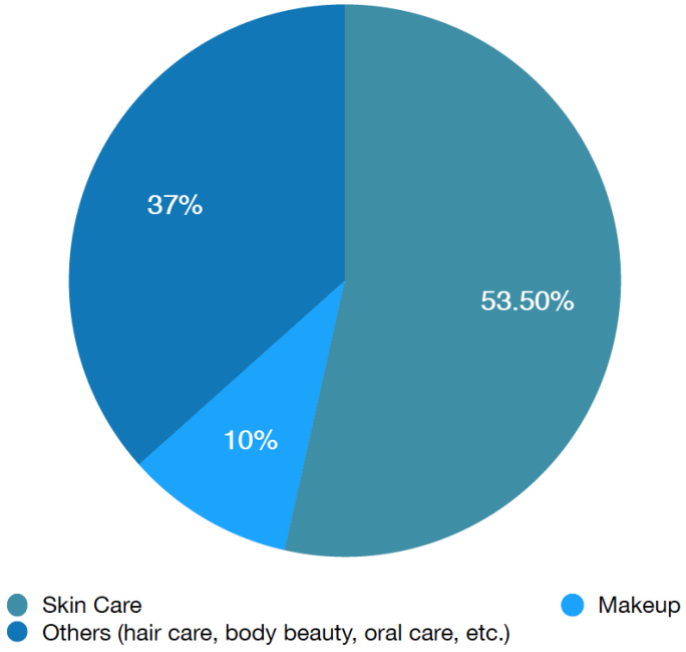

Figure 7: Cosmetic market shares (Euromonitor, 2020)

2.2.2 Analysis of the consumer demand

In the last decades, China has experienced an outstanding economic growth, as a result consumer disposable income has increased together with consumer demand for all kinds of products, from food to luxury goods. Therefore, consumption have escalated reaching the level of spending volume in well-developed Western countries. However, Chinese per-capita retail sales of cosmetics are only about a quarter of the retail sales in developed countries, and so China still has a lot of potential for growth in the future.[33]

China is one of the countries with the highest level of consumer demand for luxury brands and imported goods because they are considered as products with higher quality and symbols of high social status.

As we have discussed in the previous paragraph, the Chinese cosmetics industry really started to take off when Western companies launched their products and invested on the local market. As the cosmetic market grew, also consumer demand increased becoming more sophisticated and diversified over time.

The main target for cosmetic products can be defined as “female consumers older than 20 who live in cities, with an annual income of at least 30,000 RMB”.[34] The size of this consumer target more than doubled in the decade 2005-2015, growing from 22 million to 200 million female consumers. According to estimates, this group has overcome 400 million in 2020.[35]

[33] TMO Group, *China cosmetics industry report*, October 2020, p.5
[34] Ibidem
[35] Ibidem

Recent developments on the Chinese cosmetic market let new targets of consumers emerge, in particular, sales are mostly driven by Generation Z[36] nowadays. This new generation of young Chinese consumers are keen to express their individual personality by showing off their status and by paying greater attention to one's appearance and fashion trends, therefore they are more willing to spend money on luxury items and cosmetic products, especially on make-up.[37]

In China, about the 95% of Generation Z in China have a per-capita disposable income of more than 3,000 RMB, a higher average wage compared to the one that previous generations had at the same age.[38]

They currently account for about the 23% of the total Chinese population and they are expected to lead consumption on the Chinese market and even at international level in the next 5-10 years.[39]

While the demand for make-up products is mostly driven by young people, skincare products attract consumers of any age. Moreover, skincare nowadays appeals to all consumers regardless of their sex. As a matter of fact, in the last years, demand for male skincare products has also increased, so that the male segment is becoming an important target for cosmetic companies. Indeed, a survey conducted by CBN has shown that nearly the 90% of Chinese men believe that skincare is a necessary step in their daily routine, and they regularly buy skincare products to meet this need.[40]

As a result, retail sales of male cosmetic products reached about 15.6 billion RMB in 2019, growing by 8% on the previous year.[41]

In terms of demographics, in a market traditionally focused on big tier-1 cities, demand for cosmetics has recently taken off among consumers in tier-3 cities, smaller cities and rural areas. This demographic group was previously mostly ignored by companies due to the fact that consumers in such areas had low per-capita income compared to tier-2 and tier-1 cities. But now, while consumption in 1st tier cities represents just the 17% of the whole cosmetic market, it respectively accounts for the 23% and the 25% in 3rd tier and 4th tier cities, increasing at a steady pace and approaching consumption in 2nd tier cities (35%).[42]

[36] The generation of people born between the late 1990s and the early 2000s
[37] TMO Group, *China cosmetics industry report*, October 2020, p.9
[38] Ivi, p.11
[39] ChemLinked, "2020 China New Consumer Brands Insight Report", on "cosmetic.chemlinked.com", September 14, 2020, https://cosmetic.chemlinked.com/report/2020-china-new-consumer-brands-insight-report (08/04/21)
[40] TMO Group, *China cosmetics industry report*, October 2020, p.12
[41] HKTDC Research, "China's cosmetic market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (08/04/21)
[42] TMO Group, *China cosmetics industry report*, October 2020, p.12

2.2.3 Sales channels

At the early stages of development of the Chinese cosmetic market, cosmetic products were mainly sold through supermarkets and department stores. As the market grew, the first cosmetic stores made their appearance and had great success because of effective marketing strategies and improved customer service.

Nowadays physical stores are mainly department store, supermarkets, and cosmetic specialty stores. International brands focus primarily on department store and duty-free shops, while domestic brands are more likely to focus on supermarkets and cosmetic stores.

According to Statista's report, in 2019 the higher retail revenue was registered by specialty cosmetic chains (27.3%), followed by supermarkets (19%), multi-brands shops (18.6%) and department stores (18.1%). Drugstores and pharmacies were the least successful offline channels with just the 7.9% of total retail revenues.[43]

In recent years, due to the rapid development of online shopping and increasing popularity of e-commerce platforms, sales through offline sales channels are declining.

Nevertheless, the market share of offline sales channels still exceeds the 60%.[44] This is due to the fact that companies have successfully implemented omnichannel strategies that mix offline and online sales channels taking advantage of both the practicality of online platforms and the engaging experience of offline stores. As a result, offline stores have begun to integrate digital services into their sales model. For example, online live-streaming demonstrations of products registered from offline stores or taking orders online and delivering them in physical stores.[45]

However, it is undeniable that e-commerce and online shopping will play an increasing important role on the Chinese market, especially after pandemics, during which we are witnessing an outstanding growth of online sales due to national lockdowns and shot-downs of shops.

E-commerce also owes its success to consumers in lower tiered cities that do not have access to the major channels of distribution and so turn to online shopping in order to satisfy their needs.

Moreover, many foreign companies have taken advantage of e-commerce to export their products to China and to make cross-border transactions because of the easier process, the lighter bureaucracy and the legal gaps linked to this new mean.

Online sales of skincare products have increased from 17% in 2014 to 29.7% in 2019, whereas the online sales of make-up has risen from 20.7% to 38%.[46]

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[43] Statista, *Cosmetics market in China*, 2020, p.17
[44] TMO Group, *China cosmetics industry report*, October 2020, p.19
[45] Ivi, p.20
[46] HKTDC Research, "China's cosmetic market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (08/04/21)

The most popular e-commerce platforms are Tmall and JD.com, that help brands increase their sales thanks to the huge traffic on their platforms. According to Statista, the major retail revenue in 2019 has been registered by Tmall with the 49.6% of total retail revenue share, followed by JD.com with the 31.3%.[47]

E-commerce is thriving also thanks to the integration with social media such as TikTok (Douyin in China), Kuaishou or Xiaohongshu, which attract bloggers and consumers who share make-up tutorials and their personal evaluations on cosmetics.

Many stores now use the "Mini-programs" embedded in WeChat which link the popular instant messaging app with online stores. Given that WeChat is used by almost everyone in China on a daily basis, traffic acquisition is easier, and brands attract a more diversified consumer audience.[48]

Recently, an important driver for online sales is live-streaming displays of cosmetic products made by beauty influencers through these social media and on e-commerce platforms.

For example, on October 20, 2019, the two most popular live-streaming hosts on Taobao succeeded in selling more than 600 million RMB of merchandise, a major share of their revenue was constituted by make-up or skincare products, body shaping products, essential oils, make-up, perfumes and beauty tools.[49]

Since the outbreak of Covid-19 stopped sales of offline stores and threatened business performances, many companies have turned to online platforms to support their business and have started to employ live-streaming to promote their products so that the "market size of live streaming e-commerce is expected to reach 971 billion yuan"[50] in 2020 and it is expected to dominate the market also during 2021.

2.2.4 New trends on the market

Several new trends have emerged on the Chinese market during the last few years. Among them, male cosmetics are having great success recently. Chinese male cosmetic market was worth about 15 billion yuan in 2020, with an annual growth rate of 17%. Moreover, it has witnessed a huge growth during the Double 11 shopping festival in 2020. For example, L'Oréal sales of male products reached 50 million yuan on Tmall.[51]

At the moment, male cosmetic market in China is dominated by foreign imported brands, however, new Chinese male cosmetic brands have emerged in 2020, such as Dear Boy Friend, Martin, Zhe

[47] Statista, *Cosmetics market in China*, 2020, p.18
[48] TMO Group, *China cosmetics industry report*, October 2020, p.22
[49] Ibidem
[50] ChemLinked, "China Beauty & Care Market 2021: 10 trends to watch", on "cosmetic.chemlinked.com", December 17, 2020, https://cosmetic.chemlinked.com/report/china-beauty-care-market-2021-10-trends-to-watch (09/04/21)
[51] Ibidem

and Make Essence.

This is in line with another recent trend that has seen many new domestic cosmetic brands make their appearance on the Chinese market starting from 2019. These domestic brands leveraged online platforms and social media to build brand awareness among Chinese consumers and they became popular especially among young people.

They have implemented new strategies to stand out from their international competitors, creating products outside from usual segmented demands, promoting products through word of mouth on social media or selling only through e-commerce platforms.

One emblematic example is provided by Perfect Diary, a domestic brand of make-up and skincare products, that, together with another Chinese brand called Florasis, they are the only two Chinese cosmetic brands in the top 10 of the bestsellers in 2020. Among the best domestic cosmetic brands by sales, Florasis and Perfect Diary led the market in April, May, and June 2020 despite of recession due to the Covid-19 outbreak, and they will continue to grow in the near future.[52]

Florasis is another popular domestic brand specialized in make-up products. It claims to draw from the Chinese medicine tradition and combines it with modern make-up ingredients to produce cosmetics tailored for Asian skin. Florasis went viral online because of its sophisticated carved lipsticks and eye shadow palettes and became the first make-up brand in China during 2020, outperforming its local competitor Perfect Diary and reaching 220 million yuan during the Double 11.[53]

Another important trend in line with other countries worldwide is the greater attention of consumers toward sustainability and the search for natural safe ingredients in cosmetics.

Chinese consumers are increasingly aware of the safety issues related to cosmetics; therefore, they are beginning to prefer eco-friendly natural cosmetics. Since Chinese consumers tend to believe in traditional Chinese herbal medicine and herbal-formulated skincare products have a long history in China, cosmetics using natural herbs are now preferred by many consumers. Indeed, products processed from natural and green ingredients without preservatives or potentially harmful chemicals are getting more popular on the Chinese market.[54]

Moreover, cosmeceuticals[55] or functional products have long been popular, because of their safe, natural formula and their effectiveness.

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[52] ChemLinked, "2020 China New Consumer Brands Insight Report", on "cosmetic.chemlinked.com", September 14, 2020, https://cosmetic.chemlinked.com/report/2020-china-new-consumer-brands-insight-report (09/04/21)

[53] Ibidem

[54] Lei Tang, *The Chinese consumer market: opportunities and risks*, Oxford, Chandos Publishing, 2009, Chap.3 "The cosmetic sector in China", p.55

[55] The term "cosmeceutical" was created in 1990s from cosm(etic) + (pharma)ceutic. The cosmetic industry widely uses this term, but it is not officially recognized in regulations provided by the FDA or the EU. Cosmeceuticals are cosmetic products claiming to have medicinal or drug-like benefits, they are often marketed as cosmetics, but reputedly contain

In China, online market size of functional skincare products has reached 79.6 billion yuan in 2020. ChemLinked website has reported some data from the Chinese Journal of Dermatology and Venereology showing that, one out of three women in China has a sensitive skin problem, so they tend to prefer more natural products with both cosmetic and pharmaceutical benefits.[56]

Due to the outbreak of Covid-19, consumers' skin problems worsened because of the need of wearing masks. As a result, sale of functional skincare brands to treat specific skin issues has taken off in 2020.[57]

In line with the consumer trend of natural and healthy cosmetics, the cosmeceutical or functional skincare market has a huge potential for growth, and it is influencing the latest developments on the Chinese cosmetic market.

Requirements for high quality and better performance are increasing, and the awareness on part of consumers and legislative bodies in terms of security is also improving. Therefore, cosmeceutical manufacturers need a greater amount of safe and economical raw materials, and they also need to produce certificated natural products with low toxicity to meet market requirements.

The success of the above-mentioned products has also caused developments in terms of regulations, quality standards and safety assessment that we will discuss in the following chapters.

2.3 Competitive scenario

2.3.1 Chinese competitors

As already mentioned in previous paragraphs, the Chinese cosmetic market is mainly dominated by foreign companies, especially European and American ones, that occupy almost the 80% of the total Chinese cosmetic market.

In the last decade, only a few Chinese companies, such as Shanghai Jahwa or Proya, have been able to compete against big international firms, even though they always remained only in the lower end of the market.

Until 2017, only three domestic companies managed to appear in the top 10 companies on the Chinese cosmetic market: Shanghai Chicmax Cosmetic Co.,Ltd., Pechoin and Jala Group. For instance, the market share of Pechoin increased from 1.4% in 2014 to 2.3% in 2017, ranking the second place; the market share of Chando[58] increased from 1.3% in 2014 to 1.7% in 2017, ranking

biologically active ingredients. (Charles Patrick Davis, "Medical Definition of Cosmeceutical", on "medicinenet.com", https://www.medicinenet.com/cosmeceutical/definition.htm, 09/04/21)

[56] ChemLinked, "China Beauty & Care Market 2021: 10 trends to watch", on "cosmetic.chemlinked.com", December 17, 2020, https://cosmetic.chemlinked.com/report/china-beauty-care-market-2021-10-trends-to-watch (09/04/21)

[57] Ibidem

[58] Chando is the main brand of the Jala Group, mentioned in the previous line.

the fifth place.[59]

Even though these companies have been the predecessors of this new wave of emerging Chinese cosmetic companies, they still were not able to force foreign companies out of the market and, even though they are still in the front line of key market players, they are now in a stagnant position. Indeed, traditional domestic makeup brands were left behind, with Carslan, Marie Dalgar, and Kans that saw their market share shrink by 0.6, 0.6 and 0.4 percentage points respectively.[60]

However, new Chinese cosmetic companies are recently emerging on the market, some of them have experienced a significant growth in the last year and they could pose a threat to foreign firms in the near future. Some examples are Perfect Diary, Florasis and Lannifanke (respectively the first, second and third domestic company in terms of sales revenue in the make-up segment), or Little Dream Garden (that ranked first among the top domestic companies in 2019) or Winona (whose sales grew a lot during 2019 approaching well-established local companies like Chando and Pechoin).[61]

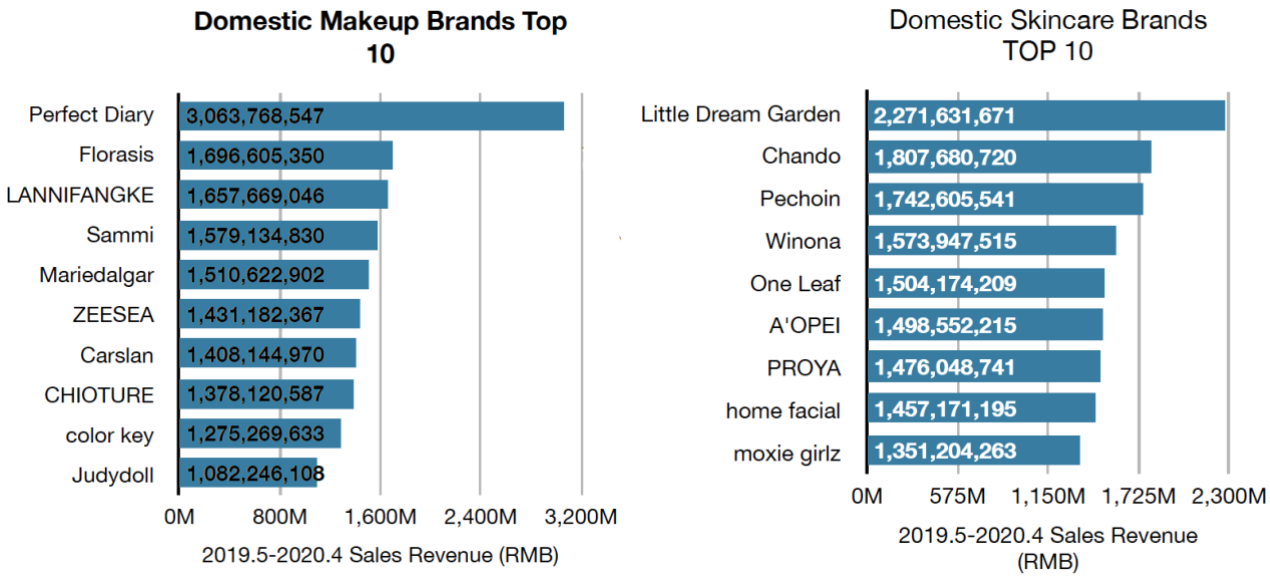

Figure 8: Top 10 domestic makeup and skincare brands in 2019 (Euromonitor, 2020)

As domestic brands continue to grow, some leading international brands are losing their market share. For example, as regard the make-up segment, Chinese makeup brands Chioture and Zeesea managed to knock international brands Laneige and Mary Kay out of the top 20 in 2019. Meanwhile, the new brand Perfect Diary ranked 6th in the top ten makeup brands, the most impressive result among domestic competitors.[62]

[59] Wang Jixing, "High-Speed Growth of the Cosmetics Market in China", *China Detergent & Cosmetics*, 3, 4, 2018, p.26
[60] TMO Group, *China cosmetics industry report*, October 2020, p.17
[61] Ivi, p.26
[62] Ivi, p.16

Perfect Diary grew by 1.6 percentage points in 2019 thanks to successful live-streaming campaigns, and many other emerging domestic makeup brands took advantage of this booming live-streaming trend showing a considerable market share growth in 2019. For example, apart from Perfect Diary, Zeesea also grew by 0.6.[63]

Unlike the makeup market, which is far more dominated by foreign brands, the top 20 skincare brands in 2019 include a total of nine Chinese brands.

Nevertheless, during the last years these domestic brands posted a negligible growth (+0.1 percentage points for Proya, and less than 0.1 for Chando and Aupres of Pechoin) or even small losses in market share (-0.1 percentage points for Herborist, -0.2 for Kans, and -0.3 for One Leaf and Hanhoo).[64]

While domestic brands continue to put up a fight against overseas competitors in the makeup segment, they have yet to find the same success when it comes to skincare because of consumers' distrust toward Chinese products in terms of safety and quality. Since skincare products are consumed at a higher rate compared to other types of cosmetics in China and the average price is more or less the same between foreign and local skincare products, consumers are willing to pay for more expensive international brands with higher reputation in terms of quality. Anyway, there are a few emerging Chinese skincare brands that are having great success, for example HomeFacial Pro, which managed to increase its market share from 0.2% in 2018 to 0.9% in 2019.[65]

Presently, although many Chinese companies are generally appreciated by local consumers, they are still facing many difficulties in gaining competitive advantage over large international companies. Nevertheless, foreign cosmetic professionals still consider them potential threats because Chinese companies are more flexible and quickly adapt to market changes, they can easily get access to bank loans and stock markets for business expansion and they are more familiar with Chinese laws and bureaucracy, culture, and business environment.[66]

In order to compete, domestic brands are relying on more localized marketing strategies, targeting niches of consumers and uncovered product demand. Moreover, instead of targeting high-income customers in tier-1 and tier- 2 cities, local players are focusing on tier-3 and tier-4 cities.[67] They are investing on e-commerce to increase their sales and they are promoting their products mainly on social media, like WeChat, to increase brand awareness. Additionally, while foreign companies

[63] Ivi, p.17
[64] Ivi, p.15
[65] Ibidem
[66] Lei Tang, *The Chinese consumer market: opportunities and risks*, Oxford, Chandos Publishing, 2009, Chap.3 "The cosmetic sector in China", p.50
[67] Wang Jixing, "High-Speed Growth of the Cosmetics Market in China", *China Detergent & Cosmetics*, 3, 4, 2018, p.27

produce high-end products, Chinese companies are concentrated on mid- to low-end cosmetic production.

Domestic companies have successfully opened up a cosmetic market with Chinese traditional characteristics, for example Florasis, which became popular for its lipsticks and eye palettes inspired by Chinese traditions, or Herborist, that develop its lines of skincare products applying Chinese medicine methods and natural ingredients.

Domestic brands are actively applying traditional Chinese medicine concepts and natural extraction methods in the development of skincare products, such as the product lines of Herborist, Tai Ji and Yu Wu Xing.[68]

At present, these strategies are proving to be fairly effective, and many Chinese local brands are having great success threatening well-consolidated foreign market shares, but it is still not enough to completely overcome foreign competitors.

2.3.2 European competitors

European cosmetic companies dominate major shares of the Chinese cosmetic market, together with other American and Japanese firms.

Their huge success is primarily due to their strong brand image and popularity among Chinese consumers that tend to automatically associate them with the idea of quality, safety, and high social status. Moreover, they benefit from significant financial resources due to their long experience in the field and their well-established business model that facilitate new investments and innovation to support their market strategies and increase customers' loyalty. Additionally, their strong capability of product development in their R&D centers and their effective marketing strategies allowed them to adapt to the Chinese market and consumers' taste.[69]

Although several Chinese cosmetic companies are trying to catch up, European companies still own the most popular brands in China such as L'Oréal, Unilever, Nivea, and Chanel.

According to data provided by Euromonitor in 2019, foreign companies dominated the make-up market in China, 14 of the top 20 brands in the Chinese makeup market were foreign-owned.[70]

Almost the 35% of total make-up market was held by European brands such as L'Oréal (6%), Dior (7%), Lancôme (4%), Giorgio Armani (4%), Chanel (3%), etc., as we can see in the following chart.[71]

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[68] HKTDC Research, "China's cosmetic market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (13/04/21)

[69] Lei Tang, *The Chinese consumer market: opportunities and risks*, Oxford, Chandos Publishing, 2009, Chap.3 "The cosmetic sector in China", p.50

[70] TMO Group, *China cosmetics industry report*, October 2020, p.15

[71] Ivi, p.16

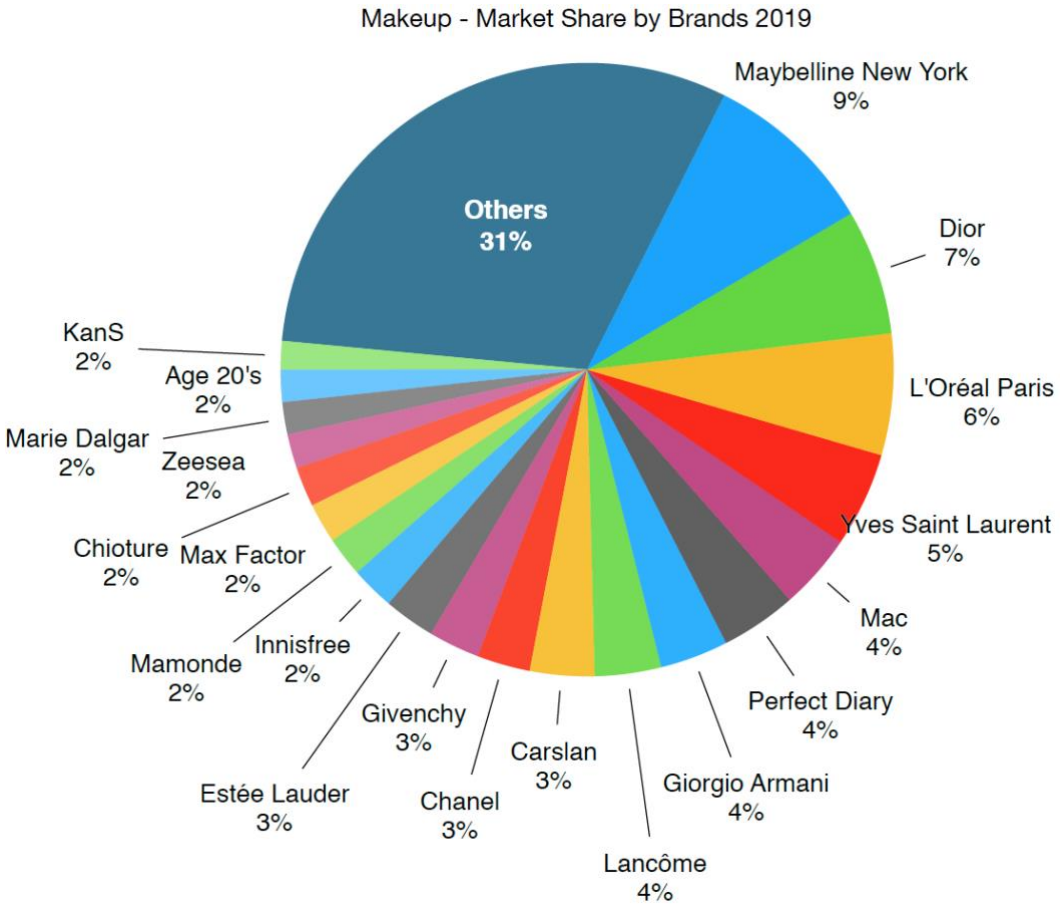

Figure 9: Makeup market share by brands in 2019 (Euromonitor, 2020)

Even though European and other foreign companies have well-consolidated market shares, Chinese make-up companies are recently emerging on the market, and they could pose a threat to foreign firms in the following years. Indeed, as domestic brands continue to grow, some leading international brands have lost market share. For example, the market share of L'Oréal shrunk by 0.6 in 2019.[72]

As regards the skincare market, the only European brands with relevant market shares in 2019 were L'Oréal and Lancôme, respectively with the 3.7%. Indeed, European brands in China are now facing the threat of Korean and Japanese skincare trend and rising popularity of some Chinese cosmetic brands. As shown by the figure below, competitive market shares were occupied by Chinese brands such as Pechoin (4.5%) or Chando (3.4%), Japanese brands like SK-II (1.7%), and Korean brands as Innisfree (1.5%).[73]

[72] TMO Group, *China cosmetics industry report*, October 2020, p.16
[73] Ivi, p.15

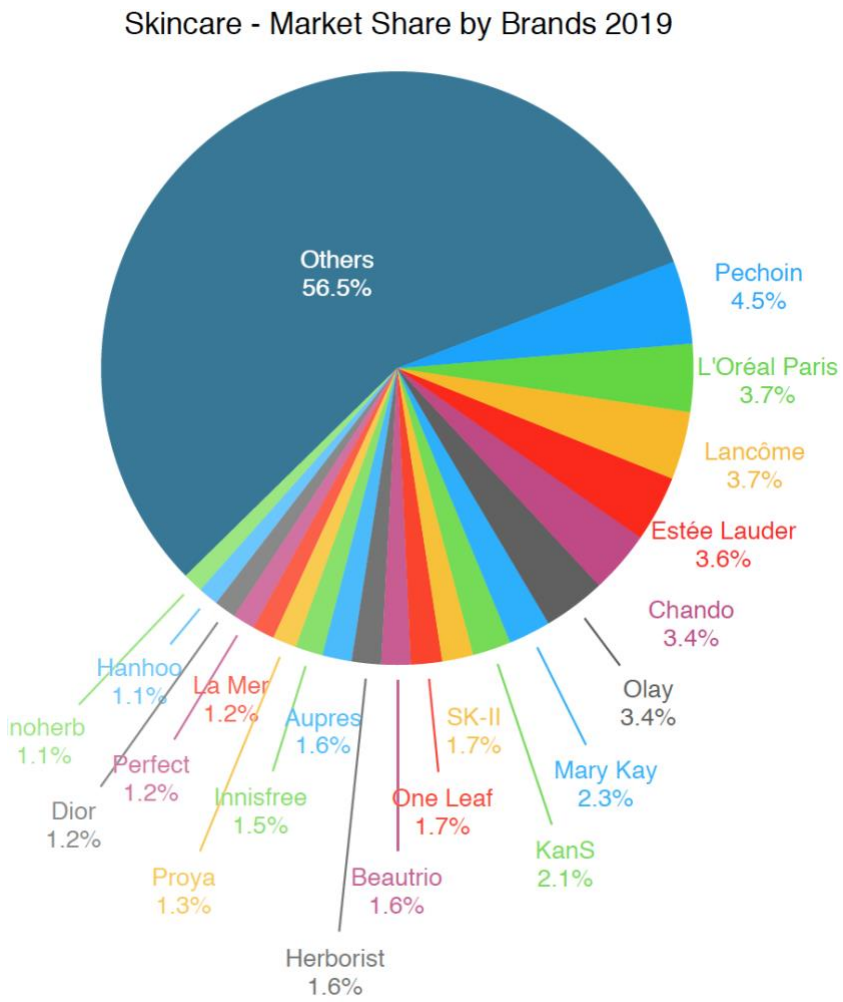

Figure 10: Skincare market share by brands in 2019 (Euromonitor, 2020)

Despite increasing competition on the skincare market, European companies are showing overall positive market performance. For instance, L'Oréal saw a respectable growth of +0.5 in 2019 thanks to its omnichannel strategies, meanwhile the international high-end cosmetic brand Lancôme first experienced a profit loss due to heavy e-commerce investments, but then post a growth by the end of the year (of +0.7 percentage points).[74]

By looking at sales revenues in 2019, many European brands were among the top 10 bestsellers both in the makeup and in the skincare market.

L'Oréal was still the first skincare brand with 4 billion RMB, while in the makeup market, the higher revenue among European brands was registered by Yves Saint Laurent that was ranked second after the American Mac.[75] Other important results were shown by Giorgio Armani and Dior in the make-up field and by Lancôme for skincare. Detailed data are reported in the following charts.

[74] TMO Group, *China cosmetics industry report*, October 2020, p.15
[75] Ibidem

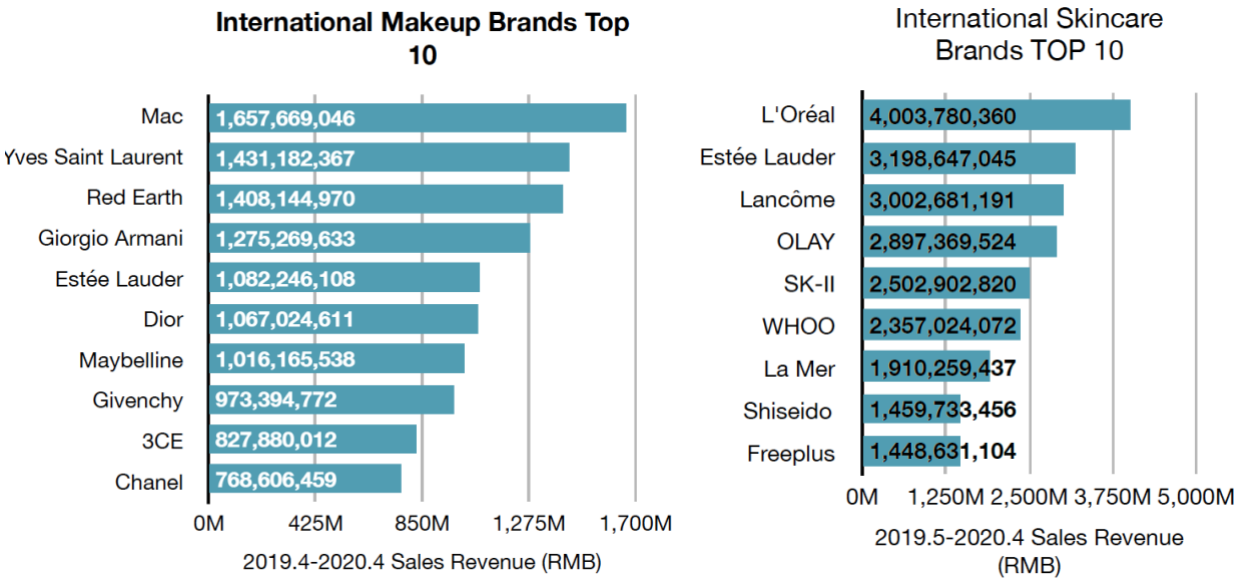

Figure 11: Top 10 international makeup and skincare brands in 2019 (Euromonitor, 2020)

In conclusion, most of European cosmetic companies on the Chinese market are big corporation with a strong brand recognized at international level. Thanks to their large resources and broad experience, they managed to conquer significant market shares and they entered among the bestselling brands in China. Now they are facing the threat posed by emerging new Chinese cosmetic companies which are becoming more and more popular, but big international corporations are managing to hold their position on the market for the moment.

For other European medium- and small-size enterprises it is more difficult to enter and consolidate their position on the Chinese cosmetic market due to strong competition and lack of resources. An example of a small-size European company that started its internationalization process to China is the Italian Kiko, which arrived in China in 2018 through cross-border e-commerce and achieved reasonable but limited success.[76] Indeed, for companies of similar entity, it is not easy to export or establish themselves on the Chinese market, not only because of the reasons already mentioned before, but also due to a series of trade barriers.

As we will discuss in the next chapter, these barriers to entry are mainly related to different regulations and standards in terms of quality and safety, the number of documents required to import products and the complex procedures to register products and brands in China.

[76] Ivi, p.39

3. Barriers to entry: new Chinese regulations, safety assessment and other legal requirements on cosmetics

In the previous chapter, we have discussed how the Chinese cosmetics market is mainly dominated by foreign companies. Imported products and production licensing have increased significantly during the last few decades. However, the potential of imported products is much bigger compared to actual data. This is due to the fact that China has always adopted a protectionist approach towards international trade, implementing measures to obstruct massive foreign entry and protecting its domestic market from a "foreign invasion".

China's protectionism has translated into strict legal requirements on cosmetics and complex mechanisms for importation of this kind of products, and that, at least in part, has contained and controlled foreign import into the Chinese market. Initially, only big foreign corporation and well-established brands, such as L'Oréal, Dior, Lancôme, etc., managed to overcome initial difficulties and establish a strong presence on the market thanks to their strong reputational and financial background.

However, things have begun to change, and huge developments have been occurring on the Chinese market in terms of regulations and legal requirements on cosmetics. Indeed, from May 1, 2020, the new *Cosmetic Supervision and Administration Regulation* (CSAR) on cosmetics has come into effect causing changes in terms of classification, importation and product registration procedures, safety assessment and other requirements in terms of documents and certificates to submit or obtain for approval, sale, and distribution of foreign cosmetics on the Chinese market. This regulation is the result of a long process of revision of the outdated *Cosmetics Hygiene Supervision Regulation* (CHSR) of 1989 that started in 2013 with the aim of modernizing Chinese regulation in line with the latest developments both on the domestic and on the international market, and of keeping up with regulations of other developed countries.

The implementation of this new regulation has caused a "normative revolution" that has invested several other provisions, measures and regulations that were in force and that have already been or are going to be revised or replaced.

All these regulatory changes will have an impact on companies that have been exporting to China and that depend on the Chinese market for a huge share of their profit, but also for many companies that are still planning to begin an internationalization process toward the Chinese market.

Since the above-mentioned regulation and other regulatory changes are very recent or still in progress, the real impact on imports will be registered in the next months or years.

What is relevant at the moment is investigating what the practical changes for companies are, what changes they need to implement in their business operations, and what challenges they are going to face.

Will these changes foster importation of cosmetics? Or are these new legal requirements just another non-trade barrier? In this chapter, we are going to get more in depth into these new regulatory changes trying to answer the above-mentioned questions.

3.1 Development of regulations and requirements on imported cosmetics

To better comprehend why the legal requirements on cosmetics have always been a trade-barrier for foreign companies and to understand the changes implemented with the latest regulatory developments, it is important to have a look at the development of Chinese regulations on imported cosmetics.

Importation procedures of cosmetic products into the Chinese market have always required strict regulatory control and compliance to stringent legal requirements.

Compared to other sectors, Chinese regulation of the cosmetics industry is quite recent since the first regulatory attempts trace back to the 1980s with China's reform and opening to the outside world.

Cosmetic products were clearly regulated for the first time in 1989 by the *Cosmetics Hygiene Supervision Regulation* (CHSR) which stipulated all the legal requirements for both domestic and imported products. It specified all the different steps of the importation procedure and all the requirements for approval and distribution of foreign cosmetics on the Chinese market.

If a foreign company wished to market its cosmetic products in China, whatever the product category was, they had to obtain pre-market approval from the competent authority, which, at the time of the first regulation, was known as State Food and Drug Administration (SFDA).[1]

The approval process was often complicated and time-consuming since it comprised of several mandatory steps, and the whole procedure was rather cumbersome. If companies wanted their cosmetic products to be approved successfully, the cosmetics' quality and hygiene had to strictly comply with the Chinese regulation.

[1] As we will discuss in detail later, the SFDA was restructured and renamed as China Food and Drug Administration (CFDA) in 2013, acquiring more supervisory power and responsibilities in line with similar regulatory entities in other countries, such as the FDA in the US that directly regulates and controls food and drug safety its domestic market. Then, in 2018, the CFDA was merged with the State Administration for Market Regulation (SAMR) and changed its name into National Medical Products Administration (NMPA). It is directly under the State Council of the People's Republic of China, and it is currently in charge of supervision and regulation of food and cosmetics safety in Mainland China.

These rules applied to the registration of cosmetics raw materials, domestic cosmetic products for special purposes[2] and all imported cosmetic products, both for special and non-special use.[3]
Any discrepancy or inconsistency with the stated legal requirements would have resulted in longer time to obtain approval and related certificates, or even in prohibition of import.
Cosmetics registration needed to follow several steps. First of all, companies needed to obtain pre-approval of cosmetics from the Chinese authority. The procedure theoretically took three to four months but in practice required nine months to a year to be completed. The pre-approval procedure involved such processes as inspection, acceptance of application, technical assessment and granting of approval documents for imports.[4] Since it required several steps and a long time, companies needed to take it into account when planning to export to China and apply in advance.
Moreover, they needed to authorize a Chinese legal company, called responsible agency, to take charge of the registration procedure. They represented the foreign company and supported it through the different steps of the procedure.
In order to be approved, cosmetics needed to comply with specific requirements in terms of formulation and ingredients. Therefore, companies needed to check their product formulas to ensure their compliance with the regulations and to be sure that all ingredients were allowed by the *Hygienic Standard for Cosmetics*[5] published by the Ministry of Health (MoH). It included a list of over 1200 banned ingredients and other ingredients restricted in their use, such as 73 chemicals, 56 preservatives, 156 colorants, 28 sun block agents and 93 dyes.[6]
After pre-approval, products had to undergo different processes for pre-market registration according to the different product category. There were two categories in the first regulation: special-use and non-special use (or ordinary) cosmetics. For ordinary cosmetics, companies had to file a record to the SFDA and obtain a Record-keeping Certificate. For special-use cosmetics, they had to apply for registration and obtain a Hygiene License that compared to the Record-keeping Certificate required more inspections and tests. It took 4-6 months to obtain Record-keeping

[2] There were two major product categories recognized by the former regulation: special use and non-special use cosmetics. Special use cosmetics included hair growth, hair dye and hair perm products, depilation products, body building products, deodorant products, and sunscreen products. Ordinary cosmetics included products for hair care, nail care, skincare, perfumes, and make-up. The regulation did not consider soaps and toothpaste as cosmetics. These categories were further revised and slightly changed by the current regulation, as we will discuss later.
[3] RJS Medical Technology, "Cosmetic SFDA Registration in China", on "sfda.com", http://www.sfdachina.com/cosmetics/info.asp?id=99 (21/04/21)
[4] RJS Medical Technology, "Guide of cosmetic products import into Chinese Market", on "sfdachina.com", http://www.sfdachina.com/info/110-1.htm (21/04/21)
[5] This set of standards was revised in 2015 and substituted by the Safety and Technical Standards for Cosmetics that entered into force in 2016. These standards were also supported by the Inventory of Existing Cosmetics Ingredients in China, discussed later in this chapter.
[6] Chemical Inspection & Regulation Service (CIRS), "CFDA Registration of Imported Cosmetics in China – Hygiene License & Record-keeping certificate", on "cirs-reach.com", http://www.cirs-reach.com/Cosmetics_Registration/China_cosmetics_regulations_registration.html (21/04/21)

Certificate for ordinary cosmetics and 8-15 months to acquire Hygiene license for imported specific use cosmetics.

The registration cost consisted of a testing fee and a consulting fee. Testing fee was charged by the SFDA designated labs. Total fee for special-use cosmetics was much higher than ordinary cosmetics because human safety tests were required in addition to hygiene safety tests. Estimated costs for ordinary cosmetics was between 10000 and 16000 RMB while costs for special use cosmetics were estimated between 19000 and 80000 RMB.[7]

In order to apply for registration, companies had to submit a dossier composed by several documents: an application form made by manufacturer or brand holder, formula of the product, details of the production process of special-use cosmetics, original packaging translated fully into Chinese, certificates of production and sale in the country of production, a safety assessment report, an authorization letter for the Chinese agent and sealed intact product samples.

If cosmetic products contained a new ingredient which had never been used on the Chinese market, whatever category it belonged to, companies needed to apply for the Hygiene License.

So, companies had to check product formula, not only to avoid prohibited ingredients, but also to be sure to apply for the right pre-market procedure and avoid delays or sanctions. To check for new ingredients, they had to compare their formula with the *Inventory of Existing Cosmetic Ingredients in China* (IECIC).[8]

To apply for the registration of new ingredients, companies had to submit additional documents: a cosmetics raw material application form; a research report stating the process of development, properties, molecular formula, and limitation of use; quality standards and testing methods; description of production process, safety evaluation information and other information that may contribute to the assessment.[9]

Moreover, before being registered, imported cosmetics had to pass inspection and related tests.

As far as testing is concerned, there were initially only 14 centers for inspection on the Chinese territory, authorized by the SFDA to perform tests on micro-organisms, physical, chemical, and toxicological characteristics, as well as human safety assessment. Physiochemical, microbiological, and toxicological tests were mandatory for ordinary cosmetics. For special-use cosmetics, human

[7] April Guo, Chemical Inspection and Regulation Service (CIRS), "Guidance on exporting cosmetics to China", on "cirs-reach.com", June 27, 2012, http://www.cirs-reach.com/Guidance_on_Exporting_Cosmetics_to_China_2012.pdf (21/04/21)

[8] The Inventory of Existing Cosmetic Ingredients in China (IECIC) has been revised and updated several times, first in 2015 and now a new version has recently been approved and entered into force in May 2021.

[9] RJS Medical Technology, "Documents required to declare the New Cosmetic Raw Materials", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=112 (21/04/21)

safety tests were also required. If a cosmetic product contained high-risk substances or components that might cause potential harm to human health, then additional tests were required.[10]

An issue that has always raised questions and controversies is compulsory animal testing for cosmetics and new ingredients registration. In fact, China has always required mandatory animal testing for approval and registration of new cosmetic ingredients and cosmetic products.[11]

The *Procedures and Methods of Safety Evaluation for Cosmetics* set out the five categories of animal testing and the testing required based on the category of cosmetic.

In particular, the above-mentioned procedures set out that all five categories of animal tests had to be taken for new cosmetic ingredients; at least three categories of animal tests were required for cosmetics which contained medicinal ingredients; at least three categories of animal tests were required for new production of cosmetics.[12]

After testing, a test report was issued by the authority within 50 to 60 days. Of course, special-use cosmetics such as spot-removing or sun block products had to undergo more tests and stricter controls taking up to 180 days or 9 months to complete inspection.[13]

In terms of inspection, companies had to apply for commodity inspection and quarantine, random inspection, routine inspection of the quality, weight, specifications, packaging and hygiene conditions, compliance inspection on the label (e.g., between claims such as "no artificial coloring", "no preservatives" etc., and the product) and labelling inspection. There were strict requirements on label contents, such as no wordings or specialist medical terms, false information, discriminative comparisons with other competitors' products, or misleading images.[14] If the product failed any one of these inspections, it would have been destroyed and banned from import.[15]

Inspection was performed both through sample inspection and through document review whereby the authority checked if the description of the product was sufficient and was coherent with the real characteristics of the product. Review procedure required 10 days, after reviewing the application

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[10] April Guo, Chemical Inspection and Regulation Service (CIRS), "Guidance on exporting cosmetics to China", on "cirs-reach.com", June 27, 2012, http://www.cirs-reach.com/Guidance_on_Exporting_Cosmetics_to_China_2012.pdf (21/04/21)

[11] The issue has always been particularly delicate in the modern context where animal tests are being rejected by most countries and consumers. In this context, the compulsory animal testing required in China has always affected its trade with other countries and has always constituted a barrier for foreign localization of production on the territory, especially for those products for which valid Animal Alternative Testing (AAT) existed. Many countries, especially the EU, have often called for a reform trying to push China to ban animal testing and adopt alternative testing methods. Recently, there have been developments in terms of animal testing and alternative testing methods that we will discuss later in this chapter.

[12] Lea Murphy, Giovanni Pisacane, "New Cosmetic's Regulation in China", *Household and Personal Care Today*, *2*, 2012, p.45

[13] RJS Medical Technology, "Guide of cosmetic products import into Chinese Market", on "sfdachina.com", http://www.sfdachina.com/info/110-1.htm (21/04/21)

[14] See later in the chapter for more information about labelling requirements.

[15] RJS Medical Technology, "Guide of cosmetic products import into Chinese Market", on "sfdachina.com", http://www.sfdachina.com/info/110-1.htm (21/04/21)

was either accepted, rejected, or suspended for further assessments of supplementary documents. If accepted, it would have been referred to the SFDA for assessment of technical documents to check if there were any discrepancies between inspection results and documents submitted for registration. Technical assessment required 25 to 30 working days for non-special cosmetics and 30 to 100 working days for special-use cosmetics.

Only after passing all these steps, companies could finally receive a Hygiene license or a Record-keeping Certificate, which then had to be submitted for further inspections at the time of physical importation into the Chinese market.

Indeed, imported cosmetic products not only had to pass pre-market inspection for approval and registration but they were also subjected to mandatory inspection of samples and labels by the China Inspection and Quarantine Bureau (CIQ) when goods arrived at the ports of entry, that, at the time of the first regulation, were limited to few locations mostly located in the Free Trade Zones. CIQ would issue an Entry Inspection Certificate[16] if goods passed inspection. Only cosmetics with Entry Inspection Certificate could be imported and sold on Chinese market.

Each time, companies had to submit additional documents for custom clearance: a self-declaration letter stating that the imported cosmetic product complied with Chinese laws, product formula, Hygiene License or Record-keeping Certificate, safety evaluation report issued by the qualified institutions; production and distribution license of the imported cosmetics in the country of production or a Certificate of Country of Origin; sample labels in Chinese; information on the product name, volume or weight, technical specifications, country of origin, batch number, expiry date, target market, and information about the packaging company.

Also in the case of custom clearance, requirements for labeling were quite stringent. According to the *Imported Cosmetics Chinese Labeling Regulation of the General Administration of People's Republic of China for Quality Supervision & Inspection and Quarantine* (AQSIQ), all imported Cosmetic Chinese labels had to be inspected by local China Inspection and Quarantine Bureau (CIQ) departments. CIQ reviewed items including the formats, layouts, text explanations, graphics and symbols printed on the label, all these items needed compliance with relevant Chinese standards. If the label met the relevant standards, local CIQ departments would issue a certificate with a filing number associated to the label, and only then the goods could be released from Customs.[17]

[16] In Chinese, 入境物检验检疫证明 *rujing wu jianyan jiangyi zhengming*

[17] RJS Medical Technology, "Imported Cosmetic Chinese Label CIQ Filing", on "sfdachina.com", http://www.sfdachina.com/info/113-1.htm (21/04/21)

In addition to the complicated procedure related to approval, registration and inspection of cosmetics, products were subject to conspicuous tariffs.

The above-mentioned processes and requirements were the first attempts from the Chinese part to regulate the sale and distribution of cosmetics on its domestic market. It is evident that the strict requirements, complex procedures, and heavy bureaucracy were a clear attempt to slow down the process of importation and to obstruct foreign companies from importing huge amounts of products. Indeed, the major critical points of the whole procedure were the long process that required up to a year to get registration of products (not to mention possible mistakes and delays due to lack of documents or small discrepancies), the pervasive inspections both pre- and post-market and the mandatory changes that companies had to apply to their products in order to get them approved by local authorities. All these elements resulted in high costs for enterprises so that only big corporations and companies with a strong financial backing were actually able to afford the import process into the Chinese market.

The regulation and related requirements have been revised over time, some criticalities were improved but many critical elements remained unchanged or were only superficially modified.

In the last decades, several Chinese governmental bodies have been handed down the authority to examine and approve all applications for cosmetic products intended for the Chinese market. From the State Food and Drug Administration (SFDA) that officially took over the authority from the Ministry of Health (MOH) in 2008, followed by the China Food and Drug Administration (CFDA) that replaced the SFDA in 2013, to the National Medical Product Administration (NMPA) that was instituted in 2018.

With the entry into play of the CFDA, the process of document review for registration became a little bit faster reaching 70 working days at most for all product categories. Moreover, at the end of the process, instead of issuing a physical certificate, it would send a notification of approval with the following information: ID number of the product with its category (ordinary or special), year of approval and serial number, name of the product and of the producer both in Chinese and in original language, country of origin and date of approval. Notification made all process faster and bureaucracy leaner since the notification was managed through digital channels. In this way, registration details also became clearer for later controls and the validity of the registration was defined and set at four years from the date of notification.

Other major changes were applied to product categories which were revised and renamed in ordinary and special-use cosmetics to clearly distinguish the two categories' purpose of use. Special-use cosmetics were revised to include products with specific functionalities such as skin-

whitening and anti-acne products.[18] As a result, the process became clearer but not easier.

The requirements in terms of documents to be submitted in order to obtain registration of cosmetics became more detailed and stringent following the amendments introduced in 2010. Apart from the former mandatory documents which remained unchanged, Chinese name of products and ingredients became explicitly mandatory together with a safety appraisal report on risky materials contained in products and a copy of the agent's business license increasing the bureaucratic burden on the importers' shoulders.[19]

In this way, the process became also more expensive because overall costs included testing fee, risk evaluation fee charged by approved inspection authorities and consulting fee. Before the revisions, cost of Record-keeping Certificate for imported ordinary cosmetics was between 10000 and 30000 RMB per product. Hygiene License for imported special-use cosmetics was between 20000 and 60000 RMB per product. Hygiene License for new cosmetic ingredient was between 80000 and 100000 RMB per ingredient. But these costs did not include the requirements introduced later in terms of risk evaluation fee and human body test.[20]

In terms of labeling, even though inspection and general provisions were already in place at the time of the first regulation, it was not until 2009 that detailed requirements entered into force through the implementation of the standard *General labelling for cosmetics (GB5296.3-2008).* According to this set of standards all ingredients had to be specifically listed on the visible part of the external packaging, and labels had to contain the following information: name of the manufacturer, importer or distributor and the address of the principal place of business, net weight, full ingredient list translated in Chinese[21], date of manufacture and shelf life or batch number and expiry date, instructions for storage and warnings for safe use, production permission certificate

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[18] April Guo, Chemical Inspection and Regulation Service (CIRS), "Guidance on exporting cosmetics to China", on "cirs-reach.com", June 27, 2012, http://www.cirs-reach.com/Guidance_on_Exporting_Cosmetics_to_China_2012.pdf (22/04/21)

[19] Lea Murphy, Giovanni Pisacane, "New Cosmetic's Regulation in China", *Household and Personal Care Today*, *2*, 2012, p.45

[20] Chemical Inspection & Regulation Service (CIRS), "CFDA Registration of Imported Cosmetics in China – Hygiene License & Record-keeping certificate", on "cirs-reach.com", http://www.cirs-reach.com/Cosmetics_Registration/China_cosmetics_regulations_registration.html (22/04/21)

[21] In terms of ingredients listing there were specific requirements: companies had to provide the names of all the ingredients, the purpose of use, the composition range. Blend materials had to be declared in the form of blend formulation, and the percentage of each ingredient had to be stated. The name of the formulation materials had to be named according to the Chinese INCI. Coloring agent had to provide the reference number according to the *Hygienic Standards for Cosmetics*. Ingredients derived from plants, animals, microorganisms, minerals, and other raw materials, had to provide their Latin name. Raw materials that contained animal organ extracts or blood product extracts had to provide a proof of the source of raw materials, specifications, and the permit of use of the primary producing country. Repacking formulation products or products with different formulation but packaged inside non-splitable packaging had to list the formulation separately. The proportion of the restricted materials contained in mixtures had to be declared. (Source: RJS Medical Technology, "The request of cosmetics product formula China SFDA submission", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=115, 22/04/21)
These requirements are still in force.

number, Hygiene License number and product standard number for special-use cosmetics or Notification Certificate number for imported general-use cosmetics, and country of origin.[22]

To uniform the translation methods of ingredients, the SFDA issued the INCI Chinese version in 2010, then revised and updated under the CFDA in 2015.

Moreover, according to the *Naming Requirements for Cosmetics*, implemented on the 5th of February 2010, the name of a cosmetic product should be concise, easy to understand and in line with the customs of the Chinese language. It must not contain anything that may mislead or deceive consumers. The *Cosmetics Naming Guidelines*, which were issued to complement the Naming Requirements, provided a list of expressions allowed or prohibited when naming cosmetic products. Eleven types of expressions were forbidden for use in the names of cosmetic products[23], many of which are conversely very common in other countries.[24]

With the CFDA, there were further specifications in terms of labeling. Two methods were allowed for labeling of imported products: original label with Chinese translation above or Chinese label in line with corresponding Chinese regulation. Before, only Chinese label was allowed.

Moreover, detailed information for the Chinese label were specified as follows: name of the product, producer details, country of origin, authorization code for sale on the Chinese market, ingredients, product and conservation date, precautions for the use, conditions of conservation, local distributor details.

All these improvements in terms of labeling requirements were adopted in order to strengthen Chinese regulatory framework and uniform it to international standards fostering trade exchanges, but actually resulted in more stringent and costly requirements for companies.

More recently, the CFDA has introduced a new packaging logo labelled with information on the corresponding cosmetics production permit, in force starting from the 1st of July 2017 as stipulated in the *Circular on Matters Related to Cosmetics Production Permit*. This new logo has made it easier for both authorities and consumers to know if the cosmetic product met all the requirements to be distributed and sold on the Chinese market.[25]

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[22] Lea Murphy, Giovanni Pisacane, "New Cosmetic's Regulation in China", *Household and Personal Care Today*, 2, 2012, p.45
Stefano Dorato, "General Concepts: Current Legislation on Cosmetics in Various Countries", chap.1, p.29, in Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017

[23] The forbidden expressions included arbitrary expressions, such as special effect, powerful effect, miraculous effect, extraordinary, skin renewing, or wrinkle removing; false claims that a product was absolutely natural; expressions that explicitly or implicitly indicated the medical effect of a product, such as anti-bacterial, detoxifying, anti-allergic, hair-growing, hair-regenerating, fat-reducing, body-slimming, face-slimming, and leg-slimming; any medical jargon and names of celebrities in the medical field. These requirements are still in force.

[24] HKTDC Research, "China's Cosmetic Market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (22/04/21)

[25] Ibidem

Improvements have also been made in terms of safety requirements. In 2015, a new version of the *Safety and Technical Standards for Cosmetics*[26] has come into play introducing changes to the list of prohibited and restricted ingredients as well as to the physical and chemical testing methods for cosmetics inspection and safety evaluation. These changes have highlighted how Chinese requirements are getting more and more in line with the EU.[27]

Safety is assessed during the registration process by means of both documents presented by the manufacturer or importer and local chemical, physical, microbiological, toxicological, and clinical testing.

Concerning safety tests on animals, in June 2014 the CFDA, in its plan to modernize its cosmetics regulatory framework, began to phase out the requirement that new locally manufactured ordinary cosmetic products had to be tested on animals and expressed the intention to suspend mandatory animal testing at least for ordinary cosmetics.[28]

As for registration procedures, in order to improve the easiness and rapidness of the process, the SFDA first implemented application and submission of documents through online channels starting from 2010.[29] Thanks to the integration of online procedures, the process became a little bit faster. The timeline is shown in more details by the following table.

[26] Full text available at: https://www.nmpa.gov.cn/hzhp/hzhpfgwj/hzhpgzwj/20151223120001986.html?type=pc&m= (22/04/21)
[27] Ibidem
[28] Human Society International, "China's Cosmetics Animal Testing FAQ", on "his.org", https://www.hsi.org/wp-content/uploads/assets/pdfs/bcf_china_cosmetics.pdf (22/04/21)
[29] RJS Medical Technology, "New Rules for Cosmetic Product Registration", on "rjs.cn", http://www.rjs.cn/info/106-1.htm (22/04/21)

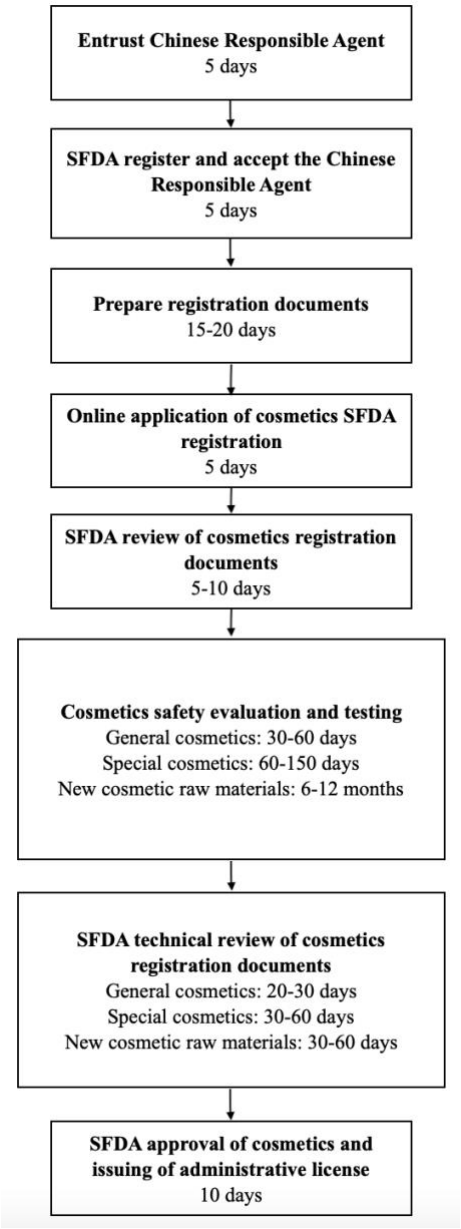

Table 2: Procedure for SFDA registration with online application (sfdachina.com)

Then, on May 17, 2013, the CFDA announced that Provincial Food & Drug Administration Authorities would be responsible for approval of imported ordinary cosmetics in China, while the administration of special-use cosmetics registration remained under the CFDA responsibility.[30] Starting from 2015, foreign ordinary cosmetics online registration procedures have been gradually introduced and extended to several local governmental institution authorized for food and drugs administration all over China. National designated laboratories carry out the pre-approval testing and check hygienic and chemical properties (e.g., heavy metals, pH, etc.), microbiological quality, toxicology, and efficacy (e.g., of sunscreens).

[30] Chemical Inspection & Regulation Service (CIRS), "CFDA Registration of Imported Cosmetics in China – Hygiene License & Record-keeping certificate", on "cirs-reach.com", http://www.cirs-reach.com/Cosmetics_Registration/China_cosmetics_regulations_registration.html (22/04/21)

The most critical issue of the procedure remained consistency (e.g., in product name) because if it was not kept throughout the application, any discrepancy would have resulted in a delay in the application process.[31]

Since May 1, 2017, China has implemented another important policy that further speeds up the importation process for initially imported ordinary cosmetics. The ordinary cosmetics imported through Shanghai Pudong New Area only required filing with Shanghai Medical Product Administration (MPA) instead of registration with NMPA. The MPA would grant a filing certificate to the applicant after a preliminary review of application dossiers, then the applicant could start to import. After a year NMPA officially expanded this to other 10 Free Trade Zones including Tianjin, Liaoning, Zhejiang, Fujian, Henan, Hubei, Guangdong, Chongqing, Sichuan, and Shanxi.

As shown by data coming from the NMPA statistics, this reform of the imported ordinary cosmetics registration has made the process faster and easier causing imported cosmetics registration quantity to increase significantly.[32]

When the CFDA was replaced by NMPA in 2018, the process of registration for general-use cosmetics was completely revolutionized. On November 9, 2018, the NMPA announced that registration of first-imported general-use cosmetics was officially replaced by record-filing management nationwide.[33]

From the 10th of November 2018, general-use cosmetics record-filing management completely replaced the outdated CFDA approval-based approach.

Before the first importation, companies must file a record and relevant documents through the official online channels to receive approval from authorized local authorities while the NMPA no longer accepts applications for first-imported general-use cosmetics administrative licenses.[34]

The manufacturer of the imported products must appoint a Chinese representative to complete the record-filing procedures via the NMPA website and obtain an electronic record-filing certificate before importing any products.[35]

Under new requirements of the NMPA, the Chinese agent, who was initially responsible only for

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[31] Stefano Dorato, "General Concepts: Current Legislation on Cosmetics in Various Countries", chap.1, p.29, in Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017

[32] Sarah & Yelena, "A Brief Discussion of the New Trend of Cosmetics Regulations Based on the Imported Cosmetics Registration Data", *China Detergent & Cosmetics*, *3*, 2020, p.39

[33] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (23/04/21)

[34] RJS Medical Technology, "Imported Non-special-purpose Cosmetics Record-filing Regulation and Process of China NMPA (From Nov.10, 2018)", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=204 (23/04/21)

[35] HKTDC Research, "China's Cosmetic Market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (23/04/21)

registration, became responsible not only for record-filing but also for import procedures and product quality and safety on the Chinese market. Companies could appoint more than one responsible person for one product in order to share duties and to better manage the procedure.[36] Moreover, the responsible person had to employ a dedicated electronic system for application so that the procedure became much faster and immediate.[37]

The new record-filing procedure compared with the former regular CFDA registration procedure, saved at least 50% time, making it quicker for companies to apply, submit documents and finally register products and receive approval, and for authorities to obtain documents, perform relevant checks and send a response back.

The former regular CFDA registration procedure involved issuing a certificate after the final technical review needing a total of 6-9 months, but with the new procedure the authority issued a record-filing number before technical review, taking up to 2-3 months, actually half of the time required with the former procedure. Technical evaluation would be conducted in the subsequent 3 months, this way allowing companies to save time because they did not have to wait for technical evaluation before starting physical importation of products.[38]

The process of decentralization of authority to local bodies for the administrative procedures of registration, inspection, and testing of imported cosmetic products has continued in the following years.

For example, as far as testing is concerned, in order to improve the efficiency of the examination and approval of cosmetics, the NMPA issued an announcement in September 2019 stating that inspection and testing institutions meeting the requirements of the *Work Specification for Cosmetics Registration and Record-filing Inspection* can undertake work on cosmetic registration and filing inspection after submitting relevant information through the information management system for cosmetics registration and filing inspection. As a result, the number of authorized institutions for testing and inspection increased and the distribution of workload among institutions improved, making the whole process more rapid and improving overall effectiveness of the import process.[39]

At the beginning a very limited number of institutions localized in few restricted areas were allowed to perform inspections and grant official approval and recognized certificates, but with the latest

[36] RJS Medical Technology, "Imported Non-special-purpose Cosmetics Record-filing Regulation and Process of China NMPA (From Nov.10, 2018)", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=204 (23/04/21)
[37] Simon Pitman, "Exporting cosmetics to China just got a bit easier", on "cosmeticdesign-europe.com", November 30, 2018, https://www.cosmeticsdesign-europe.com/Article/2018/11/26/Exporting-cosmetics-to-China-just-got-a-bit-easier (23/04/21)
[38] RJS Medical Technology, "Imported Non-special-purpose Cosmetics Record-filing Regulation and Process of China NMPA (From Nov.10, 2018)", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=204 (23/04/21)
[39] HKTDC Research, "China's Cosmetic Market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (23/04/21)

developments, companies now can turn themselves to a greater number of authorized institutions dislocated in different places in mainland China making the application procedure easier.
In the same year, the NMPA issued another amendment concerning renewal of approval certificates for imported special use cosmetics. Instead of applying for inspection and testing of products carried out by an external governmental institution to renew the approval for the import of special-use cosmetics, companies must carry out comprehensive checks by themselves and submit the related report and the renewal application on the NMPA's platform 30 working days before the expiry date. The renewal is approved in 15 working days if the relevant requirements are fulfilled.[40]
Another important milestone in the improvement of the importation procedures was the opening of new ports of entry. Initially, imported cosmetics had to first go through the 11 Free Trade Zones where the responsible agent was located and only after all inspections and importation procedures could be distributed within China. But now there are less restrictions to the ports of entry.[41]
Even though the improvements and changes implemented made the procedure slightly faster and easier, it remains a complex process that comprises of several steps with different requirements and mandatory documents to be submitted each time. Compared to other countries, it remains a time-consuming process and overall costs for companies are quite high.
For instance, import tariffs have been gradually lowered following the Chinese entry into the WTO and the commitment to comply with its requirements. Tariffs were lowered to 6.5-10% plus 17% VAT. Lip and eye make-up and manicure cosmetics are subject to 10% duty while skincare products and hair care products which were subjected to the lowest rate, 6.5%, were then further lowered to around 2% in 2018.[42] Moreover, to encourage domestic consumption, the Chinese government has cut the import taxes on skin care products from 5% to 2% starting from June 1, 2015.[43] However, the main issue for companies is the consumption tax imposed on manufacturing, processing, importation and selling of cosmetics on the Chinese market, with the only exception of goods used by manufacturers for further productions. The general consumption tax rate for cosmetics is 30%, a rather important rate considering that cosmetics are a commonly marketed product and are characterized by a high demand and increasing consumption.[44]

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[40] HKTDC Research, "China's Cosmetic Market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (23/04/21)
[41] Simon Pitman, "Exporting cosmetics to China just got a bit easier", on "cosmeticdesign-europe.com", November 30, 2018, https://www.cosmeticsdesign-europe.com/Article/2018/11/26/Exporting-cosmetics-to-China-just-got-a-bit-easier (23/04/21)
[42] HKTDC Research, "China's Cosmetic Market", August 7, 2020, on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (24/04/21)
[43] Fung Business Intelligence Center, "China's Cosmetic Market", on "fbicgroup.com", June 2015, https://www.fbicgroup.com/sites/default/files/China's%20cosmetics%20market%20JUN%2015.pdf (24/04/21)
[44] Lea Murphy, Giovanni Pisacane, "New Cosmetic's Regulation in China", *Household and Personal Care Today*, *2*, 2012, p.46

In general, according to statistics issued by the National Medical Products Administration's official website on the number of imported cosmetics record-filing and registration between 2012 and 2019, it is evident that the number of approved first imported non-special use cosmetics is increasing year by year, especially after the implementation of the new policy for the record-filing procedure of imported non-special cosmetics in 2017 which made the whole process a lot faster and easier. However, there was no significant increase in the quantity of imported special-use products during the same period.[45] This is probably due to the fact that approval of special-use cosmetics has not changed a lot during time, representing a big trade obstacle due to the complex procedure and the strict mandatory requirements.

In conclusion, from this analysis it is evident that in the past few decades China has been introducing major changes in terms of regulation and legal requirements on imported cosmetic products, increasing its harmonization with international requirements, allowing the process to become gradually more efficient and faster and letting companies save time and financial resources. However, many critical issues remain in place. The procedure remains complex and characterized by several detailed steps, and bureaucracy is heavy requiring a lot of documents to be submitted, allowing little space for mistakes and negligence, and increasing the chances to slow down the whole process in case of any inconsistency or discrepancy within the documents. Moreover, there are many overlapping competent authorities with a lack of coordination that significantly slows down the registration process.

The non-implementation of alternative testing methods and the required animal testing for special cosmetics and new ingredients registration create marketing problems for companies and pose trade problems with countries that banned this kind of testing methods.

In addition, the whole import process requires spending huge financial resources since consumption tax and overall business costs to fulfill requirements and manage procedures are quite high.

Even though China showed interest in improving its importation procedures and in getting in line with international standards and requirements, there are still major critical points that represent actual trade barriers for some foreign companies. But things are rapidly evolving, and huge developments are in progress in China.

Recently, starting from January 2021, China enacted a new *Cosmetics Supervision Administration Regulation* (CSAR) that replaces the outdated regulation of 1989. As we will discuss in the next paragraph, it is considered a milestone in the development and improvement of the Chinese cosmetics sector that introduces new important changes and improvements, rectifies many unsolved

[45] Sarah & Yelena, "A Brief Discussion of the New Trend of Cosmetics Regulations Based on the Imported Cosmetics Registration Data", *China Detergent & Cosmetics*, *3*, 2020, p.40

problems, and specifies many grey areas in the former regulation in order to adapt to the new developments and conditions on the market.

It is early to assess the effects of this new regulation on trade and on companies operating on the market. What is now possible is investigate what the actual changes for foreign companies will be.

3.2 The new Chinese regulation on cosmetics

On the 29th of June 2020, the State Council announced the *Cosmetics Supervision and Administration Regulation* (CSAR), an overarching regulation which took effect the 1st of January 2021, replacing the *Cosmetics Hygiene Supervision Regulation* (CHSR) of 1989.

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

Compared to the former regulation, the new CSAR is more detailed and clearer, it has 37 more articles with the objectives of optimizing the business environment, stepping up corporate legal responsibility, setting up an effective administration system, clarifying ambiguities and specifying all detailed requirements, and increasing penalties in case of violation. For instance, newly added penalties stipulate that, in addition to being fined, the person or persons in charge of an entity that has been found in serious violation of laws will be prohibited from engaging in cosmetics production and business activities for a defined period or even for life.[46]

Compared to the past CHSR, the new regulation is a turning point in Chinese regulatory framework toward more advanced management measures and more attention to risk management, safety evaluation and efficacy assessment.

To support the new regulation, China has been releasing and will implement a series of supporting regulations in the next few years.

Given that the CSAR puts forward several new requirements for cosmetic enterprises, transitional measures were also released.[47]

[46] HKTDC Research, "China's Cosmetic Market", on "research.hktdc.com", August 7, 2020, https://research.hktdc.com/en/article/MzA4Nzg0MTgw (24/04/21)

[47] Prior to implementing the subsidiary regulations on registration and notification, the registrants and notifiers shall submit registration and notification dossiers in accordance with the current regulations and requirements. The notification is deemed completed after the submission of notification dossiers. The medical products administration departments will carry out the registration management in accordance with the procedures and time limit stipulated in the CSAR. (ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation, 25/04/21)

The following table shows the complicated regulatory framework revolving around the management and administration of cosmetics on the Chinese market.

Type	Regulation	Effective date	Status
General regulation	Cosmetic Supervision and Administration Regulation (CSAR)	Jan.1, 2021	In force
Requirements on ingredients	Safety and Technical standards for Cosmetics 2015	Dec.1,2016	In force but is being revised
Requirements on ingredients	Inventory of prohibited ingredients	Not yet in force	Draft
Requirements on ingredients	Inventory of Existing Cosmetic Ingredients in China (IECIC 2021)	May 1, 2021	In force
Requirements on ingredients	INCI Chinese version 2010 Catalogue of Standard Chinese Name of International Cosmetic Ingredients	Dec.14, 2010	In force but is being revised. A new draft came out in 2018.
Requirements on registration and notification procedures	Administrative measures on Cosmetics Registration and Notification	May 1, 2021	In force
Requirements on registration and notification procedures	Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers	May 1, 2021	In force
Requirements on safety assessment	Technical Guidelines for Cosmetic Safety Assessment	May 1, 2021	In force
Requirements on efficacy claim	Standards for Cosmetic Efficacy Claim Evaluation	May 1, 2021	In force
Requirements on manufacturing in China	Practice for Cosmetics Production Licensing	Jan.1, 2016	In force
Requirements on labeling	Administrative Provisions on Cosmetics Labeling	Sep.1, 2008	In force but will be replaced, recently a new draft "Administrative Measures on Cosmetics Labeling" came out.

Enterprise obligations	- Supervision and Administration Measures on Cosmetics Manufacture and Operation - Good Manufacturing Practices for Cosmetics	Not yet in force	Drafts
Requirements on post-market surveillance	- Measures for the Management of Cosmetic Adverse Reaction Monitoring - Standards for the Management of Cosmetic Sampling Inspection	Not yet in force	Drafts
Requirements on testing methods	Working Rules for Cosmetic Registration and Notification Testing	Sep.10, 2019	In force
Requirements on inspection of imported products	Administrative Measures on Inspection and Quarantine of Import and Export Cosmetics	Nov.23, 2018	In force

Table 3: Regulatory framework: existing main cosmetic regulations in China (chemlinked.com)

The main competent authorities are the State Administration for Market Regulation (SAMR)[48] which is in charge of the overall supervision of food, cosmetics, pharmaceuticals, and medical devices in terms of market entry registration, quality and safety supervision and standardization of procedures; the National Medical Products Administration (NMPA)[49] which replaced the CFDA and it is responsible for registration of imported and domestic special cosmetics, the notification of imported general cosmetics and the registration and notification of new cosmetic ingredients, other responsibilities include safety supervision and quality control, standardization of processes, post-market risk management, post-market supervision and inspection, it delegates to local provincial government for supervision on their areas, notification of domestic general cosmetics and issuance

[48] In Chinese, 国家市场监督管理总局 (*guojia shichang jiandu guanli zongju*). For further information: http://www.samr.gov.cn

[49] In Chinese, 国家药品监督管理局 (*guojia yaopin jiandu guanli ju*). For further information: https://www.nmpa.gov.cn

of production licenses; and the General Administration of Customs (GAC)[50] which is responsible for import inspection and quarantine of cosmetics.[51]

The reference body for cosmetic companies is the NMPA and its delegated administration departments of provinces, autonomous regions, and municipalities which, according to the product category, have to approve cosmetic products before they can be imported or marketed into China.

3.2.1 Definition of "cosmetics" and product categories

In terms of definition of cosmetics, there were no changes. As stated in art.3 of the regulation:

> 第三条 本条例所称化妆品，是指以涂擦、喷洒或者其他类似方法，施用于皮肤、毛发、指甲、口唇等人体表面，以清洁、保护、美化、修饰为目的的日用化学工业产品。[52]

The definition is in line with that of other countries at international level as we mentioned in the dedicated paragraph in the first chapter of this thesis.

The major change in terms of definition regards toothpaste. For the first time, there is a first mention of toothpaste managed as general cosmetics in art.77:

> 第七十七条 牙膏参照本条例有关普通化妆品的规定进行管理。[53]

This means that now toothpaste requires notification, safety assessment, efficacy evaluation and all other requirements related to general cosmetics. Therefore, companies that market this kind of product will have to adapt and adopt adequate measures.

Under the new regulation, according to art.4, the categories of cosmetic products have been renamed into special and general cosmetics[54]. The category of special cosmetics was revised, from 9 types to 6 including hair dyes, hair perming products, freckle removing (whitening) products, sunscreens, anti-hair loss, and cosmetics with new efficacy. Products for hair growth were replaced by anti-hair loss products as special cosmetics, and they are now considered either general cosmetics or drugs. They are classified as general cosmetics if they improve hair quality and

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[50] In Chinese, 中华人民共和国海关总署 (*zhonghua renmin gongheguo haiguan zhongshu*). For further information: http://www.customs.gov.cn

[51] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (03/05/21)

[52] "Art.3 "Cosmetics" herein refers to daily chemical products intended to be applied on human skin, hair, nails, lips, etc., by spreading, spraying or other similar ways for cleansing, protecting, beautifying, or grooming purposes." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[53] "Art.77 Toothpaste shall be managed with reference to the provisions on general cosmetics herein." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[54] In Chinese, 特殊化妆品 (*teshu huazhuangpin*) and 普遍化妆品 (*pubian huazhuangpin*)

prevent hair breakage, but they fall under the drug category[55] if they promote hair growth.[56]
Depilating products, breast beauty products, slimming products, and deodorants are no longer managed as special cosmetics, they can either be classified as general cosmetics or drugs according to their efficacy claims, mechanism of action and results of testing reports.
Considering these new requirements, we can assume that products with strong physiological effects and high risks are likely to fall under the category of drugs or quasi-drugs.[57]
Companies will have to perform additional tests to prove the actual effects of their products to support their application according to the different classifications.
The new distinctions in the product classifications are crucial, companies must understand them clearly and adopt adequate measures because different classifications require different approval procedures and safety and testing requirements, so companies have to pay careful attention when applying for the approval of these kinds of products in order to avoid delays or sanctions.
Definition is important for those cosmetics that can be considered halfway between cosmetics and other types of products such as cosmeceuticals or wet-naps and other beauty tools. It is important to adequately differentiate products and follow the suitable process in order to avoid rejection, prohibition or sanctions from the authorities.
Definition is the first element to consider especially because the same product can fall under different definitions in different countries, thus requiring a different importation or acceptance procedure.

3.2.2 Import procedure of general and special cosmetics

According to art.4, imported and domestic special cosmetics and new cosmetic ingredients require pre-market registration[58] with the NMPA, while general cosmetics are subject to pre-market filing[58] with the provincial Medical Products Administration (MPA) where the responsible person or agent is located.
Imported general cosmetics must apply for pre-market filing procedure and receive a notification certificate from the local authorities (the provincial MPAs). This procedure is not completely new since it is the result of a process of regulatory modernization that China has started in 2017.[59]

[55] It is important to specify that drugs follow completely different procedures and rules, while cosmetic products that explicitly claim medical effects or are defined as "medical products" are illegal in China since 2019.
[56] Zhe Su, Fei-ya Luo, Xin-rong Pei, Feng-lan Zhang, Shu-xia Xing and Gang-li Wang, "Final Publication of the 'Regulations on the Supervision and Administration of Cosmetics' and New Prospectives of Cosmetic Science in China", *Cosmetics*, *7*, 98, 2020, p.5
[57] Ivi, p.6
[58] In art.4, the procedure for special cosmetics is defined as "注册管理" (*zhuce guanli*, literally "registration management") while the procedure for general cosmetics is "备案管理" (*beian guanli*, literally "filing [or notification] management").
[59] The development process of this procedure has already been discussed in the previous paragraph of this chapter.

Starting from 2018, registration of imported non-special cosmetics with the NMPA has been fully replaced by the filing management and now this is explicitly stated in the new regulation becoming mandatory on national level.

The filing management allows the whole importation process of general cosmetics to become more rapid and immediate, and this is a great advantage for companies that can save precious time in a long complex importation procedure. The company shall notify the provincial MPA through a dedicated online platform submitting the product formula[60] and packaging (including labels) and other relevant information regarding ingredients, description of the production process, product technical requirements and testing reports for future examination. Meanwhile, the responsible agent in China shall prepare the same documents and submit them in hard copy.

The local authority will check the documents in 5 working days and issue an electronic filing certificate in case of acceptance or a notification of rejection with explanations. With the filing certificate, companies can immediately start the physical importation of the products without waiting for technical review of all documents that will be performed in the next 3 months after filing.[61]

For imported special cosmetics, the procedure is more complicated and requires more steps and compliance with stricter requirements.

First of all, companies shall designate a responsible agent who must be a Chinese legal entity located in the Chinese territory, as required by art.23:

> 第二十三条 境外化妆品注册人、备案人应当指定我国境内的企业法人办理化妆品注册、备案，协助开展化妆品不良反应监测、实施产品召回。[62]

The responsible agent can be a subsidiary based in China, an importer or a third party who has specific expertise on cosmetics and works in the field.

Based on new specifications on the role of the responsible agent, his name must be communicated to the NMPA for approval, he has less responsibilities in terms of compliance of submitted documents and fairness of the procedure since the new regulation officially attribute all

[60] It is important to note that, in relation to the product formula, among the required documents listed in art.19 of the regulation, there is "产品配方或者产品全成分"("formula or full ingredient list of the product"). The full ingredient list (全成分) must be displayed also on cosmetics labels, as stated by art.36. The requirement to disclose all ingredients employed in the formula is a critical point of the new regulation and it has been rising concern from foreign companies that want to protect their business secrets. This critical point and other negative aspects of the new legal requirements will be discussed later in this chapter.

[61] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (04/05/21)

[62] "Art.23 Overseas cosmetics registrants and notifiers shall designate an enterprise legal person in the territory of China to handle cosmetics registration and notification and assist in monitoring of cosmetics adverse reactions and implementation of product recalls." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

responsibilities to the main responsible person (the company that wants to import the product), the responsible agent just acts as an intermediary. However, he is responsible for keeping business secrets and guard confidential information such as production processes and product formula. Before submitting any document or application, companies shall check the product formula, label, and prepare proofs of efficacy claims.

As for formulas, the product cannot contain any prohibited substances or use restricted substances beyond permitted concentrations and application scopes as stated in the *Safety and Technical Standards for Cosmetics*.[63] Meanwhile, it is also necessary to check if there is any new ingredient contained in the formula because new cosmetic ingredients also need NMPA's approval, and they must undergo a separate registration procedure. Therefore, companies shall compare their product formula with the *Inventory of Existing Cosmetic Ingredients in China* (IECIC)[64] which has now been revised and entered into force in May 2021 to integrate the new regulation on cosmetics. It contains a collection of all recognized cosmetic ingredients employed on the Chinese market, more than 8000 banned cosmetic ingredients and those ingredients with a use limited to a maximum level.

Moreover, companies should prepare documents and testing report to support any efficacy claims of their products, as required art.22 of the new regulation which states as follows:

> 第二十二条 化妆品的功效宣称应当有充分的科学依据。化妆品注册人、备案人应当在国务院药品监督管理部门规定的专门网站公布功效宣称所依据的文献资料、研究数据或者产品功效评价资料的摘要，接受社会监督。[65]

Efficacy claim evaluation shall be performed through specific tests, especially human tests, and it is mandatory for specific product characteristics such as freckle removing or whitening, sunscreen, anti-hair loss, acne-removing, nourishing, or repairing. Other efficacy claims such as anti-wrinkle, exfoliating, moisturizing, hair breakage prevention, and specific claims on the efficacy of an ingredient can be supported both by specific tests (human and lab tests) and research data already existing in the field.[66] This means additional costs for companies that must perform adequate tests

[63] Implementation and general content of this set of standards have already been discussed in the previous paragraph of this chapter. (Full text available at: https://www.nmpa.gov.cn/hzhp/hzhpfgwj/hzhpgzwj/20151223120001986.html?type=pc&m=, 04/05/21)

[64] Full text available at: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210430162707173.html?type=pc&m (04/05/21)

[65] "Art.22 Efficacy claims of cosmetics shall be supported by sufficient scientific basis. Cosmetics registrants and notifiers shall disclose the summary of the document literature, research data or product efficacy evaluation document on which the efficacy claims are based on the special website prescribed by the NMPA of the State Council, and accept social supervision. (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[66] Angelita Hu, "CSAR Subsidiary Regulations: China Finalizes Standards for Cosmetic Efficacy Claim Evaluation", April 12, 2021, on "china.chemlinked.com", https://cosmetic.chemlinked.com/news/cosmetic-news/csar-subsidiary-regulations-china-finalizes-standards-for-cosmetic-efficacy-claim-evaluation (04/05/21)

by themselves in order to have evident proofs of efficacy and avoid any delay in the approval procedure.

The above-mentioned elements are preventive measures that companies shall take before applying for registration. Then, they shall submit product samples to be tested by laboratories on the Chinese territory authorized by NMPA even if the product has already been tested and approved abroad. Among the types of tests performed there are chemical tests for heavy metals, preservatives, sex hormones, sun-screening agents, hair dying agents, antibiotics, vitamins D2, D3 and E, microbiological tests, animal tests for toxicity, cutaneous and skin irritation, skin hypersensitivity, allergy and skin phototoxicity, applicability and efficacy tests such as human skin patch test (for deodorant, sunscreen, spot-removing), human tests for SPF and waterproof property and efficacy tests for moisturizing cosmetics, anti-fat cosmetics, anti-wrinkle cosmetics and whitening cosmetics.[67]

Testing methods and time depends on the nature and properties of the product. It usually takes 80 days at maximum for completing tests. In addition, it is important to highlight the fact that China still requires animal testing for special cosmetics, and this can pose an obstacle for companies that are explicitly "cruelty free" or come from countries that have banned this kind of testing methods like the EU.[68]

In the meantime, companies shall submit registration documents and product samples to the NMPA. It takes 5 days for NMPA administrative office to perform a full check on submitted documents and issue an acceptance notice, while it takes 90 days to conduct the technical review of the product confronting the testing reports with the submitted documents relating to safety and quality of the product samples. Then, the NMPA needs 20 days to issue an approval certificate.

Special attention during the technical review is placed on product label, formula, chemical, microbiological and toxicological testing data, and human safety evaluation. These are the key elements that companies should carefully prepare in compliance with the Chinese regulation to avoid slowing down an already time-consuming and costly procedure.

In terms of labels, companies shall comply with the *Administrative Provisions on Labeling*[69] and

[67] RJS Medical Technology, "Safety, Applicability and Efficacy test of Cosmetics in China", on "sfdachina.com", http://www.sfdachina.com/cosmetics/info.asp?id=103 (04/05/21)

[68] Testing results drawn from non-animal testing methods are not likely to be trusted and accepted by NMPA technical review experts. Even though China has removed animal testing requirements for general cosmetics and has been demonstrating an interest in banning it, animal testing is still required for special cosmetics, new cosmetic ingredients and products which contain the new ingredient that has been filed and approved but not included in the IECIC, and products manufactured by enterprises which have bad records. Animal testing issues will be discussed in more detail later in this chapter.

[69] Full text available at: https://members.wto.org/crnattachments/2014/tbt/CHN/14_5430_00_x.pdf (04/05/21)

concentrate on mandatory labeling items, warning statement, Chinese translation of imported product label, appropriate efficacy claims and correct use of any expression on the packaging.[70]
In terms of product formula, we have already mentioned the requirements on prohibited and restricted use ingredients. Moreover, product claiming new efficacies or specific effects, such as hair growth or slimming, need a proof of efficacy and explanation of their usage and information of production process and standards for the retention of quality.
In terms of testing, the presence of heavy metals, microorganism, restricted and active ingredients must meet relevant requirements and the testing reports must match the formula statement. The product should not cause obvious skin and eye irritation and elicit no obvious skin allergic reaction and/or phototoxicity, and this must be shown by the safety and testing reports.
When applying for registration of special cosmetics, companies must prepare a dossier and submit several documents to the provincial MPAs. As stated in art.19 of CSAR, these documents include an application form made by manufacturer or brand holder, Chinese product name and complete product formula[60], description of the production process, specifications on the quality control system to ensure that the quality of the product meets specific standards, original packaging and label, testing reports, safety assessment report, scientific proof and evidence of any efficacy claim[71], business license and documents of the responsible agent in China, documents of production and sale of the product in the country of origin, other documents that may be helpful and necessary for review and sealed intact product sample.
After submission of all documents, if they respect all requirements, the NMPA will issue an administrative license and the products can finally be imported in China.
The duration and cost of testing and registration process depend on the category and property of cosmetics. Generally, it takes around 80 days for testing of special cosmetics (without considering additional time required for those cosmetics that need supplementary efficacy tests) and 6 months to be registered. Costs are particularly high since they include testing fee, translation fee, notary fee and consulting fee.

After the products are approved by NMPA, foreign firms can start exporting cosmetic products to China immediately. Both for general and special cosmetics, distributors or importers in China need to apply for custom inspection by submitting required documents, such as NMPA product approval license or certificate, product formula, Chinese label samples, etc. The inspection process includes

[70] The Administrative Provisions on Labeling and other requirements in terms of labels will be discussed later in this chapter.
[71] Efficacy claims can be supported by human trial, consumer use tests, laboratory tests, research reports or scientific journals.

on-site examination of the label and package, sampling and testing and the issuance of the Certificate of Inspection and Quarantine of Imported Goods, which is the ultimate requirement for custom clearance.

Importation procedures for both general and special cosmetics have not been subjected to important changes under the new regulation. The main changes can be summarized as follows:

- The registrant or notifier is the sole responsible for the whole procedure and he bears the responsibility for any fault, mistake, false information, or misleading behavior. In the past, the responsible agent in China bore more responsibilities and could be held accountable for any mistake. In general, responsibilities were not stated clearly, they were either attributed to the Chinese responsible agent or shared between the company and its agent, but now the new regulation precisely frames the responsible person and clarifies the obligations of the company and of governmental bodies entrusted with the supervision and management of the registration procedure, with the aim of increasing the responsibilities of the subject and the predictability of the success of the whole process. This change puts more pressure on foreign companies.
- For general cosmetics, companies must submit complete product formula with all the list of ingredients and a document describing the production process. This requirement is aimed at imported cosmetics, it does not apply to domestic cosmetics. This is one of the main critical issues of the new regulation, as we will discuss later, and it has been raising concerns from foreign companies.
- Companies now can turn themselves to local authorities nationwide. In the past only few local authorities, mainly located in the Free Trade Zones, could manage approval of cosmetics, so companies based in other areas of China had to apply to NMPA. With the latest developments, the process has become more rapid and immediate since companies can manage registration and notification procedures locally.
- Documents must be submitted online, so document review and issuing of certificates happens through digital channels making the whole process a lot faster.
- The procedure for general cosmetics has become easier since companies can start to import when they receive the certificate without waiting for the whole product testing and technical review, which now happens during a post-market supervision of three months. However, the procedure for special cosmetics has not changed and still represents a major obstacle to importation and trade of foreign cosmetics in China.

Other important changes brought about by the new regulation regards management of new cosmetic ingredients, attention to safety and quality of cosmetics, and full account of violations and related penalties.

3.2.3 Management of new cosmetic ingredients

Art.11 of the new regulation introduces new requirements on the management of new cosmetic ingredients, and it states as follows:

> 第十一条 在我国境内首次使用于化妆品的天然或者人工原料为化妆品新原料。具有防腐、防晒、着色、染发、祛斑美白功能的化妆品新原料，经国务院药品监督管理部门注册后方可使用；其他化妆品新原料应当在使用前向国务院药品监督管理部门备案。国务院药品监督管理部门可以根据科学研究的发展，调整实行注册管理的化妆品新原料的范围，经国务院批准后实施。[72]

This article defines new cosmetic ingredients as any natural or artificial ingredient that has never been employed on the Chinese market before and is now introduced in China for the first time with a new product, either imported or domestic. Before the new ingredient can be used, it must be approved by the NMPA. This means that, before a cosmetic product can be registered or notified, if it contains a new cosmetic ingredient, companies first have to deal with the new cosmetic ingredient approval process, and only then can they apply for product registration or notification procedure. This requirement on new cosmetic ingredients further complicates and slows down the importation process for foreign companies.

To check if the ingredients employed are already recognized or not in China, companies can refer to the new version of *Inventory of Existing Cosmetic Ingredients in China* (IECIC)[64], already mentioned previously in this chapter.

Under the new Chinese regulation, new cosmetic ingredients must undergo different approval procedures according to different categories. Cosmetic ingredi[64]ents classified as “high-risk” ingredients require registration with the NMPA, those recognized as “low-risk” are subject to notification. High-risk ingredients include preservatives, UV filters, hair dyes, colorants, freckle removal or whitening agents; all ingredients that are not included among the high-risk ingredients fall under the low-risk category.

The specificity of this new classification of cosmetic products and raw materials according to the

[72]“Art.11 The natural or artificial ingredients used in cosmetics for the first time in the mainland of China belong to new cosmetics ingredients. New cosmetics ingredients with functions of preservative, sun protection, coloring, hair dyeing, freckle removal and whitening can be used only after being registered by the NMPA of the State Council. Other new cosmetics ingredients shall be notified with the NMPA of the State Council before use. The NMPA of the State Council may adjust the scope of new cosmetics ingredients subject to registration management in accordance with the development of scientific research, which shall be implemented after approved by the State Council.” (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

level of risk and the requirement to implement a proper risk evaluation system shows the increasing modernization of the Chinese regulatory framework which is strengthening risk management to ensure product safety and is gradually aligning to international standards.

China regulates that overseas companies shall authorize a Chinese responsible person to apply for notification or registration of new ingredients. This legal entity is responsible for application, for arranging the testing of the new cosmetic ingredient and for preparation of the application dossiers.

First, companies shall apply by submitting the following documents: information of registrant and notifier of new cosmetic ingredient, safety risk monitoring and evaluation system overview of registrant and notifier of new cosmetic ingredient, original authorization letter of the domestic responsible person and the original notarial certificate for overseas registrant or notifier.

Then, companies must submit the new ingredient for testing and prepare a dossier including the name, address, and contact information of the registrant, notifier, and domestic responsible person; new cosmetic ingredient R&D report; research documents on the ingredient preparation techniques, stability, and quality control standards; safety assessment document and technical requirements.

In the case of notification, after successful submission of the documents online the notifier can directly import or use the new ingredient. In the case of registration, there will be first a preliminary format review within five working days to verify the completeness of submitted documents; then, a complicated technical review process which takes from a minimum of 90 working days to a maximum of 128. Companies that pass the review will obtain a registration certificate.

The certificate must be submitted together with other documents during the registration or notification procedure of cosmetic products and only those who possess the registration certificate can import or use the new high-risk ingredient.

During the three years following registration or notification, companies shall implement a safety monitoring system of the new cosmetic ingredient and submit safety reports annually. During this period there could be random inspections and on-site inspections of foreign companies' subsidiaries to control and make sure that quality and safety standards of new cosmetic ingredients are respected over time.[73] If no safety issue arises during the three years of monitoring, the new cosmetic ingredient will be included in the IECIC. If there is evidence showing that the new ingredient may have safety risks, companies will be required to carry out safety re-assessment and, if the new cosmetic ingredient is confirmed to have safety risks, it will be prohibited or subject to restrictions. Moreover, within the monitoring period, the new ingredients will be managed as "new ingredients"

[73] Demi Ding, "Prepare for Cosmetic Registration and Notification under China's New Regulations", p.14, on "chemlinked.com", April 13, 2021, https://cosmetic.chemlinked.com/new-webinar/prepare-for-cosmetic-registration-and-notification-under-chinas-new-regulations (05/04/21)

so any other company that intends to produce or import products with that ingredient shall follow registration or notification procedures and obtain approval independently.[74]

In addition to the registration or notification process, if a new ingredient is identified as a new chemical under the China Chemical Regulation, it should also be notified to the Ministry of Environment (MEP) before manufacture or import requiring a parallel registration procedure that further complicates the introduction of new ingredients and products on the Chinese market.

Apart from the complicated procedure for new cosmetic ingredients, an element that raises concerns among foreign companies is the fact that in the last ten years only ten new cosmetic ingredients have successfully passed approval from both MOH and NMPA indicating the extreme difficulty to get a new ingredient registered in China. However, things are expected to change with the new CSAR, since in the last months four new cosmetic ingredients have already been approved by the NMPA, suggesting that the strict regulatory measures are being softened. This is a positive signal for foreign companies that want to introduce new products on the market, but at the same time detailed requirements in terms of tests and documents and related costs are the key elements that negatively affect the entrance of foreign products in China.

3.2.4 Safety and quality requirements

In the last few decades, China has shown an increasing interest towards ensuring safety of cosmetics on its domestic market. This interest resulted in increasing requirements on safety evaluation methods and monitoring of cosmetics safety in order to improve the Chinese cosmetics standards and business environment and get in line with the regulatory framework and standards of other countries. With the new regulation on cosmetics, China further highlights this tendency towards increasing and improving procedures and supervision over quality, safety, and truthfulness of what stated on the application documents in order to encourage innovation and control in the industry.

As regards safety and quality issues, art.6 states as follows:

> 第六条 化妆品注册人、备案人对化妆品的质量安全和功效宣称负责。
>
> 化妆品生产经营者应当[…]保证化妆品质量安全。[75]

It specifically identifies companies as direct responsible and requires them to ensure the safety and quality of their cosmetics.

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[74] Zhe Su, Fei-ya Luo, Xin-rong Pei, Feng-lan Zhang, Shu-xia Xing and Gang-li Wang, "Final Publication of the 'Regulations on the Supervision and Administration of Cosmetics'and New Prospectives of Cosmetic Science in China", *Cosmetics*, *7*, 98, 2020, p.9

[75] "Art.6 Cosmetics registrants and notifiers are responsible for the quality, safety and efficacy claims of cosmetics. Cosmetics producers and operators shall […] ensure the quality and safety of cosmetics." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

To further increase companies' responsibilities and commitment in terms of safety, art.21 indicates as follows:

> 第二十一条 化妆品新原料和化妆品注册、备案前，注册申请人、备案人应当自行或者委托专业机构开展安全评估。
>
> 从事安全评估的人员应当具备化妆品质量安全相关专业知识，并具有5 年以上相关专业从业经历。[76]

Differently from past regulation, companies are responsible for conducting safety assessment tests, while in the past safety assessment was performed by laboratories authorized by the Chinese authorities. The results of these tests must be submitted together with other mandatory documents when applying for registration or record-filing procedure.
Moreover, companies must be sure that these tests are performed by qualified personnel with specific expertise and five-year work experience in the field of quality and safety management.
New quality requirements are introduced by art.29:

> 第二十九条 化妆品注册人、备案人、受托生产企业应当按[…]建立化妆品生产质量管理体系，建立并执行供应商遴选、原料验收、生产过程及质量控制、设备管理、产品检验及留样等管理制度。
>
> 化妆品注册人、备案人、受托生产企业应当按照化妆品注册或者备案资料载明的技术要求生产化妆品。[77]

Companies are required to establish a system for managing, ensuring, and supervising the quality of their products and to implement measures in order to properly select, manage ingredients, control production process, perform product and samples inspection in order to ensure an adequate level of quality. The quality standards of products must be in line with what stated on documents submitted for registration or record-filing.
In order to ensure quality and safety, companies must have qualified personnel to manage, control and ensure product safety and quality. The responsible person must have specific expertise in the

[76] "Art.21 Before registering and notification new cosmetics ingredients and cosmetics, registrants and notifiers shall conduct safety assessment by themselves or by entrusting a professional institution.
Personnel engaged in safety assessment shall possess professional knowledge related to cosmetics quality and safety and have more than 5 years of relevant professional work experience." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)
[77] "Art.29 Cosmetic registrants and notifiers and entrusted production enterprises shall […] establish a cosmetics production quality management system, and build and implement management systems such as suppliers selection, ingredients acceptance, production process and quality control, equipment management, product inspection and sample retention, etc.
Cosmetics registrants and notifiers and entrusted production enterprises shall produce cosmetics in accordance with the technical requirements specified in the cosmetics registration or notification documents." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

field and a past work experience of five years in cosmetic production and quality and safety management. This requirement is clearly stated in art.32 as follows:

> 第三十二条 化妆品注册人、备案人、受托生产企业应当设质量安全负责人，承担相应的产品质量安全管理和产品放行职责。
>
> 质量安全负责人应当具备化妆品质量安全相关专业知识，并具有5 年以上化妆品生产或者质量安全管理经验。[78]

This means that companies will have to find people with adequate skills and knowledge to perform the job, and, as we will discuss later, this represents one critical issue for companies.

Moreover, companies have to regularly conduct self-inspection on their cosmetic quality management, immediately take corrective measures if quality standards do not meet the requirements, and even stop production and immediately report to the local medical products administration departments in case of serious problems that may affect quality and safety of cosmetics, as stated in art.34.[79]

This requirement is further reinforced by art.52 which specifies that companies shall monitor possible adverse reactions of their cosmetics, carry out evaluations, and immediately report to the cosmetic monitoring agency in accordance with the provisions of the NMPA.

Companies are pushed to engage in self-monitoring of safety and quality with the aim of encouraging innovation and ensure high standards of cosmetics that circulate on the domestic market. But the new provisions actually result in additional pressures and risks for companies that want to market their products in China.

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[78] "Art.32 Cosmetics registrants and notifiers and entrusted production enterprises shall be equipped with the quality and safety responsible personnel to undertake corresponding product quality and safety management and product release duties.
The person in charge of quality and safety shall have professional knowledge related to the quality and safety of cosmetics and more than 5 years of work experience in cosmetic production or quality and safety management." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[79] 第三十四条 化妆品注册人、备案人、受托生产企业应当定期对化妆品生产质量管 理规范的执行情况进行自查；生产条件发生变化，不再符合化妆品生产质量管理规范要求的，应当立即采取整改措施；可能影响化妆品质量安全的，应当立即停止生产并向所在地省、自治区、直辖市人民政府药品监督管理部门报告。
"Art.34 Cosmetics registrants and notifiers and entrusted production enterprises shall regularly conduct self-inspection on the implementation of cosmetics production quality management standard; where the production conditions encounter any changes and are no longer meet the requirements of the cosmetics production quality management standard, rectification measures shall be taken immediately; where the quality and safety of cosmetics may be affected, production shall be stopped immediately, and it shall be reported to the medical products administration departments of the local people's government of the province, autonomous region, or municipality directly under the Central Government." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

3.2.5 Violations and penalties

In the last part, Chapter V "Legal Liability"[80] of the new regulation introduces a full account of all violations and related penalties and illegal circumstances. From art.59 to art.76, there is a detailed collection of cases of infractions and related liabilities and penalties for the transgressors. This is an important step in the modernization and improvement of the Chinese regulatory framework since it clarifies ambiguities and legislative voids present in past regulations. The new regulation clearly frames violations and illegal circumstances, degree of penalties and amount of the administrative sanctions, and persons accountable for such violations.

On one hand, the new regulation clarifies which behaviors to avoid and which actions to take in order not to incur into sanctions. On the other hand, it increases the administrative sanctions and penalties making the whole system stricter and intransigent even on the smallest details.

The most serious violations are stated in art.59[81] and they include production without license, production or import of unregistered or prohibited ingredients, and use of expired or recycled products or ingredients. These violations lead to strict sanctions such as suspension of notification certificate or registration license for ten years or, in the most serious circumstances, prohibition from engaging in cosmetics production or import for life.

New sanctions are introduced in the following articles, which are linked to the new changes introduced by this regulation. For example, it is interesting to note that art.61[81] stipulates that companies that do not put a person in charge of quality and safety in line with the requirements that we have already discussed risk prohibition of production or importation for five years. Since this new professional figure represents a critical point for companies[82], the fact that they risk suffering huge sanctions put further pressure on them.

Huge fines are introduced by art.62[81] in case of failure to disclose scientific proofs for efficacy claims. This is another critical point since the regulation does not specify which kinds of proof can be considered valid and compliant in terms of efficacy. The same sanctions are imposed in case of failure to conduct self-inspection to ensure quality standards or failure to monitor and report cosmetic adverse reactions.

The new regulation does not leave space for mistakes or negligence, indeed, art.68[81] states that, even if companies fulfill their obligations but their products are not compliant with mandatory national standards, but there is evidence that they were not aware of this, they will not be fined but registration and notification documents will be withdrawn anyway.

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[80] "第五章 法律责任", in the Chinese text.

[81] Full Chinese text and translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation (04/05/21)

[82] This point will be discussed later in this chapter.

From the previous analysis we can draw the following conclusions. Even though the new regulation improves the Chinese regulatory framework in terms of cosmetics and clarifies some ambiguities of previous regulations, it still contains critical points that do not make the importation process easier for foreign cosmetic companies. On the contrary, it puts more pressures and limits to their business activities since the process continues to be complicated, costly, risky, and subject to the arbitrary decisions of Chinese authorities that are intransigent and do not hesitate to punish and adopt punitive measures even for the smallest details.

3.3 Supplementary regulations and other legal requirements on cosmetics

3.3.1 Administrative Measures on Cosmetics Registration and Notification

On the 12th of February 2021, the *Administrative Measures on Cosmetics Registration and Notification*[83] were published to further specify new requirements for cosmetics and integrate the requirements of the new CSAR. These measures clarify the qualification of cosmetic registrants and notifiers and remark the duties of the main responsible person, particularly, it adds one responsibility for the domestic responsible person who has to bear corresponding quality and safety responsibilities of imported cosmetics and new cosmetic ingredients placed on the domestic market in agreement with the registrants and notifiers. It gives particular importance to safety of cosmetics and ingredients, indeed all ingredients employed in the cosmetic formula must be monitored on the Chinese market, when safety issues or possible threats to human health arise, the competent authority must be immediately notified and distribution or production must be immediately stopped, otherwise the responsible person will incur into sanctions.

The measures emphasize the protection of cosmetic formula. Since companies are now required to fully disclose their product formula with a detailed list of all ingredient names, many companies that rely on their business secrets and know-how and that have spent huge resources into R&D to obtain effective cosmetic formulas fear the unauthorized disclosure of their ingredients and secret formula to third parties. As a result, the aim of these measures is to further emphasize the importance of protection of cosmetic formulas and the promise to implement the adequate measures to ensure such protection and avoid possible leaks of confidential information. However, the concrete measures that will be adopted and how China will ensure the protection of cosmetic formula has not been fully clarified yet.

Moreover, the measures extend the validity of special cosmetic registration license and introduce a

[83] Full text available at: http://gkml.samr.gov.cn/nsjg/fgs/202101/t20210112_325127.html (06/05/21)

new system for the submission of cosmetic formulas during the application procedure for registration or notification of cosmetics.[84]

According to this new system, the registrant or the notifier must fill in ingredient submission codes provided by their ingredient manufacturers to directly associate the ingredient safety information to the related ingredient without the need to upload related documents each time. So, manufactures are now required to submit ingredients detailed information to obtain the submission code required for new registration and notification procedures. This will standardize the classification of cosmetic ingredients and related safety standards nationwide and make it easier and faster for companies to submit ingredient information.

3.3.2 Labelling requirements

Among the integrative regulations and measures to the new CSAR, there is the *Administrative Measures on Cosmetics Labelling*[85] which has not entered into force yet but has been drafted and proposed for discussion. For now, companies shall continue to comply with the Instruction for *Use of Consumer Products—General Labelling for Cosmetics (GB 5296.3-2008).*[86]

According to these provisions, the following information shall be indicated on the labels of imported cosmetics: product name, name and address of the manufacturer or distributor, country of origin, ID number on the administrative license or record-filing certificate, list of ingredients indicated with Chinese INCI names and listed in descending order of quantity, net content, production date and shelf life or the batch number and expiration date, warnings (for products containing restricted substances and special use cosmetics), instruction and storage condition, other information important for safety and quality of the product.

The new regulation has not introduced changes to the required label contents which are confirmed and reported in art.36 as follows:

第三十六条 化妆品标签应当标注下列内容：
（一）产品名称、特殊化妆品注册证编号；
（二）注册人、备案人、受托生产企业的名称、地址；
（三）化妆品生产许可证编号；
（四）产品执行的标准编号；
（五）全成分；
（六）净含量；

[84] Angelita Hu, "7 Noteworthy Changes in the Administrative Measures on Cosmetic Registration and Notification", on "cosmetic.chemlinked.com", January 28, 2021, https://cosmetic.chemlinked.com/news/cosmetic-news/7-noteworthy-changes-in-the-administrative-measures-on-cosmetic-registration-and-notification (06/05/21)

[85] In Chinese, 化妆品标签管理办法（征求意见稿）*huazhuangpin biaoqian banfa (zhengqiu yijiangao)*. The final version has recently been approved on June 3, 2021, and will enter into force in 2022. (Draft available at: https://members.wto.org/crnattachments/2020/TBT/CHN/20_7026_00_x.pdf, 06/05/21)

[86] For further information: https://www.chinesestandard.net/PDF/English.aspx/GB5296.3-2008?Redirect=YES (07/05/21)

（七）使用期限、使用方法以及必要的安全警示；
（八）法律、行政法规和强制性国家标准规定应当标注的其他内容。[87]

Two options are available for labeling imported cosmetics. Companies can design a label specifically for the Chinese market according to the requirements of the Chinese labeling regulation or use the original package with a compliant label translated in Chinese.

This label requirement is also remarked in art.35 of the new regulation, which states as follows:

> 第三十五条 化妆品的最小销售单元应当有标签。标签应当符合相关法律、行政法规、强制性国家标准，内容真实、完整、准确。进口化妆品可以直接使用中文标签，也可以加贴中文标签；加贴中文标签的，中文标签内容应当与原标签内容一致。[88]

In addition to basic requirements, foreign companies must pay attention to one crucial issue regarding labeling: the right choice of words and expressions on the packaging.

According to the Chinese regulations, cosmetic companies cannot claim functions or features that the products do not possess. Art.37 of the new regulation expressively prohibits medicinal function claims, expressed or implied medical effects[89] and any misleading or false wording. The Chinese label cannot include false information, exaggerated words, medical terms, doctor's names, and foreign letters, numbers, or symbols, apart from brand names and ingredient codes.[90]

These requirements are further supported and remarked in the new Administrative Measures. Some expressions are specifically forbidden for example "whitening" or "spot removing", while others are acceptable such as "anti-spot". Companies need to find a balance between compliance with Chinese claim requirements and the added value derived from the inclusion of certain claims in

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[87] "Art.36 Cosmetics labels shall be indicated with the following contents:
(I) The product name and registration certificate number of special cosmetics;
(II) The name and address of registrant and notifier and the entrusted production enterprise;
(III) The cosmetic production license number;
(IV) The product executive standard number;
(V) Full ingredients;
(VI) The net content;
(VII) The shelf life, direction for use, and necessary safety warnings;
(VIII) Other contents that shall be indicated in accordance with laws, administrative regulations and mandatory national standards." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[88] "Art.35 The minimum sales unit of cosmetics shall be labeled, which shall comply with relevant laws, administrative regulations and mandatory national standards, and the content therein shall be true, complete and correct. Imported cosmetics can use a Chinese label directly, or they can be affixed with a Chinese label; where a Chinese label is affixed, the content therein shall be consistent with that of the original label." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[89] For example, the terms "cosmeceuticals" (in Chinese 药妆 *yaozhuang)* or "medical skincare products" (医学护肤品 *yixue hufupin*), while common in many countries, are forbidden in China since 2019. However, cosmeceutical can still be sold in China as general cosmetics with proper function claims. Indeed, many of these products are sold as "functional skincare products" and are having great success recently. (Ye Chen, "Cosmeceutical in China", on "cosmetic.chemlinked.com", April 8, 2021, https://cosmetic.chemlinked.com/news/cosmetic-news/cosmeceutical-in-china, 07/05/21)

[90] Demi Ding, "Prepare for Cosmetic Registration and Notification under China's New Regulations", p.14, on "chemlinked.com", April 13, 2021, https://cosmetic.chemlinked.com/new-webinar/prepare-for-cosmetic-registration-and-notification-under-chinas-new-regulations (07/05/21)

their marketing strategies. Claims on some imported products, such as "hypoallergenic", "dermatologically tested" or "100% natural" are not allowed by the Chinese regulation.[91]

Other crucial changes will be introduced by the new *Administrative Measures on Cosmetics Labeling.* For the first time, there is an official requirement on ingredient listing method. For years, ingredients have been conventionally listed in descending order of concentration in the cosmetic formula, but there was no official requirement on the matter. After the publication of the draft this is the first time that this requirement on ingredient listing is actually stated.

According to the new provisions, all ingredients with a formula concentration equal or inferior to 0,1% must be labeled as "other ingredients' traces" or "other micro-ingredients" ("其他微量成分").[92] However, some ingredients with high efficacy are added in smaller quantities due to stability and safety issues. This can mislead consumers that may believe that the ingredient is not so important for the final effectiveness of the cosmetic product or that the product is not efficient enough because that important ingredient is present in a small percentage.

Many key ingredients for the product efficacy are not added in large quantities because of stability needs of the formula but they play an important role since they are crucial for efficacy purposes, and they make the product more expensive because they are more sophisticated and difficult to obtain and manage.

The labeling requirement of the new provisions could deceive consumers that may consider such ingredients irrelevant, or that their small percentage does not justify the high product price.

Another important change is related to the declarations of efficacy, in line also with the new requirements in the CSAR, any efficacy claim must undergo efficacy assessment tests on humans before it can be stated on the label.[93] However, consumers may believe that only products verified through human tests can be considered safe or effective. Moreover, after the draft, enlisting for human tests will increase, meaning more workload for authorized testing labs, and costs for companies will rise.

But there are also positive changes introduced by the new provisions. For example, they require to create a database of prohibited ingredients and the implementation of a more flexible management of ingredient requirements.[94] The aim is to reduce the double standards in the recording of general cosmetic ingredients due to discrepancies in the denomination of the same cosmetic ingredient

[91] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (07/05/21)

[92] Dong Yingjie 董莹洁, Huazhuangpin biaoqian guanli banfa lai le, zhe 5 dabianhua rang meizhuangpinpai geng fangxin 化妆品标签管理办法来了，这 5 大变化让美妆品牌更放心, *Huazhuangpin guancha*, on "cbndatacom", September 22, 2020, https://cbndata.com/information/94996 (07/05/21)

[93] Ibidem

[94] Ibidem

across the country.

At present, there are still differences between the ingredient denomination recognized by Chinese regulations and the denominations employed by foreign companies, this has caused several problems to companies that had to submit specific cosmetic information about ingredients and formula. This happened because there is not a uniform database that collects all the different denominations of the same ingredient employed on the market.

Thanks to a specific database, it will be easier to detect if there are prohibited ingredients in the cosmetic formulas, to confront these ingredients with other products on the market and to avoid differences at national level. If an ingredient is considered non-usable, then it will be more easily added into the list of prohibited ingredients and its prohibition will be clearer for companies.

The database will be useful for companies (since there will be a uniform system for labeling of cosmetic ingredients and it will be easier to find the right information to put on the labels), for authorities (since it will reduce efforts and costs of supervision) and for the industry (because there will be an equal treatment for all companies and products on the market).

Another important advantage introduced by the new provisions is the explicit requirement of the use of electronic labels.[95] They are an advantage for authorities, consumers, and companies. On one hand, they are very efficient for authorities that need to check cosmetic information or for consumers that wants to know more product details, because you just need to scan the electronic label with a cellphone to obtain all the related information. On the other hand, they are useful for small-size products that cannot physically contain all required information on their external packaging.

Moreover, another positive element is that for the first time there is an explicit mention concerning label defects. Label defects such as spelling errors or punctuation, not clear, difficult to read, faded or missing information are tolerated and not sanctioned if these faults do not deceive consumers or undermine safety.[96] Under previous regulation and requirements, any little fault would have resulted in huge sanctions and even in suspension or ban of the cosmetic product. These provisions mark a great change and provide an undoubted advantage for companies.

[95] Ibidem
[96] Ibidem

3.3.3 Additional requirements on safety assessment

As for safety assessment, on July 29, 2020, China opened a public consultation on *Technical Guidelines for Cosmetic Safety Assessment*, another CSAR's subsidiary regulations. On April 9, 2021, the finalized *Technical Guidelines for Cosmetic Safety Assessment*[97] was officially published and took effect on May 1, 2021.

Cosmetic registrants and notifiers can conduct cosmetic safety assessments on their own or entrust professional institutions. Cosmetic product safety assessment should be based on the assessment of all the ingredients and possible risk substances. If there are chemical or biological interactions between certain ingredients, the risk substances or potential safety risks arising from the interactions should also be assessed.

To ensure a smooth transition, the NMPA also introduced the following transitional measures. Starting from January 1, 2022, cosmetic registrants and notifiers shall conduct cosmetic safety assessments in accordance with the Technical Guidelines and submit product safety assessment documents when applying for special cosmetics registration or general cosmetics notification. This is an advantage for companies that will have direct control over tests performed and report results.[98]

3.3.4 Animal testing requirements and alternative testing methods

In terms of testing, in the last decade China has been working on the implementation of alternatives to animal testing in order to get in line with international standards and regulations. Indeed, in the last few years many countries have already banned animal testing, for example the EU prohibited sale and distribution of animal-tested products in 2013.

China remained behind on this matter, pre-market animal testing was required for all kinds of cosmetic products before getting approval and Chinese authorities did not trust alternative methods of the safety assessment of products. This caused many problems to all those overseas "cruelty-free" enterprises that wanted to enter the Chinese market and even prevented them from selling their products to China. However, over the past few years China has gone to great lengths to phase out animal testing of cosmetics and align its cosmetics regulation and industry capacities with global practices and trends with the aim of staying competitive and fostering trade inside its domestic market.

In 2014, China took the first steps allowing companies to avoid pre-market animal testing if

[97] Full text available at: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210419163037171.html?type=pc&m= (07/05/21)

[98] Hedy He, "CSAR Subsidiary Regulations: China Details Cosmetic Safety Assessment Requirements", on "cosmetic.chemlinked.com", April 12, 2021, https://cosmetic.chemlinked.com/news/cosmetic-news/csar-subsidiary-regulations-china-details-cosmetic-safety-assessment-requirements (08/05/21)

products were locally manufactured. At the same time, it also allowed make-up and personal-care products to avoid this kind of testing if they were sold and distributed through online channels, instead of physical stores.[99]

Recently, on March 4, 2021, the NMPA issued the *Provisions for Management of Cosmetic Registration and Notification Dossiers*[100] which came into force on May 1, 2021. These provisions, apart from introducing detailed documentation requirements for cosmetics and new cosmetic ingredients, regulates that imported general cosmetics can be exempt from animal testing under certain conditions and alternative methods for new ingredients registration or notification can be conditionally accepted. For applications submitted from May 1, 2021, to December 31, 2021, the applicants can submit a simplified version of safety assessment report in accordance with the *Technical Guidelines for Cosmetic Safety Assessment (2021)*[101] to obtain exemption.[102]

This is a milestone in Chinese regulatory modernization, and it will provide a lot of advantages for foreign companies that market "cruelty-free" cosmetics or come from countries that have banned animal testing.

Companies can apply for exemption of animal testing for general cosmetics, but they must fulfill two preliminary requirements: the company must submit a GMP[103] certification issued by the cosmetic regulatory authority of the local government, and the results of the cosmetic product safety report can fully verify and ensure the product's safety.

The required certificate must be issued either by a local government cosmetic department or local cosmetic associations, or by international cosmetic industry organizations.[104]

Together with this certificate a full dossier must be submitted including product formula, executive standard, quality control specification, description of the manufacturing process, testing report and cosmetic product safety report, efficacy claim proofs, product name, packaging, and Chinese label,

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[99] AP, Tiffany, "China Ends Animal Testing For Imported Cosmetics", *WWD: Women's Wear Daily*, *13*, July 6, 2020, p.13

[100] In Chinese, 化妆品注册备案资料管理规定 *huazhuangpin zhuce beian ziliao guanli guiding* (full text available at: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20210304140747119.html, 08/05/21)

[101] In Chinese, 化妆品安全评估技术导则（2021 年版）*huazhuangpin anquan pinggu jishu daoze (2021nianban)* (Full text available at: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210419163037171.html?type=pc&m=, 08/05/21)

[102] Angelita Hu, "China Formally Implements A Brand-new Cosmetic and New Cosmetic Ingredients Pre-market Approval System on May 1", on "cosmetic.chemlinked.com", May 1, 2021, https://cosmetic.chemlinked.com/news/cosmetic-news/china-formally-implements-a-brand-new-cosmetic-and-new-cosmetic-ingredients-pre-market-approval-system (08/05/21)

[103] The "Good Manufacture Practices" (GMP) is a standard drew up by the World Health Organization (WHO) in 1969. The purpose of this standard is to guarantee that products have adequate quality when they reach the market, and it covers all aspects from to the shipping of the finished product. (Takeo Mitsui, *New Cosmetic Science*, Amsterdam, Elsevier, 1998, p.208-209)

[104] Demi Ding, "Prepare for Cosmetic Registration and Notification under China's New Regulations", on "chemlinked.com", April 13, 2021, p.22, https://cosmetic.chemlinked.com/new-webinar/prepare-for-cosmetic-registration-and-notification-under-chinas-new-regulations (08/05/21)

authorization papers, compliance statement of the ingredients from Mad Cow Disease area, certificate of free sale in the country of origin.[105]

However, the exemption from animal testing is still subject to certain limitations as currently there are very few foreign government agencies that can issue an official GMP or ISO certification. Moreover, there are still three circumstances where animal testing is required: the product is specifically for children, it contains new cosmetic ingredients that are still in the safety monitoring period, and in the case of special use cosmetics.[106]

Moreover, animal testing is required for companies that have bad records and are under supervision due to past safety issues of their products.[107]

Where total exemption is not possible, there is now the opportunity to apply for alternatives methods to animal testing since in the past few years a total of seven alternative testing methods have been approved in China.

The first alternatives were introduced by the *Cosmetic Safety and Technical Standards* in 2015[108], followed by other four new alternatives approved in 2019.[109] Recently, with the entry into force of the new Regulation on January 1, 2021, the above-mentioned four methods officially came into effect. Currently, other alternative methods are under research and waiting to be approved.[110]

However, these alternative methods are not developed enough and there is still a lot of room for improvement because the majority of these testing methods are designed only for cosmetic ingredients, and there is only one method for finished products.[111]

In order to speed up the process of approval, China set up the Chinese Center for Alternatives Research & Evaluation (CCARE) with the aim of coordinating and accelerating the in-vitro testing research in China and a five-year plan for the integration of non-animal methods has been developed for the acceptance of more than ten alternative methods during this period of time.

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[105] Ivi, p.23

[106] ChemLinked, "Global Regulatory Updates of Animal Testing in 2020", on "chemlinked.com", December 29, 2020, p.6, https://cosmetic.chemlinked.com/report/regulatory-updates-of-animal-testing-in-2020 (08/05/21)

[107] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (08/05/21)

[108] Namely, in-vitro 3T3 skin phototoxicity test, in-vitro skin corrosion TER test and skin photoallergy test (ChemLinked, "Global Regulatory Updates of Animal Testing in 2020", on "chemlinked.com", December 29, 2020, p.7, https://cosmetic.chemlinked.com/report/regulatory-updates-of-animal-testing-in-2020, 08/05/21)

[109] Namely, DPRA skin sensitization test, STE in-vitro eye irritation test, LLNA:DA skin sensitization test, and LLNA:BrdU-ELISA skin sensitization test (Winnie Xu, "China Approves 4 New Alternatives to Animal Testing", on "cosmetic.chemlinked.com", May 27, 2019, https://cosmetic.chemlinked.com/news/cosmetic-news/china-approves-4-new-alternatives-animal-testing, 08/05/21)

[110] Namely, PCOP eye irritation test, in-vitro micronucleus genotoxicity test, FL eye irritation test and 442E(h-CLAT):442D skin sensitivity test (ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation, 08/05/21)

[111] ChemLinked, "Global Regulatory Updates of Animal Testing in 2020", on "chemlinked.com", December 29, 2020, p.7, https://cosmetic.chemlinked.com/report/regulatory-updates-of-animal-testing-in-2020 (08/05/21)

China has also been supported by international organizations, such as the Institute for In Vitro Sciences, for the integration of non-animal alternatives in the Chinese safety assessment procedures.[112]

In addition, on November 2020 the *Instructions for the Use of New Cosmetic Ingredient Registration and Notification Dossier* introduced the approval of some international alternatives recognized by some international authorities, such as the OECD, the ICCR and others, as valid alternatives to animal testing in case of notification or registration of new cosmetic ingredients. To receive the approval from Chinese authorities, companies shall submit supporting documents to prove the reliability of the testing results such as research papers and scientific works openly published with a detailed analysis or testing reports issued by internationally compliant labs. They shall also include a brief description of the testing method process, comparative research data of at least 10 test substances, result analysis, and other relevant documents.[113]

Similar to the animal testing exemption for general cosmetics, the conditions for the acceptance of international alternatives are also quite stringent. It is quite difficult for companies to provide such supporting documents as there are few existing qualified research papers and recognized scientific works are rare, it is difficult and costly to acquire adequate supporting material, and the fees for conducting the required testing and obtaining the testing reports are quite expensive.

In conclusion, even though a lot of changes have been made and several improvements have been implemented, animal testing still remains a critical issue for foreign cosmetic companies that want to operate on the Chinese market since it is still required in several circumstances, and it is difficult and expensive to receive approval of valid alternatives.

3.4 Critical points and future perspectives

From the previous analysis on the latest developments of legal requirements on cosmetics, both negative and positive aspects for foreign companies emerge.

On one hand, there is an interest from the Chinese part to speed up the processes for registration and notification of cosmetics and make the entrance of foreign cosmetic products easier and smoother, while improving its requirements and gradually aligning them to international ones. On the other hand, increasing requirements in terms of safety and quality, heavy bureaucracy due to the number of documents to be submitted and the complicated procedures characterized by several steps and

[112] Roger Curren, Brian Jones, "China is Taking Steps toward Alternatives to Animal Testing", *Alternatives to Laboratory Animals*, *40*, 1, 2012, p.1

[113] ChemLinked, "Global Regulatory Updates of Animal Testing in 2020", on "chemlinked.com", December 29, 2020, p.8, https://cosmetic.chemlinked.com/report/regulatory-updates-of-animal-testing-in-2020 (08/05/21)

detailed requirements that need to be followed thoroughly still represent important barriers to entry for foreign companies that do not have enough experience and financial resources.

During the above analysis we have already mentioned some advantages and disadvantages of the new regulation and legal requirements on cosmetics but what is relevant now is to highlight the major critical points that arose.

The main critical point remains the registration process of special cosmetics and new cosmetic ingredients. China simplified the process for approval of general cosmetics with the notification process which requires less time for approval of cosmetics since companies do not have to wait for technical review of all documents and samples. After getting a notification of approval, which usually takes around a week, companies can immediately start the importation process and technical review will be completed in the following three months. This procedure makes it easier and faster for foreign companies to import their cosmetics in China. However, the procedure for special cosmetics remains complicated, time-consuming, and uncertain. Compared to the notification process, the registration process for special cosmetics has more steps, stricter requirements and only after all relevant controls, the NMPA will issue a license that is mandatory before starting the importation process. The whole procedure can take from three to six months, which is a long time for business management. Without considering the fact that, if new cosmetic ingredients are employed in the cosmetic formula, then a parallel complex registration procedure of the new ingredient must be started. The registration of the new ingredient will require additional time and costs, making the importation process more difficult to complete. There is a great number of required documents that must be prepared sticking to detailed requirements. If any of these requirements are missing or information is inconsistent, incoherent, or incomplete, the whole process can suffer long delays or even be stopped. The NMPA will request additional documents, tests, or proofs, which means additional costs for companies. If requirements are not fulfilled properly, the NMPA can even decide to stop the process and ban the product or prevent the company to import products for a determined period and, in serious circumstances, even for life. Even the smallest detail is important and can undermine a successful outcome of the process. Preparing the documents in line with the Chinese regulation is not easy and many companies need to turn themselves to consulting companies or third parties with specific expertise in the field to be sure to prepare themselves properly.

The procedure also requires performing a series of expensive tests on safety, quality, and efficacy. Many of these tests are not required in other countries, so they represent additional costs for companies, exclusively for the Chinese market.

The huge costs need to be justified by the certainty of a future profit, but the uncertainty of this process makes it hard for companies to make such predictions.

There is strict control and pervasive inspections performed by authorities that have strong powers and can arbitrarily decide upon the process outcome. As stated in art.46 of the new regulation, authorities are allowed to conduct on-site inspections which are often done without notice and randomly, they are allowed to inspect and copy relevant contracts, bills, accounts, and other confidential documents and companies do not have the right to reply on this matter. If during inspection authorities find some non-compliant element or decide that something may pose a threat to human's health and safety, they are allowed to seal up and detain cosmetics, causing stop of production and profit losses.[114] It is an arbitrary process that does not leave any room for mistakes or negligence, so even the most careful companies may make mistakes and lose their investments. It is an unpredictable procedure that is often outside companies' control, it is subject to external authorities that have strong decision powers, and, as such, it makes the importation process risky for companies that decide to invest in it.

Another critical point is that, according to art.19 of the new regulation, companies need to submit the entire cosmetic formula and declare all ingredients inside the product when they intend to apply for special cosmetics registration or general cosmetics notification. For many companies, ingredient formulation is the key to their success and the secret of their business, it is strictly kept confidential, therefore they are reluctant to give away such precious information because they fear possible leaks of information or data theft on the part of ill-intentioned individuals that want to imitate the product for profit. Moreover, they do not trust the authority responsible for the control of the submitted documentation to adopt the proper data protection system to ensure the security and protection of sensitive information.

In addition to art.19 of the new regulation, in May 2021, the *Administrative measures on cosmetics registration and notification* entered into force to integrate the new regulation. They include in art.27 further specifications on the requirement to submit detailed information including all raw materials, ingredient formulation reports, concentration limits of the ingredients employed to ensure

[114] "Art. 46 When performing supervision and inspection on cosmetics production and operation, the medical products administration departments have the right to take the following measures:
(I) Entering the production and operation site to conduct on-site inspection;
(II) Conducting sampling inspection of the cosmetics produced and operated;
(III) Checking and copying relevant contracts, bills, account books and other relevant documents;
(IV) Sealing up and detaining cosmetics and their ingredients and packaging materials in direct contact with cosmetics that do not comply with the mandatory national standards, technical standards, or that proved to possibly endanger human health, and tools and equipment that proved to be used in illegal production and operation;
(V) Sealing up sites that engage in illegal production and operation activities." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

stability and quality of the formula, purpose of use, and suppliers of the raw materials and ingredients. In order to comply with all these requirements, the full cosmetic formula will be openly disclosed.

Product formulation is part of the know-how of a company, the key to its success and its competitiveness on the market. It is the result of years of tests, experience and R&D investments and it is part of the intellectual property of the company.

In order to prevent possible leaks of information, the regulation further states that those involved in the revision and storage of the application documents do not have to disclose such information unless required by law or it is a matter of national public interest. Art.47 of the regulation states that authorities entrusted with supervision and inspection shall keep the business secrets regarding the inspected cosmetics acquired during the process of inspection and supervision strictly confidential.[115] However, according to art.56, all information acquired during inspection and supervision must be disclosed[116] and, even though the article explicitly states that the parties' business secrets must be kept, the confidentiality of such information is still at risk considering multiple cases of counterfeiting or intellectual property theft on the Chinese market. It is no surprise that companies do not completely trust authorities with the management of their confidential data.

Another major issue is raised by art.32 of the new regulation which requires applicants, registrants, and manufacturing subsidiaries to appoint employees responsible for quality and safety assessment with more than five years of experience in the production of cosmetics or in the quality and safety management area.[78] Moreover, art.61 of the new regulation introduces significant penalties for those who do not appoint an employee responsible for quality and safety assessment in compliance with the regulation.

This new professional figure plays a key role in the daily activities of the company and for the proper implementation of the legal requirements, so the higher penalties for violators will encourage companies to take action and abide to the regulation.

However, for many manufacturers and small or medium enterprises that need to recruit new employees with such specific experiential background, this means higher costs for the global management of the importation process. Moreover, this qualified professional figure does not exist

[115] "Art.47 […] The supervision and inspection personnel shall keep the business secrets of the inspected units acquired in the supervision and inspection confidential in accordance with law. […]" (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[116] "Art.56 Medical products administration departments shall promptly disclose the supervision and administration information such as cosmetics administrative licenses, notifications, daily supervision and inspection results, and investigation and handling of violations in accordance with law. During the announcement of supervision and administration information, the parties' business secrets shall be kept. […]" (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

in many countries so many companies, also big corporations, may encounter difficulties in finding the right person to fit this job position.
In addition to this new key figure, companies are required to implement a quality and safety assessment system and carefully supervise their manufacturing subsidiaries, therefore overall costs will be higher. In addition, there are no further specifications on how to constitute a proper quality and safety assessment system and which are the guidelines to follow. This legislative void could cause some problems since companies do not have a clear idea on how to set up a suitable quality and safety assessment system and they cannot be sure to get approval from Chinese authorities. Moreover, if they implement different methods, there will not be a unified system at national level, so it will be difficult to ensure equal safety and quality standards nationwide.
Additional requirements to ensure safety are also introduced by art.52 which further specifies details for monitoring of adverse reactions.[117] The registrant or notifier must monitor adverse reactions and safety issues related to his products on the Chinese market and immediately report findings and possible risks. They are also required to control the production process and be sure that the manufacturing subsidiaries report possible risks and safety issues immediately. How to report safety issues and adverse reactions and to which degree is a question that still needs to be answered. This new regulation stresses the corporate social responsibility, the company needs to manage the entire process, strengthen supervision on each step and directly take actions in case of problems related to safety or quality and punish those who do not comply with the standard procedure. Those who do not comply with the new requirements will incur into big sanctions or even in ban of import and distribution on the Chinese market for a determined period.
The new regulation shows a shift of focus from attention to safety to more interest in efficacy of the products. In the past, the Chinese governmental bodies usually verified product safety but not its efficacy. The efficacy cannot be declared as one likes, the registrant or the applicant is responsible for any efficacy claim and he must submit relevant proofs.
The company usually employed efficacy claims to promote its products, make them more pleasing at the eyes of consumers and build its brand image, but no one officially monitored if these efficacy claims actually met the real effects of the products.
The new regulation clarifies that the registrant or applicant is held responsible not only for quality and safety but also for claimed efficacy of cosmetics. The name and other personal information of the responsible will be reported on the packaging so the consumers will know who bears responsibility for any problem or inconsistency encountered during the use of the product.

[117] Full Chinese text and translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation (09/05/21)

For companies that will invest in efficacy tests to prove the actual benefits of their products, on one hand, these tests represent additional costs but, on the other hand, their results will be valuable material to support new advertising campaigns and to strengthen their reputation. However, looking at the short term, the efficacy evaluation methods are not uniform and standardized in the cosmetic industry, small and medium enterprises lack technical expertise and financial resources to support investments for this kind of tests and many companies do not have direct control over the production methods because they delegate it to external companies.

Another critical point is the fact that these tests are not only expensive but also time-consuming since they can require from several months to more than one year in order to measure the actual effects of the products. This will affect the development and launch of new products and related costs.

Finally, another critical point that must be highlighted is the animal testing issue. While countries in the West are strictly against animal testing and most of them, like the EU, already banned animal-tested products, it was a mandatory requirement in China, that is why many cosmetic businesses were reluctant to import or set up subsidiaries in China. China's mandatory requirement of animal testing for cosmetics registration has been a long-standing criticality that has made Chinese cosmetics regulatory framework incompatible with that of the EU and other countries where such testing is prohibited for all kinds of products. The different animal testing policies have made global trade between these regions difficult. Chinese companies cannot sell cosmetics in the EU and European companies that are known as "cruelty-free" cannot enter the Chinese market.

However, the two-year period 2019-2020 was a turning point for the Chinese cosmetics industry and its regulatory framework. With the new regulation and other supporting provisions, China demonstrated an interest toward gradually lifting animal testing requirements and allowing alternative testing methods. Even though general cosmetics, which represent a huge share of the Chinese cosmetic market, are currently exempted from animal testing, this kind of tests are still required for other types of products such as special cosmetics and products for children, which have a strong consumers' demand and are widely distributed in China. Moreover, many foreign companies find it difficult to get approval of the test results obtained through alternative methods for several reasons. Firstly, recognized alternative methods are very few and Chinese laboratories are still not prepared or advanced enough to perform these kinds of tests. Secondly, Chinese authorities require a great amount of specific supporting documents that are difficult to obtain and very costly. Lastly, even though alternative methods have been recognized in theory and there is a strong effort in searching for viable animal-testing alternatives to be approved, China is still at the beginning of its regulatory process compared to other countries, scientists have not had the time to

get familiarity and adequate knowledge on these methods and Chinese authorities are still reluctant to accept since they do not completely trust the results coming from these tests.[118]
As a result, European companies that support the animal testing ban and other overseas cosmetic companies that openly define themselves "cruelty-free" find it difficult to import their products in China without losing their reputation and international credibility.
China has demonstrated a tendency to align its regulations and requirements to the Western ones in order to keep up with the development level of other countries and be able to compete at international level, therefore, hopefully, things are going to change in the near future. A positive signal was undoubtedly the ban on animal testing for general cosmetics, which showed the Chinese intention not only to get in line with international regulations due to global pressures, but primarily to satisfy an increasing internal demand for natural and cruelty-free products.[119] However, animal testing currently remains a major trade barrier for foreign import and international trade of cosmetics between China and other Western countries.

From the analysis of the latest developments in terms of regulations and legal requirements on cosmetics, it is evident that the Chinese legal framework is becoming more and more modern, sophisticated and in line with that of other developed countries.
The new regulation and legal requirements have shown a greater attention toward ensuring safety and quality of cosmetic products circulating on the Chinese market, in line with international safety and quality standards.
This is a milestone in the development of the Chinese cosmetics market. After years of unregulated trade of cosmetic products, safety and quality issues that have affected the Chinese reputation on international level and a backward domestic cosmetics industry compared to other countries, China is gradually improving its regulation and legal requirements in order to keep up with other developed countries and remain competitive at international level.
New requirements in terms of testing and latest development on animal testing shows a tendency to align the Chinese legal requirements to those of world's leading countries, such as the EU countries. Under the new regulations, foreign companies are directly responsible for their actions and products, they have increasing duties to fulfil and higher standards to respect, they are subject to stricter controls from authorities, and they risk heavier sanctions. As a result, the whole process is increasingly difficult, expensive, and risky.

[118] Roger Curren, Brian Jones, "China is Taking Steps toward Alternatives to Animal Testing", *Alternatives to Laboratory Animals*, *40*, 1, 2012, p.1
[119] This is a popular market trend registered in China and in many other countries at international level, as we have already discussed in Chapters 1 and 2 of this thesis. The issue of animal testing, the Chinese regulatory shift in line with the EU and the real reasons behind it will be further addressed in Chapters 4 and 5.

The new requirements, on one hand, can improve international trade because requirements and standards are becoming more advanced and similar between China and other countries, on the other hand, they are becoming more stringent and costly for companies so that they are still major trade barriers for foreign companies that want to import and sell their products in China.

In the near future, this regulation will surely provoke a series of changes in the industry: some non-compliant companies will be forced out of the market while companies that invested a lot to carve a space in the market will need to adapt to new changes and invest big resources to enact the measures required by the new regulation.

China is becoming an increasingly important and attractive market for key players in the cosmetic industry but not every company will be able to get access to the Chinese market, only the ones with greater resources and flexibility to change.

As Jiang Ligang Chief, R&D officer of Proya, said in his public statement during the CRAC-HCF 2020:[120]

> 这部法规及其为之配套的相关条例、规定、方法等，无论从顶层的管理理念设计，以及具体实操落地措施，都是目前世界上最先进的，将深刻影响到中国化妆品产业，继而我想它会影响到全世界化妆品产业。[121]

The new Chinese regulation and legal requirements are important not only for the Chinese development but also for international trade and the world cosmetics industry will have to keep an eye on them.

Therefore, it is important to look at the Chinese regulatory developments from a broader future perspective. Will China increasingly get in line with international standards and requirements, especially to the EU? What are the real intentions behind China's regulatory developments? Does it want to foster international trade? Or it is just another way to protect its domestic market while hiding behind the goodwill to improve its regulations in line with other countries? We will try to answer the above-mentioned questions in the following chapters.

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[120] The 12th Chemical Regulatory Annual Conference (CRAC) and 2nd Helsinki Chemicals Forum (HCF) in Asia, held together as a merged virtual forum in 2020.

[121] "This regulation and other supportive measures, provisions and regulations, regardless of the top-level management concept design and the specific practical implementation measures, they are currently the most advanced in the world, which will profoundly affect the Chinese cosmetics industry, and then, I think it will affect the global cosmetics industry" (my translation)
Source: Da Buding 大布丁, Huazhuangpin xintiaoli shishi, 'peifangquanfen tijiao' re zhengyi 化妆品《新条例》实施，"配方全成分提交"惹争议"，on "cbndata.com", January 15, 2021, https://cbndata.com/information/127685 (10/05/21)

4. Comparison between European and Chinese regulatory framework on cosmetics

From the previous analysis on the new Chinese regulation and legal requirements on cosmetics, we have introduced how, in the last few years, the latest regulatory developments occurring in China seem to suggest an increasing alignment with the EU regulation and standards.

The European Union was a pioneer in cosmetics legislation on international level and, as such, it exerted a strong influence on regulations and standards implemented by other countries.

This is evidenced by the fact that around 30 countries have adopted the EU model and other countries all around the world, including China, have drawn from the EU and have reproduced certain elements in their regulatory framework.

Therefore, to better understand the latest developments in the Chinese cosmetics regulation and legal requirements, and to envision future developments on the cosmetics market, it is useful to make a comparison between the European and Chinese regulatory framework on cosmetics in order to further highlight major remaining differences and increasing similarities. But first, we introduce some of the main contents of the EU regulation on cosmetic products in order to have a thorough understanding on the reasons why it exerted such a strong influence on many countries including China.

4.1 The EU Regulation and its influence at international level

The core of the EU regulatory framework on cosmetics is the *Regulation (EC) No 1223/2009 on cosmetic products*[1], which applies to all finished cosmetic products on the EU market, both domestic and imported. It is a milestone in cosmetics regulation at the international level and it served as a model for many countries that decided to improve their regulations and standards in line with the European ones because more sophisticated and up to date.

Its main distinctive characteristics were the special focus on the safety of cosmetic products placed on the EU market with the aim of protecting human health and facilitating trade between different countries. It was the first regulation of its kind to simplify the administrative procedures and to allow the free movement of cosmetic products between different countries. With this innovative regulation, the EU proved to other countries that it was possible to both ensure safety on the domestic market and foster international trade.

The Regulation (EC) No 1223/2009 replaced the Directive 76/768/EC[2], which was implemented in

[1] Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

[2] The EU Directive adopted in 1976 represented one of the first attempts to regulate the cosmetic industry at international level. It was based on the principle of risk assessment and on a high level of protection of

1976 and revised several times over the years. Compared to the old Directive, the current regulation is directly enforced in each Member State making the process of regulatory harmonization across EU countries immediate and faster. It provides a more advanced regulatory framework which reinforced product safety while taking into consideration the latest technological developments on the market. It also introduced several innovative concepts and requirements such as the regulated use of nanomaterials and the official ban of animal testing.

The first innovative content introduced by the EU Regulation is a clear and detailed definition of cosmetic products and responsible person that does not leave room for ambiguities and misunderstandings.

According to the definition provided by the EU Regulation on cosmetics, a responsible person is a legal or natural person within the European Community who is responsible for the cosmetic product placed on the EU market. He or she must be located in the EU and can be a manufacturer, a distributor, an importer or any other entity that can be directly held accountable for the cosmetic product. The responsible person has a series of obligations to fulfill.[3] In particular, he or she must ensure that all requirements of the Regulation are complied with,[4] and must notify the product information through the EU Cosmetic Product Notification Portal (CPNP)[5] before placing or importing the product in the EU market.[6] Moreover, he or she will be held responsible for any safety issue or non-compliance arising after the product is placed on the market.

The EU Regulation simplified and facilitated the introduction and importation of new products in the EU market since it substituted the complex procedure of pre-market registration or certification of cosmetics with a simple centralized and uniform system of notification across the EU through the online CPNP.[7] In order to ensure safety, the system of notification is supported by a subsequent

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human health. However, it did not provide great advantages in the regulation of the cosmetic market since each Member State had to implement and adapt its provisions in their own national laws. The implementation procedure was too slow and caused inevitable divergences among the different national legislations. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31976L0768)

[3] The full list of responsibilities can be found in Article 5 of the Regulation (EC) No 1223/2009. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526)

[4] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art. 4-5, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

[5] Official CPNP website: https://webgate.ec.europa.eu/cas/login?loginRequestId=ECAS_LR-13738840-aeZtbGhg5rWzgfn7yfpuJMkeQjxmOiISTdkzs9CuoUkzqFfzhOsZk706njsABm1shKezVjIk5sPEBYzbdozOKzoV-rS0vSrmBGYCQuv7bVHqC7u-oLmlLQttqn532ujinO61Fk15JAf7BENIRWiDSvYdpoFzO0G4ruhaBVMihzPKzUgazh1K4PRZRaaWzmNDCXQRFKV (23/05/21)

[6] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.13, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

[7] The Cosmetic Products Notification Portal (CPNP) is a free of charge online notification system created for the implementation of the notification system required by the Regulation (EC) No 1223/2009 on cosmetic products. When a product has been notified in the CPNP, there is no need for any further notification at national level within the EU. The CPNP makes this information available electronically to competent authorities for the purposes of market surveillance and poison centers or similar bodies established by EU countries for the purposes of medical treatment.

system of in-market surveillance and constant supervision over product compliance performed by competent authorities in each Member State.

The most important definition is provided by art.2 which defines a cosmetic product as a "substance or mixture intended to be placed in contact with external parts of the human body, epidermis, hair, nails, lips, external genital organs, teeth, mucous membranes of the oral cavity, with the main purpose to clean, perfume, change appearance, protect, keep in good condition, and correct body odors".[8] Many countries have adopted a similar definition or have aligned their definition to the European one because it was more detailed, accurate, and provided a clear distinction between cosmetics and pharmaceuticals with no intermediate categories.

Indeed, cosmetic products in the EU are not subdivided into categories as in other countries, all products that fall under the definition and have characteristics in compliance with art.2 are categorized as cosmetics. Under the EU definition, cosmetics include several kinds of products, such as creams, lotions, gels, face masks, soaps, perfumes, bath foams, depilatories, deodorants, hair colorants, hair-setting products, hair-cleansing and hair-conditioning products, shaving products, make-up and products for removing make-up, products for teeth, products for nail care, products for external intimate hygiene, sunbathing products, products for tanning, skin-whitening products and anti-wrinkle products.[9]

Any other product that does not fall under the definition or is not included in the above list is not considered a cosmetic product. For example, products for treating or preventing diseases or with healing properties are categorized as medical or pharmaceutical products.

The classification of products often depends on the claims which the manufacturer makes for those products, these claims are regulated by art.20 of the Regulation. Any claim, including text, pictures, or other signs on labels or in advertising describing characteristics or functions that the product does not really possess are prohibited. Claims requirements introduced by the EU regulation were integrated by the Commission Regulation (EU) N° 655/2013 of 10 July 2013 which established common criteria for the justification of claims used in relation to cosmetic products.[10] According to this regulation, claims mainly have an informative function and the information conveyed should be useful for consumers, in order to take decisions and choose the product that better suits their needs and expectations, and for companies to differentiate their products fostering

(European Commission, "Cosmetic product notification portal", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en, 23/05/21)

[8] CE.way Regulatory Consultants Ltd., "Cosmetic Product Classification", on "ceway.eu", https://www.ceway.eu/cosmetics-regulatory-services/product-classification/ (23/05/21)

[9] Ibidem

[10] European Commission, *Commission Regulation (EU) No 655/2013 Laying Down Common Criteria for the Justification of Claims Used in Relation to Cosmetic Products*, July 10, 2013, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R0655 (23/05/21)

fair competition. One important aspect highlighted in the regulation is that "it is necessary to consider the […] (consumers') expectations, taking account of the specific context and circumstances in which the claim is made, including social, cultural and linguistic factors" in order to protect final consumers from misleading information. However, the regulation does not explicitly present a list of expressions and wordings that can or cannot be used for product claims, it rather establishes common criteria and provides some examples in order to ensure a coherent approach on claims within the EU. The common criteria are legal compliance, truthfulness, evidential support, honesty, fairness, and informed decision-making.[11]

As we have already mentioned, the central theme of the EU Regulation is a special attention to product safety. The EU requires that every cosmetic product placed on its internal market must be safe to use and its safety must be ensured by specific safety evaluations made by qualified safety assessors[12] before the product is launched on the market. The responsible person is personally accountable for the correct execution of the safety assessment and related testing, and for the proper fulfilment of all safety requirements.[13]

National authorities in each Member State are in charge of reviewing the results of the performed safety assessments and checking the compliance of products circulating on their market. In case of any safety issue arising before or after the product is placed on the market, national authorities must promptly report to the European central authorities.

The European Commission with the support of scientific committees evaluates health and safety risks of cosmetic ingredients circulating on the market and provides opinions and guidelines on safety standards and testing methods.

The most important European body for cosmetic safety is the Scientific Committee on Consumer Safety (SCCS)[14], which provides independent scientific expertise on health and safety risks of

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[11] Concrete examples of allowed claims in accordance with the common criteria are included in the *Technical document on cosmetic claims agreed by the sub-working group on claims*, a non-binding document that collects best practices and provides guidance for the application of Commission Regulation (EU) No 655/2013. It comprises a series of annexes about illustrative examples on allowed claims, best practices for the justification of claims, and specific guidance on "free from" and "hypoallergenic" claims. (Full text available at: https://ec.europa.eu/docsroom/documents/24847, 23/05/21)

[12] As required by art.10.2 of Regulation (EC) No 1223/2009 on cosmetic products. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526)

[13] European Commission, "Scientific and technical assessment", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/assessment_en (23/05/21)

[14] Formerly known as Scientific Committee on Consumer Products (SCCP), the SCCS is a specific competent authority for setting safety assessment guidelines at European level. It is composed of independent scientists in the field of medicine, toxicology, pharmacy, dermatology, biology, chemistry, and other disciplines. The SCCS specifically addresses questions in relation to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health. (Vera Rogiers, Marleen Pauwels, *Safety Assessment of Cosmetics in Europe*, Basel, Karger Medical and Scientific Publishers, 2008, p.6)
For further information about the SCCS: https://ec.europa.eu/health/scientific_committees/consumer_safety_en (23/05/21)

several consumer products, such as cosmetics, clothing, toys, etc.

To improve compliance with the EU cosmetics regulation, the SCCS issued the *Notes of guidance for testing of cosmetic ingredients and their safety evaluation.*[15]

The EU regulation particularly stresses the importance of cosmetics safety and requires that the responsible person shall prepare a cosmetic safety report[16] in accordance with the requirements provided by Annex I of the Regulation.

As mentioned in the *Guidelines on Annex I to Regulation (EC) N°1223/2009*, "the most important element of the product information file, from a safety point of view, is the cosmetic product safety report" [17], together with "a clear description of the cosmetic product, a description of the method of manufacturing and a statement on compliance with good manufacturing practice, the proof of the effects claimed, and data on animal testing".[18]

The cosmetic safety report must be drawn up in a clear, detailed, well-argued way in order to allow an easy understanding of its content and a proper safety evaluation of the related product. Any information included in the report must be supported by existing scientific proofs and research evidence readily available in electronic or printed format. Moreover, the report must be updated according to any development occurring on the market.

Annex I clearly defines the structure and contents of this report dividing it into two parts, namely Part A and Part B. Part A gathers all data to prove and ensure the product safety, while Part B draws final conclusions on the product safety.

In Part A, the safety assessor must include all relevant information about potential risks to human health that can be drawn from any certified source such as scientific literature, results of studies performed on the product or its ingredients, information available in scientific databases, documents provided by suppliers, etc.

In this section, the complete product formula must be specified, stating the name and function of each raw material and its amount in terms of weight percentage inside the product formula. Also, a detailed description of physical and chemical characteristics of the product and its ingredients is required not only to assess safety but also to establish minimum quality standards under normal usage conditions. In addition, an assessment on formula stability is needed to evaluate safety and

[15] Full text available at: https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf (23/05/21)

[16] Referred to in Article 10.1 of the Regulation (EC) No 1223/2009 on cosmetic products. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31976L0768)

[17] European Commission, *Commission Implementing Decision on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products*, November 25, 2013, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D0674#ntr3-L_2013315EN.01008301-E0003 (23/05/21)

[18] Ibidem

quality under normal storage conditions and determine the date of minimum durability. Moreover, any impurity or trace of unintended substances in the formula must be disclosed.

Information about the packaging material in direct contact with the product is also important in terms of safety assessment and it must be supported by scientific evidence about safety of the material and possibilities of migration of substances. In this case, experience with similar packaging combinations already existing on the market can be useful.[19]

Risk exposure in case of contact with mucous membranes and eyes are to be carefully calculated and meticulously specified in Part A in order to evaluate potential risks. Lastly, the cosmetic product safety report must include all available data on serious undesirable effects linked to the use of the product or other similar products on the market.

In order to monitor the safety of the product after it has been placed on the market and to promptly take corrective action in case of need, the responsible person must set up a system to collect documents, understand the causes and manage the undesirable effects caused by the product. When the undesirable effects are serious, the responsible person must notify the competent authority of the Member State where the problem occurred.[20]

In Part B, final conclusions about the performed safety assessment are drawn by the safety assessor. In this section, the product must be clearly defined as "safe", "safe with restrictions" or "not safe for human health when used under normal or reasonably foreseeable conditions of use".

Part B must also include an explicit list of warnings and precautions of use, and the reasoning behind the safety assessment with the aim of clearly explaining how the safety assessor conducted his evaluation and drew the consequent conclusions. In the reasoning, the assessor must be sure that all relevant information and data about the safety assessment are included, and he (or she) must justify any missing information required in Part A because considered unnecessary for the final evaluation.

Moreover, the safety report must include the credentials of the safety assessor who must be a professional figure with adequate knowledge and specific expertise in the field of safety assessment, medicine, pharmacy, or similar disciplines, certified by a diploma recognized by a Member State.[21]

The cosmetic safety report is the central part of the Product Information File (PIF). According to the EU Regulation, the PIF must be prepared and kept by the responsible person. This Product

[19] Reference can be made to another EU regulation, the *Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food* (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AL%3A2004%3A338%3ATOC, 23/05/21)

[20] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.23, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

[21] Ivi, art. 10.2

Information File contains all the information about the cosmetic product, including cosmetic formula, description of the manufacturing process and statement of compliance with GMP[22], raw materials and packaging, a cosmetic product safety report containing all data regarding testing methods, risk evaluation and safety assessment of the finished product and its ingredients, data on any claim related to the product, any information on animal testing performed to meet the legal requirements of third countries, and any other relevant information about the product.[23]

As regards testing methods, the EU regulation provides for mandatory testing on cosmetic formulas and recognized alternatives to animal testing in order to ensure proper compliance with EU safety standards and requirements. The tests can be performed by any laboratory within the EU in accordance with the European official methods of analysis.[24]

The Regulation No 1223/2009 officially introduced the ban on animal testing[25] in art. 18 and it specifically established the prohibition to test products and ingredients that are intended for the EU market on animals, or to market any imported product which has been previously tested on animals within the EU market.[26] This policy had a strong impact on the international cosmetic market since it forced foreign cosmetics companies from all over the world to develop alternatives methods to animal testing in order to meet the EU requirements.[27]

Several alternative testing methods have been recognized and approved by the European Center for Validation of Alternative Methods (ECVAM)[28] providing a benchmark for other countries that have adopted the same provisions during the last few years. The recognized alternative testing methods are included in Annex VIII of the EU Regulation.

The EU also launched a collaborative initiative between the European Commission, European trade

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[22] Good manufacturing practice (GMP) is an international standard to ensure the quality of the cosmetic production process. Compliance with GMP is required by Article 8 of Regulation (EC) No 1223/2009 but no specific certification is mandatory, and companies can choose the type of GMP standards to comply with. In Europe, the standard ISO 22716 is in force to certify compliance with GMP, but its certification is not mandatory, companies can choose which guidelines to follow as long as compliance with general GMP is respected.

[23] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art. 11, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

[24] European Commission, "Scientific and technical assessment", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/assessment_en (23/05/21)

[25] The ban was fully implemented in 2013 irrespective of the fact that proper alternative methods were not already recognized or developed. In March 2013, with the *Communication on the animal testing and marketing ban and the state of play of alternative methods in cosmetics*, the European Commission finalized the testing ban and outlined the intention to continue to support research and innovation in the area of alternative testing methods while promoting animal welfare worldwide. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0135, 23/05/21)

[26] European Commission, "Ban on animal testing", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en (23/05/21)

[27] Sreedhar, Manjula, Ajay, Shilpa, Ligade, "Ban of Cosmetic Testing on Animals: A Brief Overview", *International Journal of Current Research and Review*, *12*, 2020, p.114

[28] The ECVAM is a European institution that plays a key role in the development, validation, and international recognition of alternative methods which reduce, refine, or replace the use of animals in testing. (For further information: https://ec.europa.eu/jrc/en/eurl/ecvam, 23/05/21)

associations and individual companies, called European Partnership for Alternative approaches to Animal testing (EPAA)[29], to promote the development of modern alternative approaches in safety testing and the implementation of the innovative concept of 3Rs methods[30] introduced by the EU Regulation.

The Regulation No 1223/2009 stipulates that EU countries must implement an internal system of market surveillance. Each Member State appoints national inspectors, responsible for the in-market surveillance system, who shall monitor compliance, visit local manufacturing sites to check products, take products from the marketplace to official laboratories for further testing, act against those companies that may pose a threat to consumers and have access to product information via direct consultation of companies' material made available to authorities.[31]

In order to ensure a uniform approach to market surveillance at the European level, the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) has been established. This platform aims at coordinating national responses to issues related to cosmetic products within the EU and facilitating the exchange of information, expertise, and best practices for market surveillance between Member States.[32]

Together with the PEMSAC, the EU Regulation on cosmetic products also created the basis for a uniform system of communication of "serious undesirable effects" (SUE) within the EU market. It provides for a quick system of notification of SUEs to national authorities and notification of any corrective measure taken by the responsible person or distributor.[33]

Moreover, art. 7 of the Regulation establishes a system of traceability and identification within the supply chain so that the responsible person can identify the distributors entrusted with products and vice versa in order to ensure a quick system of tracking and an effective response in case of reported SUEs.[34]

In order to comply with the safety requirements on cosmetics, cosmetics must also fulfill specific requirements on ingredients and product formulation. Cosmetic products should not contain certain prohibited ingredients, which are listed in detail in Annex II of the Regulation, they should respect limitations in the use of restricted substances, as stated in Annex III, and they need to conform with specific requirements on colorants (Annex IV), preservatives (Annex V) and UV filters (Annex

[29] For further information: https://ec.europa.eu/growth/sectors/chemicals/epaa_en (23/05/21)
[30] The 3Rs stand for "replace" and "reduce" animal testing, and "refine" alternative methods to animal tests.
[31] Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017, p.6
[32] European Commission, "Market Surveillance", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/market-surveillance_en (23/05/21)
[33] Ibidem
[34] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.7, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)

VI).[35] These ingredients lists, thanks to their advancement and specificity, provided a benchmark for the development of parallel lists in other countries all over the world.

The EU Regulation also provides for specific restrictions on CMR (carcinogenic, mutagenic, or toxic for reproduction) substances[36] and nanomaterials[37], respectively in art.15 and 13.[38]

Another important element of the EU Regulation is the mandatory requirements on labelling, stated in art.19.[38]

The packaging must bear several mandatory information in indelible, legible and visible wording, such as name and address of the responsible person established in the EU; the country of origin for cosmetics manufactured outside the EU; the nominal content given by weight or volume, unless the package contains less than 5g or 5ml; the number of items inside the packaging if not visible from the outside; the batch number of manufacturer for identifying the goods; the function of the product if it is not clear; a list of ingredients in descending order of weight; the date of minimum durability and additional information about the conditions that must be satisfied to guarantee the stated durability.[39] Date of minimum durability is preceded by the statement "best used before the end of" but it is not mandatory for cosmetic products that have a minimum durability exceeding 30 months, instead these products need to indicate the Period after Opening (PaO) for which the product is safe to use. The PaO is expressed in years or months, inside or alongside the following symbol.

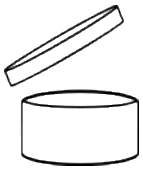

Figure 12: Symbol for Period after Opening (Regulation (EC) No 1223/2009, Annex VII)

Manufacturers must make sure that the packaging is not labelled with text names, trademarks, pictures, or other signs which imply that the product has characteristics that it does not actually have.[40]

Where it is impossible for practical reasons to put mandatory information on the packaging, the

[35] For further information: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526
[36] CMR substances are prohibited because of their chemical hazard classification, but there are exceptions. Some CMR substances can be allowed if they are certified as safe by the Scientific Committee on Consumer Safety (SCCS).
[37] Nanomaterials are defined as "insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm" and they are subject to a special pre-notification procedure that must be made six months before the product release on the market. (Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017, p.9-10)
[38] Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526
[39] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.19.1, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)
[40] Pira International Ltd., *Packaging Legislation and Regulations for Cosmetics and Toiletries*, iSmithers Rapra Publishing, 2012. p.32

following symbol can appear suggesting the consultation of enclosed or attached information inside the packaging.

Figure 13: Symbol for attached or enclosed information (Regulation (EC) n°1223/2009, Annex VII)

It is also important that statements about the product are made in the national language of the respective country.[41]

From the above analysis on *Regulation (EC) No 1223/2009*, we can argue that several innovative changes were introduced for the first time in the cosmetic regulatory framework. The most significant changes can be summarized as follows:

- A clear definition of "responsible person" as a legal entity localized in the EU that is accountable for the cosmetic products placed on the EU market and a distinction between manufacturer and distributor.
- Stricter safety requirements for cosmetics including the mandatory preparation of a cosmetic safety report for each product before its launch on the market.
- Innovative requirements on nanomaterials and CMR substances.
- Detailed and exhaustive lists of allowed, restricted, or prohibited cosmetic ingredients and substances together with a common glossary of ingredient names, called CosIng[42], to ensure uniform denominations and labelling within the EU.
- A centralized system of notification for all products, both domestic and imported, before they are placed on the EU market. The system is known as Cosmetic Product Notification Portal (CPNP).[43]
- Obligation to report Serious Undesirable Effects (SUEs) caused by the use of the cosmetic products through a system of notification to national competent authorities. All interested parties, such as health professionals and consumers, will be warned by the authorities in order to ensure the protection of people's health within the EU market.
- Authorization and rules for the use of nanomaterials in cosmetic products including guidelines for full safety assessment and labelling requirements.[44]

[41] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art. 19.5, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (23/05/21)
[42] For further information: https://ec.europa.eu/growth/sectors/cosmetics/cosing_en (23/05/21)
[43] For further information: https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en (23/05/21)
[44] European Commission, "Legislation", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/legislation_en (23/05/21)

These changes were introduced mainly to foster harmonization of different national regulations within the EU and to simplify procedures and solve ambiguities at the European level since the current Regulation, differently from the old Directive, directly applies to all Member States and it is directly implemented and incorporated in the different national legislations.
Consequently, it exerted a strong international influence since it was so innovative and first of its kind that it became a model for other countries and set guidelines for cosmetics regulations at international level in terms of definitions of cosmetics and responsible person, main responsibilities and obligations, safety standards and surveillance system to ensure higher protection of consumers' health.[45]
In the last few years, many countries have updated their regulatory framework following the EU model, some of them adopted the same definitions and systems, while others adapted the EU requirements to their regulatory framework. As a result, different national regulations and requirements are increasingly aligning with the EU, creating international standards, and fostering international harmonization.
Increasing international harmonization raised an important question in the cosmetic industry: is international regulatory harmonization possible?[46]
We try to answer the above question by analyzing the example of China. The latest developments in the Chinese cosmetics regulation seem to show a tendency to align with the EU requirements and standards. However, some major differences are still in place, and this makes us wonder if China will fully align its regulation in the future and to what end. This point will be discussed in the next paragraphs, but first we propose a comparison between the EU and the Chinese regulatory framework on cosmetics in order to clearly understand similarities and differences.

4.2 Increasing similarities between the Chinese and the EU regulation on cosmetics

In the last few years, the EU Regulation on cosmetic products has been so innovative that it had an unequivocal impact on the international cosmetic industry. As a result, many countries have implemented changes increasingly aligning their regulations to the European one. Their aim was, on one hand, to allow domestic companies to easily engage in international trade with the EU, since it is one of the most important markets for cosmetic products, and, on the other hand, to keep up with the developments and innovations occurring on the market in order to stay competitive.
As many other countries, China is also gradually improving its regulation and legal requirements on cosmetics drawing from the innovative concepts introduced by the EU Regulation.

[45] Consulenza Cosmetici, "Il Regolamento (CE) 1223/2009", on "consulenzacosmetici.it", https://www.consulenzacosmetici.it/index.php?p=27&id=18 (23/05/21)
[46] This question will be specifically addressed in paragraph 5.2 of the next chapter

With the enforcement of the new *Cosmetic Supervision and Administration Regulation* (CSAR) in January 2021, increasing similarities between the Chinese and the EU regulatory framework on cosmetics are becoming more evident.

The first evidence can be found by comparing the definition of "cosmetics" provided by the EU and China, respectively in art.2.1(a) and art.3. As we have already introduced in paragraph 1.2 of this thesis, the basic concept lying behind the definition of cosmetic products provided by the two regulations is basically the same. According to the EU Regulation, a cosmetic product is defined as "any substance or mixture intended to be placed in contact with the external parts of the human body […] to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors".[47] Even if the choice of words slightly differ, substantial correspondence can be found in the Chinese Regulation where cosmetics are defined as chemical products[48] that are applied to external body parts such as skin, hair or nails[49] with the aim of cleaning, protecting, keep in good condition or embellish, and change the appearance or decorate.[50]

Before the implementation of the new Chinese Regulation, there was one major difference compared to the EU regulation. While the EU included products that can be applied to "teeth and the mucous membranes of the oral cavity"[47], there was no mention of such kind of products in the Chinese definition, as a result products like toothpaste were not considered as cosmetics in China and they were subjected to different rules and import procedures. Things have changed with CSAR, which has introduced for the first time a mention to toothpaste in art.77 as follows:

> 第七十七条 牙膏参照本条例有关普通化妆品的规定进行管理。牙膏备案人按照国家标准、行业标准进行功效评价后，可以宣称牙膏具有防龋、抑牙菌斑、抗牙本质敏感、减轻牙龈问题等功效。[…][51]

By implementing this change, China has further aligned its definition to the EU. Now toothpaste and products for the oral cavity officially fall under the scope of cosmetics and are managed as general cosmetics through the simpler and faster procedure of notification, which makes it also easier for foreign companies to import this kind of products in China.

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[47] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.2.1(a), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (24/05/21)

[48] In the original text, 化学工业产品 *huaxue gongye chanpin*

[49] In the original text, "施用于皮肤、毛发、指甲、口唇等人体表面"

[50] In the original text, "清洁, 保护, 美化, 修饰". (Full text and translation available at: https://cosmetic.chemlinked.com/database/view/1094)

[51] "Art.77 Toothpaste shall be managed with reference to the provisions on general cosmetics herein. After toothpaste notifiers conduct the efficacy evaluation in accordance with national standards and industry standards, they can claim that the toothpaste has efficacy such as anti-caries, plaque inhibition, anti-dentine hypersensitivity, and relieve gingiva problems, etc." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

Moreover, both regulations do not allow pharmaceuticals or other products with medical functions to be considered or managed as cosmetics on their domestic market. Indeed, they do not allow an intermediate category between cosmetics and medical products.

In the EU, the product type is decided by the national competent authorities through a case-by-case analysis, taking into account all the characteristics of the product.[52] A product that restores, corrects, or modifies physiological functions will be qualified as a medical product; while one that has an effect on the human body but does not significantly modify the metabolism and body functions will be considered as a cosmetic product.[53] The same approach is also adopted in China.

Both regulations explicitly stress the responsibility of companies to ensure safety and compliance with the respective provisions.[54] This aspect is reinforced by the notion of "responsible person" introduced by the EU regulation in art.4, who is "a legal or natural person […] designated within the Community […]"[55], either a manufacturer, an importer or any other person responsible for placing the product on the European market and he (or she) bears the responsibility to ensure that cosmetic products are safe for consumer use.

The same concept has been taken up by the new Chinese Regulation that attributes all responsibility for cosmetics safety and quality to the person responsible for registration or notification of cosmetics on the Chinese market, referred to as 注册人 (*zhuceren*) or 备案人 (*beianren*) in the Chinese text.[56]

In the EU, the importer will be the direct responsible for the products imported in the EU market and he shall be located in the Community territory or shall "designate a person established within the Community as the responsible person".[57] In the same way, in China the importer must appoint an agent located on the Chinese territory that will support the importation procedure.[58]

Both in the EU and China, the direct responsible answering for any safety issue or any breach of duty will be the main responsible person, either the manufacturer, importer or any person directly in charge of managing the product.

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[52] European Commission, "Borderline products", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_nn (24/05/21)

[53] European Commission, *Guidance document on the demarcation between the cosmetic products Directive 76/768 and the medicinal products Directive 2001/83 as agreed between the commission services and the competent authorities of Member States*, October 5, 2005, https://ec.europa.eu/docsroom/documents/13032/ (24/05/21)

[54] As required by art.4.2 of Regulation (EC) No 1223/2009 and art.6 of the CSAR

[55] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.4.1, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (24/05/21)

[56] As stated in art.6 of CSAR (Full text and translation available at: https://cosmetic.chemlinked.com/database/view/1094)

[57] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.4.5, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (24/05/21)

[58] As provided by art.23 of CSAR (Full text and translation available at: https://cosmetic.chemlinked.com/database/view/1094)

Chinese reception of the concept of "responsible person" in its regulation shows its intention to hold companies directly accountable for the safety of products in order not only to ensure higher safety standards but also to enhance innovation and quality of the products circulating on its domestic market with the aim of staying competitive at an international level.

Another revolutionary element introduced by the new version of the Chinese cosmetics regulation, which further moves it closer to the EU, is the introduction of a centralized notification system for general cosmetics[59], both domestic and imported.

Mandatory information to be submitted at the moment of notification is almost the same between China and the EU. Art.13 of the EU Regulation requires companies to submit the following general information: the category and denomination of the product, the name, address and contact details of the responsible person, the country of origin, ingredients inside the product formula, the original label and, if available, a picture of the original packaging.[60]

Information required for notification in China is basically the same, as we can see in art.19:

> 第十九条 申请特殊化妆品注册或者进行普通化妆品备案，应当提交下列资料：
> （一）注册申请人、备案人的名称、地址、联系方式；
> （二）生产企业的名称、地址、联系方式；
> （三）产品名称；
> （四）产品配方或者产品全成分；
> （五）产品执行的标准；
> （六）产品标签样稿；
> （七）产品检验报告；
> （八）产品安全评估资料。[61]

The only difference between the Chinese and the EU regulation is that China requires companies to submit an inspection report and the results of product safety assessment, differently from the EU. The EU does not require to submit these kinds of documents because they are included in the Product Information File (PIF), a detailed dossier on the product which is kept by the responsible

[59] Introduced by art.4 of CSAR (Full text and translation available at: https://cosmetic.chemlinked.com/database/view/1094)

[60] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.13, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (24/05/21)

[61] "Art.19 The following documents shall be submitted for registration of special cosmetics or notification of general cosmetics:
(I) The name, address and contact information of the registrant and notifier;
(II) The name, address and contact information of the production enterprise;
(III) The product name;
(IV) The formula or full ingredient list of the product;
(V) The standard that the product complies with;
(VI) The sample manuscript of the product label;
(VII) The product testing report;
(VIII) The product safety assessment documents."
(Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

person and can be consulted by authorities in case of need. These documents are still mandatory for notification in China and represent a big burden for companies that have to invest a lot of resources to prepare them in compliance with the Chinese requirements.[62]

In China, all documents shall be notified through the online platform of the National Medical Products Administration[63] which provides a centralized online service at national level similar to that provided by the European Cosmetic Product Notification Portal (CPNP).

This system of notification has made the process of importation of foreign general cosmetics more rapid and easier providing a great advantage to foreign companies that want to import and sell their products in the Chinese market. However, major differences still exist between the Chinese and the EU importation procedure. In particular, China still requires imported special cosmetics, which represent a big share of the market, to be subjected to a long, complex and expensive procedure of registration that makes it difficult for foreign special cosmetics to enter the Chinese market.[64] So, from this point of view, there is a lot of room for further improvements in the future from the Chinese part.

While improving the procedure for general cosmetics, China also introduced and strengthened in-market surveillance, introduced in art.53 as follows:

> 第五十三条 国家建立化妆品安全风险监测和评价制度，对影响化妆品质量安全的风险因素进行监测和评价，为制定化妆品质量安全风险控制措施和标准、开展化妆品抽样检验提供科学依据。[65]

Nowadays China has implemented a decentralized market supervision system allowing many national authorities to conduct inspections and testing at national level under the management of the central NMPA, while strengthening their coordination in order to increase efficacy of government supervision and monitoring on the market.[66] Chinese authorities have the right to conduct inspections and tests on cosmetics circulating on the market and decide to stop or even ban their distribution if there are serious concerns about product safety and quality. The Chinese system of centralized market surveillance is in line with the requirements of the EU Regulation as we can see by analyzing art.22 which states as follows:

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[62] This point will be further discussed in the next paragraph of this chapter.

[63] As stated in art. 13 of CSAR (Full text and translation available at: https://cosmetic.chemlinked.com/database/view/1094)

[64] This point will be further discussed in the next paragraph about differences between the Chinese and the EU regulation.

[65] "Art. 53 The state shall establish a cosmetics safety risk monitoring and evaluation system to monitor and evaluate the risk factors that affect the quality and safety of cosmetics, and provide a scientific basis for formulating cosmetics quality and safety risk control measures and standards and conducting cosmetics sampling inspections." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[66] European Union Chamber of Commerce in China, *European Business in China Position Paper 2019/2020* (欧盟企业在中国建议书 2019/2020), 2019, p.192, https://www.fbcbj.org/sites/default/files/content-files/European_Business_in_China_Position_Paper_2019_2020%5B756%5D.pdf (24/05/21)

> Art.22 Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.[67]

And to ensure safety of cosmetics on the market, China has also established a monitoring system of adverse reactions to cosmetics in art.52 whereby companies, operators and medical institutions shall monitor cosmetics safety and report any adverse reaction or risk for human health. This system takes inspiration and shares similarities with the European system of Notification of Serious Undesirable Effects (SUEs).[68] However, the Chinese system is still at the early stages of its development, it is not as advanced as the European one, and the Chinese Regulation does not provide practical details on how to notify adverse reactions.[69]

Another important element for ensuring product safety in both regulations is undoubtedly the safety assessment report, respectively required by art.10 of the EU Regulation and art.21 of the Chinese CSAR. In both regulations the safety assessment shall be conducted by qualified safety assessors with specific knowledge and expertise in the field.

However, the EU Regulation provides more details on this matter since it dedicates an entire part of the regulation, namely Annex I, to specific guidelines on the contents and methods of preparation of the so-called "cosmetic safety report".[70] Instead, the Chinese regulation, apart from mentioning its compulsoriness, does not provide further details on how to prepare this report or on its specific contents.[71] From the new requirements on safety, China is showing a growing interest in ensuring product safety so, hopefully, there will be further developments and implementation of new provisions in the future in order to keep up with the more advanced EU regulatory framework.

A fundamental step for the safety assessment of cosmetics is testing. With the enforcement of the *Regulation (EC) No 1223/2009 on cosmetics*, the EU has officially banned animal testing. Specifically, art.18.1 prohibits

> (a) the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Regulation, has been the subject of animal testing using a method other than an alternative method […];

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[67] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.22, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (24/05/21)

[68] Regulated by art.23 of the Regulation (EC) No 1223/2009

[69] This difference will be further discussed in the next paragraph.

[70] In Annex I, there is specific mention to the following mandatory contents: quantitative and qualitative composition of the product, physical chemical characteristics and stability of the product, microbiological quality, traces, packaging material, use, exposure to cosmetic product or substance, toxicological profile, undesirable effects, information on the product, assessment conclusion, labeled warnings and instructions of use, reasoning, and assessor's credential. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526)

[71] See the next paragraph of this chapter for a more details.

> (b) the placing on the market of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Regulation, have been the subject of animal testing using a method other than an alternative method […];
> (c) the performance within the Community of animal testing of finished cosmetic products in order to meet the requirements of this Regulation;
> (d) the performance within the Community of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation, after the date on which such tests are required to be replaced by one or more validated alternative methods […].[72]

Moreover, the EU currently provides many of the most advanced alternative testing methods at an international level, included in Annex VIII of the EU Regulation.

For years, animal testing has been the major difference between the Chinese and the EU regulatory framework since China specifically required animal testing on any product intended for its domestic market. However, things are changing and the latest developments in the Chinese regulation have witnessed an interest from the Chinese part to face out requirements on animal testing. After years of pressures coming from consumers, who are increasingly demanding cruelty-free products, from companies, that wants to market their products in China while retaining their cruelty-free reputation, and from international institutions, China has officially removed animal testing requirements for general cosmetics, and it is pushing for the development and recognition of alternative testing methods. However, even though this is a big step toward alignment with international standards, differences continue to exist in terms of testing as we will further discuss in the next paragraph of this chapter.

In order to comply with all safety requirements, both countries have implemented provisions on allowed, restricted, and prohibited ingredients inside cosmetic formulas.[73] The EU Regulation includes a series of Annexes, specifically from Annex II to Annex VI[74], dedicated to exhaustive lists of ingredients which comprise of detailed information on denominations, restrictions, and potential risks of the majority of substances employed in cosmetics circulating on the market. These lists are the result of a long process of research and collection of information, and they are constantly updated according to market developments. The EU lists were first of their kinds in terms of accuracy and completeness, so that they have become a model for other countries all around the world. Most countries and regions have adopted the same EU standards and restrictions

[72] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.18.1, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (25/05/21)
[73] Specific provisions are stated in art.14 of the Regulation (EC) No 1223/2009. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526)
[74] Specifically, Annex II provides a list of prohibited ingredients, Annex III lays down restrictions on several substances, Annex IV includes a list of recognized colorants, Annex V comprises of allowed preservatives and Annex VI lists authorized UV-filters. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526)

on substances, and China has implemented provisions on ingredients that are similar to those of the EU.[75]

As we have already discussed in paragraph 3.2 of the previous chapter, China has recently implemented a new version of the so-called *Inventory of Existing Cosmetic Ingredients in China (IECIC 2021)*.[76] This updated collection of recognized and allowed cosmetic ingredients on the Chinese market draws from the EU model but it is still not advanced enough. The EU provides long Annexes to the regulation, each one is specific for a different category of ingredients, and it has also introduced innovative provisions on CMR substances and nanomaterials (the latter still missing in many legislations).

To keep up with the EU requirements, China has engaged in a process of modernization of its regulatory framework on cosmetics. It has drafted a new inventory of prohibited ingredients, which is still to be enforced, and it is gradually updating the IECIC. Moreover, in order to push for innovation and recognition of new ingredients on the market, China requires companies to submit complete ingredient lists and engage in a complex procedure of registration of new cosmetic ingredients which we have already discussed in the previous chapter.

There is a long way to go but China is gradually aligning to the EU requirements on ingredients. Ingredients are a fundamental element of labelling requirements in both countries, so in order to harmonize denominations of cosmetic ingredients, the EU and China have implemented glossaries providing uniform denominations and translations at national level. Nowadays, international ingredients denominations and listings are conventionally based on the International Nomenclature of Cosmetic Ingredients (INCI) created by the Personal Care Products Council (PCPC) of the US.[77] Most countries have adopted and developed their version of INCI so that ingredient lists in one country can find a specific correspondence in another country. Therefore, the *INCI Chinese version*[78] and the *Glossary of common ingredient names* mentioned in art.33 of the EU Regulation share a lot of similarities. Both glossaries have been recently updated, the EU published a new

[75] Kazutami Sakamoto, Robert Lochhead, Howard Maibach, Yuji Yamashita, *Cosmetic Science and Technology: Theoretical Principles and Applications*, Amsterdam, Elsevier Science, 2017, chap.9, "Regulations on cosmetics*"*, p.140.

[76] For further information please refer to paragraph 3.2 of this thesis. (Full text available at: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20210430162707173.html?type=pc&m, 25/05/21)

[77] Kazutami Sakamoto, Robert Lochhead, Howard Maibach, Yuji Yamashita, *Cosmetic Science and Technology: Theoretical Principles and Applications*, Amsterdam, Elsevier Science, 2017, chap.9, "Regulations on cosmetics*"*, p.139

[78] Full text available at: http://law.foodmate.net/show-172248.html (25/05/21)

version in 2019[79] and China drafted its updated version in 2018[80] which is in the process of being enforced.

Together with the ingredient list, there are several mandatory elements for labelling both in the EU and in China. By comparing art.19 of the EU Regulation and art.36 of CSAR on labeling, several similarities emerge. Both countries require that labels contain name and address of the responsible person, batch number of the manufacturer, ingredients list, nominal content in terms of weight or volume, the period during which it is safe to use the product[81], any information on the correct use or precautionary information for safety, and country of origin for imported products.

Moreover, both regulations have strict requirements on specific contents displayed on the label and on the packaging in order to protect final consumers from misleading and false information. Specifically, art.20.1 of the EU Regulation provides as follows:

> In the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

The content of this article is reflected by art.37 of the Chinese regulation which provides that

> 化妆品标签禁止标注下列内容：
> （一）明示或者暗示具有医疗作用的内容；
> （二）虚假或者引人误解的内容；［…］[82]

Nowadays, different national regulations regarding cosmetic labeling generally share the same mandatory elements. Indeed, China and the EU regulations have also aligned in terms of labeling requirements.

By comparing the Chinese and the EU regulatory framework on cosmetics, one element comes to our attention: the latest developments have highlighted increasing similarities between the two national regulations and legal requirements on cosmetics. From stronger attention to safety to labeling requirements, there are many common characteristics between China and the EU. However, major differences and divergences of approach between the two regions still exists.

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[79] Implemented by the *Commission Decision (EU) 2019/701 of 5 April 2019 establishing a glossary of common ingredient names for use in the labelling of cosmetic products*. (Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0701&from=IT, 25/05/21)

[80] Full text available at: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/zhqyj/zhqyjhzhp/20180907170201306.html (25/05/21)

[81] The EU Regulation defines it "minimum durability date", while, in the Chinese regulation, it is defined as 使用期限 (literally usage period or lifespan).

[82] "Cosmetics labels are prohibited from being indicated with the following contents:
(I) The expressed or implied contents related to medical effects;
(II) The false or misleading contents […]"
(Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

Some differences have been overcome during the past few years through a long procedure of Chinese regulatory modernization, but many differences continue to pose trade barriers, especially for foreign companies that aim at importing in the Chinese market.
We have mentioned some differences between the EU and the Chinese regulation on cosmetics in this section, but they will be discussed in more detail in the following paragraph.

4.3 Major differences between the Chinese and the EU regulation on cosmetics

As we have mentioned in the previous paragraph, although China is gradually implementing changes in line with the EU Regulation so that now they share several common requirements, obvious differences can be noticed by carrying out a detailed analysis.
Firstly, in terms of definitions, the EU Regulation proves itself to be more specific, advanced, and detailed since it does not only provide a clear definition of "cosmetics", but it also clarifies many other terms and meanings. For instance, in art.2.1, it provides a useful distinction among manufacturer, distributor and importer and it lists many other definitions such as "substance", "mixture", "undesirable effects", "preservatives", etc. This set of clear definitions does not leave room for ambiguity and grey areas and makes the EU regulatory framework clearer and more specific. Instead, the Chinese Regulation still lacks such a high degree of specificity and clarity.
Although the two regulations share a similar definition of the term "cosmetics", China provides a further distinction of products into categories, namely special and general cosmetics. As we have already discussed in the previous chapter of this thesis, the two categories are subject to different approval and importation processes. According to art.4 of CSAR

> 化妆品分为特殊化妆品和普通化妆品。国家对特殊化妆品实行注册管理，对普通化妆品实行备案管理。[83]

The introduction of the notification process for general cosmetics has made the importation process easier and immediate since it can be managed by submitting documents in electronic format through the NMPA online platform and the review and approval process can be managed locally by administrative medical departments spread all over the Chinese territory.
On the contrary, the registration process of special cosmetics is one of the main trade barriers for foreign products. It is a long and complex procedure that requires the investment of great financial resources, and it is characterized by a high degree of uncertainty due to many grey areas and ambiguities still existing among the Chinese requirements.

[83] "Cosmetics are divided into special cosmetics and general cosmetics. The state shall implement registration management for special cosmetics and notification management for general cosmetics." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

In the EU, all cosmetic products, whether domestic or imported, are managed through the same standardized process which requires compliance with clear requirements and defined standards. The EU process makes it easier for foreign companies to prepare and launch their products on the EU market. Indeed, companies just need to notify general product information before introducing the product on the market.

The EU notification process is a one-time centralized electronic procedure, managed through the CNPC online platform, already mentioned in the previous paragraph of this chapter.

After the notification, the product information is immediately available at European level.

The EU does not require extensive pre-market approval of cosmetic products and the submission of full toxicological dossier on ingredients and finished products, as required by the Chinese regulation. Instead, the EU requires a stronger post-market surveillance to check the compliance with safety and quality standards.[84] If there are concerns about potential risks to human health caused by the product, then the responsible person must notify the so-called "Serious Undesirable Effects" (SUEs) through a specific procedure described in detail in art.23.[85] The notification of SUEs happens through a centralized system at European level that traces back all information about the product by going through all steps of the supply chain and finally reaches all involved parties, from the responsible person to final consumers, in order to inform them about the safety issue and stop the distribution of dangerous products. This system is so advanced that it is able to inform while ensuring the protection of confidential information about the company and avoiding the circulation of misleading or false information that could damage the company's reputation.

China also requires the responsible person to promptly communicate any potential risk or non-compliance with safety and quality standards, but the Chinese regulation does not specify how and to what extent the report should be made. Over time, this legislative gap has caused many damages to both consumers and companies because many non-compliant products have been able to circulate on the Chinese market, from counterfeited products to high-risk substances. On one hand, this resulted in scandals and severe health problems reported by consumers that eventually undermined the international reputation of China; on the other hand, it also caused the widespread circulation of unfounded product safety issue that damaged the reputation of several companies working on the Chinese market. Therefore, China should draw from the EU model and clearly state specific

[84] Vera Rogiers, Marleen Pauwels, *Safety Assessment of Cosmetics in Europe*, Basel, Karger Medical and Scientific Publishers, 2008, p.5

[85] For more details, full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (30/05/21)

working guidelines regarding the supervision and reporting of cosmetics adverse reactions in order to protect both companies and consumers.[86]

Another major difference between China and the EU is related to mandatory documents for the importation of cosmetics. While China requires to submit a detailed and cumbersome product dossier, including safety assessment results, testing reports, and documents to support any efficacy claim, the EU notification process only requires the submission of general relevant information excluding the cosmetic safety report, which is separately prepared and kept by the responsible person and consulted by authorities only in case of need.

The submission of such a great number of documents as required by the Chinese Regulation makes the importation process more complicated and riskier for foreign companies because companies can start importing in China only after approval. This approval process is completely under the judgement of an external institution and any inconsistency or little mistake can result in denial or even ban of the product from the Chinese market.

On the contrary, in the EU companies can start to market their products right after notification without pre-market approval. Compliance is assessed afterwards through the in-market surveillance system and companies are required to keep a Product Information File (PIF) which is a confidential dossier on the product information regulated by art.11 as follows:

> Art.11.1 When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.
> 2. The product information file shall contain the following information and data which shall be updated as necessary:
> (a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
> (b) the cosmetic product safety report referred to in Article 10(1);
> (c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;
> (d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;
> (e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries. […] [87]

The PIF must be kept updated and be available in electronic or other format at the premises of the responsible person, so that, if there is any problem regarding the product, the competent authorities

[86] European Union Chamber of Commerce in China, *European Business in China Position Paper 2019/2020* (欧盟企业在中国建议书 2019/2020), 2019, p.191, https://www.fbcbj.org/sites/default/files/content-files/European_Business_in_China_Position_Paper_2019_2020%5B756%5D.pdf (30/05/21)

[87] European Commission, Regulation (EC) No 1223/2009 on cosmetic products, November 30, 2009, art.11, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (31/05/21)

can have access to all documents and check their compliance with the provisions set by the EU Regulation.

These requirements allow the process to be immediate promoting international trade of cosmetic products while ensuring safety of products marketed within the EU. On the contrary, the Chinese regulation poses relevant obstacles to international trade due to stringent requirements on mandatory documents for approval and the complex procedure of registration of special cosmetics. Moreover, a parallel complex procedure of registration is mandatory for new high-risk cosmetic ingredients while notification is required for new low-risk ingredients.[88] Companies before entering the Chinese market must check their product formula and individually apply for ingredient registration or notification according to the provisions set in Chapter II from art.11 to 14 of the Chinese Regulation.[89]

This process further complicates the importation procedure of foreign cosmetic products.

In the EU, there are specific lists of prohibited and restricted ingredients provided by Annexes from II to VI of the EU Regulation, already mentioned in previous paragraphs of this chapter.

If an ingredient is explicitly prohibited by the EU Regulation, companies cannot market their products within the EU. If an ingredient is restricted in its use, the company shall comply with the related limitations of usage and concentration inside the cosmetic formula. If a colorant, preservative, or UV-filter is not included in the related Annexes of the Regulation, then the products cannot be sold in the EU. Companies must strictly comply with the content of these Annexes and cannot individually apply for ingredients approval.

It is up to the SCCS to independently evaluate and approve ingredients on the EU market through a constant process of review and monitoring of market developments. Indeed, the EU lists are constantly updated by the SCCS whenever there is new knowledge or information about safety of cosmetics. Whenever some change in terms of ingredients is applied in the EU, it is followed by similar updating and restrictions in other regions, such as China, due to the strong international influence of the EU. However, delay in other countries cannot be avoided and it takes time for complete alignment.[90]

Although the Chinese ingredient lists are based on the EU model, the number of restricted materials

[88] "New ingredients" are ingredients introduced in China for the first time and not included in the IECIC. Management of new cosmetic ingredients has been discussed in the previous chapter of this thesis. For more information, please refer to paragraph 3.2 of this thesis.

[89] Full text and translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation (31/05/21)

[90] Kazutami Sakamoto, Robert Lochhead, Howard Maibach, Yuji Yamashita, *Cosmetic Science and Technology: Theoretical Principles and Applications*, Amsterdam, Elsevier Science, 2017, chap.9, "Regulations on cosmetics", p.141-142

differs greatly.[91] Even though China is trying to keep up and to promote improvements, the Chinese lists of allowed, prohibited, and restricted ingredients cannot compare to the those of the EU in terms of completeness and specificity.

The IECIC is constantly getting updated to keep up with market developments, but it is still not advanced, and it lacks a systematic approach. At the same time, even though China has drafted a list of prohibited ingredients in 2018, this list has not been enforced yet, but, hopefully, it will soon enter into force since it is also mentioned in art.15.[92]

Moreover, while the EU has integrated the above-mentioned lists in one single comprehensive regulation on cosmetics, China is separately implementing integrative measures and provisions which make the whole regulatory framework more complex and difficult to coordinate and implement in a uniform way.

In terms of ingredients, another element which distinguishes the EU Regulation and makes it stand out from any other existing cosmetics regulation at international level is the specific requirements on nanomaterials and CMR substances. The EU was the first institution to regulate these kinds of substances providing clear, detailed guidelines. According to art.15, CMR substances are carefully divided into categories, denominated with numbers from 1 to 3, and they are prohibited because of their high risk for human's health but some CMR can be exempted from the ban if they are evaluated as safe by the SCCS.[93]

This is an interesting point considering that in many countries, including China, if an ingredient is deemed as high risk and is banned, it cannot be introduced on the market under any circumstance.

Requirements on nanomaterials are listed in art.23 of the EU Regulation[94] and represent the most innovative element introduced by the EU in the cosmetic industry. In the Chinese regulatory framework, there is not even a mention to this kind of materials, and this further emphasizes the backwardness of the Chinese requirements in comparison with the EU.

As we have already mentioned, safety is the central theme of both regulations. There are strict requirements on safety assessment both in the EU and in China, companies must evaluate the safety of their products and their safety assessment must be carried out by qualified safety assessors. Both regulations attribute all responsibilities for cosmetic safety to the responsible person, that is to say

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[91] Ibidem

[92] 第十五条 禁止用于化妆品生产的原料目录由国务院药品监督管理部门制定、公布。
"Art.15 The inventory of ingredients prohibited for production of cosmetics shall be formulated and announced by the NMPA of the State Council." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

[93] Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017, p.9

[94] Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (30/05/21)

the company recognized as responsible for that product, either the manufacturer, the importer, or the distributor. However, the EU requires that the company itself carries out safety tests and prepare a specific cosmetic safety report that they shall keep for themselves and will be consulted by competent authorities only in case of need, whereas China forces companies to prepare in advance detailed and costly safety and testing reports that must be submitted at the moment of registration or notification. Only if these documents are judged as compliant by the Chinese competent authorities, can companies start the importation process on the Chinese market. As we have already mentioned, this requirement does nothing but increase the financial burden of companies and further slows down the whole process.

Moreover, the EU allows companies to freely choose and delegate any certified institution for the safety assessment. Instead, in China products are first tested by companies in order to prepare the safety assessment documents required for registration or notification procedure and then, they are evaluated by national laboratories and institutions designated by the government in order to check the correspondence of safety results with the information in the submitted documents.

The process of approval is difficult, and it is further complicated by the fact that most safety assessments on foreign imported cosmetics can only be made by the central authority, the NMPA. In the past few years, China has been implementing a system of decentralization delegating the responsibility for safety evaluation to local administrative bodies in order to ease the burden of the NMPA and speed up the approval process. However, this decentralization process is still at the beginning, and it needs further improvements.

In addition, there are other critical issues related to safety assessment. For example, the full public disclosure of companies' documents after inspection and testing from the Chinese authorities is another critical issue for foreign companies.

At the end of the inspection process, the results, whether positive or negative, are often published without verifying the actual correspondence with products or the authenticity of the test's rationality, and without consulting the company in question. This often results in misunderstanding, misinterpretation, and unnecessary consumer panic, while also seriously damaging the company's brand image and causing the leak of companies' confidential information.[95]

Moreover, many foreign products have been assessed as non-compliant over the years because China lacks adequate knowledge and technology to evaluate some advanced characteristics of new foreign products. In addition, Chinese authorities do not approve safety reports issued by other

[95] European Union Chamber of Commerce in China, *European Business in China Position Paper 2019/2020* (欧盟企业在中国建议书 2019/2020), 2019, p.198, https://www.fbcbj.org/sites/default/files/content-files/European_Business_in_China_Position_Paper_2019_2020%5B756%5D.pdf (30/05/21)

countries so, if a product is erroneously rejected by the Chinese safety assessment process, companies are not able to reply with supporting evidence and additional material.

In order to improve knowledge and expertise in the field, China has implemented specific provisions on responsible persons in charge of quality and safety management of cosmetics inside business organizations.

Companies are now required to hire personnel with specific knowledge in the field of cosmetics and safety assessment in charge of the quality and safety management of products intended for the Chinese market. This provision is stated in art.32 of the Chinese Regulation, which requires as follows

> 第三十二条 化妆品注册人、备案人、受托生产企业应当设质量安全负责人，承担相应的产品质量安全管理和产品放行职责。
> 质量安全负责人应当具备化妆品质量安全相关专业知识，并具有5 年以上化妆品生产或者质量安全管理经验。[96]

While the EU only requires that the safety assessor, who can also be an external entity, must have adequate knowledge to perform the safety evaluation, China requires that companies must have specific professional figures inside their organization in charge of both pre-market safety assessment and in-market surveillance over product quality and safety compliance. This requirement has caused problems to many companies that must adapt and invest additional resources in order to hire suitable people and comply with the new Chinese provisions.

In terms of testing, as we have already mentioned in previous paragraphs, although China has implemented a ban of animal testing on general cosmetics in line with the EU Regulation, special cosmetics are still subject to animal tests. Moreover, there are few recognized alternative testing methods in China which are not advanced or specific enough in order to completely substitute the correspondent animal tests.

China still lacks specific knowledge and modern technology developed by the EU. Therefore, even though China is moving toward gradually removing animal testing requirements, the process is actually very slow, and it is further slowed down by the difficulty in recognizing new alternative methods and the reluctance showed by Chinese authorities toward their reliability.

Conversely, the EU process started more than a decade ago, now the ban on animal testing has been successfully in force since 2013. The EU approved the ban irrespective of the availability of

[96] "Art.32 Cosmetics registrants and notifiers and entrusted production enterprises shall be equipped with the quality and safety responsible personnel to undertake corresponding product quality and safety management and product release duties.
The person in charge of quality and safety shall have professional knowledge related to the quality and safety of cosmetics and more than 5 years of work experience in cosmetic production or quality and safety management." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

suitable alternative testing methods[97], indeed many alternatives have been approved after the ban was implemented. Now the EU alternative methods are the most advanced at international level and are taken as an example in many other countries.

In the EU, the process of validation of alternative methods was more rapid compared to the Chinese. This may be due to the fact that the EU has established a specialized institution for the approval of alternative measures, known as the ECVAM.[98] On the contrary, China lacks a specific competent authority in this field. In China, testing methods are validated by the NMPA that has a lot of other duties to fulfill so the whole process is taking a long time.

Although the Chinese NMPA has recognized new alternative methods to animal testing[99], there remains a gap in both quantity and scale of validated alternative testing methods compared to the rest of the world, and many of these alternatives are only for cosmetics ingredients, not for finished products.[100]

The implementation of animal testing ban was undoubtedly a sign of the Chinese increasing alignment with the EU Regulation; however, it is a partial ban since special cosmetics are still required to be tested on animals. This reluctance to fully embrace the animal testing ban suggests that China does not share the same aim of the EU and it is not willing to completely align with the EU in order to protect its domestic market. By maintaining the animal testing requirements, China is able to indirectly affect foreign import and foreign companies on its domestic market in order to prevent them from taking full control over the Chinese market. However, as we have mentioned in Chapter 2, a latest trend on the Chinese market has highlighted the increasing interest of Chinese consumers toward eco-friendly and cruelty-free products. Chinese consumers are showing a greater attention toward animal protection, and they are increasingly reluctant to buy animal-tested products. This increasing pressure coming from a growing internal consumer demand are pushing China to reconsider its position on animal testing, therefore things are expected to change in the future.[101]

As regards labelling, we have already discussed many similarities between Chinese and EU requirements. However, slight differences can be noticed, for example in the requirements on usable product lifespan. In the EU, product label must state the "minimum durability" of products but products that exceed a minimum durability of 30 months are not required to explicitly state this

[97] Vera Rogiers, Marleen Pauwels, *Safety Assessment of Cosmetics in Europe*, Basel, Karger Medical and Scientific Publishers, 2008, p.7

[98] For more information, please refer to paragraph 4.1 of this chapter.

[99] This point has been discussed in the previous chapter of this thesis, for more details please refer to paragraph 3.3.4

[100] Pira International Ltd., *Packaging Legislation and Regulations for Cosmetics and Toiletries*, iSmithers Rapra Publishing, 2012. p.203

[101] Future developments in Chinese regulations and China's real intentions about regulatory alignment with the EU will be further discussed in the next chapter by also taking into account the animal testing issue.

date but need to show the so-called "Period after Opening" (PaO), the period during which the product maintains its characteristics and functions after it is opened for the first time.[102] This requirement does not find correspondence in the Chinese regulation which only refers to a general mandatory product lifespan for all kinds of products. The EU guarantees a minimum product lifespan of 30 months, while China is presumably the only country that requires labeling for this period, regardless of the product characteristics.[103]

Even though China's labeling requirements are based on the EU ones, it is evident that the EU requirements are more specific and provide more guarantees to consumers. Another example is provided by the fact that the EU requires specific symbols in order to better suit the size of labels in compliance with the requirements, such as the symbol which refers to information omitted from the label that can be found attached or inside the packaging.[104]

Moreover, the EU Regulation requires that all mandatory information must be displayed in a legible, visible, and understandable way. Legibility requires an appropriate font and good contrast between the print and the background, especially when the container is transparent, and it is recommended that the markings are displayed on the front or top of the container.[105]

The Chinese requirements do not provide such specific details, they only require that all information is explicitly stated on the label.

Another difference can be found in the mandatory disclosure of full ingredient list and product formula. Both regulations provide this requirement, the EU Regulation requires mandatory ingredient list on labels in art.19.1[106], while the Chinese Regulation refers to 全成分 (*quanchengfen*, literally "complete composition") in art.36.[107]

In view of evaluating safety of a cosmetic product, having access to its quantitative and qualitative composition is crucial, however the EU does not impose disclosure of all details. In several cases, it may be legal that the label and documents about the product do not reveal the full product composition.[108] If the manufacturer or trader would like to keep some of the ingredients secret so

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[102] For more information, please refer to paragraph 4.1 of this chapter.
[103] Kazutami Sakamoto, Robert Lochhead, Howard Maibach, Yuji Yamashita, *Cosmetic Science and Technology: Theoretical Principles and Applications*, Amsterdam, Elsevier Science, 2017, chap.9, "Regulations on cosmetics", p.139
[104] Further information in paragraph 4.1 of this chapter.
[105] Pira International Ltd., *Packaging Legislation and Regulations for Cosmetics and Toiletries*, iSmithers Rapra Publishing, 2012. p.36-37
[106] Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210526 (31/05/21)
[107] Full text available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation (31/05/21)
[108] Vera Rogiers, Marleen Pauwels, *Safety Assessment of Cosmetics in Europe,* Basel, Karger Medical and Scientific Publishers, 2008, p.16

that its full composition remains confidential, then he can make a request to the Department of Trade and Industry (DTI) which may grant omission of certain ingredients from the list.[109]
While in the EU certain ingredients can be omitted through a confidentiality provision, China does not allow any omission. This point has raised some concerns among foreign companies, that, considering past cases of counterfeiting on the Chinese market, fear that confidential information about cosmetic formulas and their business secrets could be used by third parties in bad faith.
Apart from mandatory requirements on labels, both regulations provides that the labels shall not contain misleading or false information. China further reinforces this provision by requiring that all claims about the product shall be supported by scientific proofs. As stated in art.22

> 第二十二条 化妆品的功效宣称应当有充分的科学依据。化妆品注册人、备案人应当在国务院药品监督管理部门规定的专门网站公布功效宣称所依据的文献资料、研究数据或者产品功效评价资料的摘要，接受社会监督。[110]

This requirement further complicates the importation procedure for foreign companies since they must invest a lot of resources and time in order to perform specific tests and prepare supporting documents for each claim.
The EU Regulation does not impose this kind of additional tests since it relies more on companies' good faith and corporate social responsibility.
Moreover, China has explicitly stated misleading contents and forbidden wordings for the efficacy claims of cosmetics. Art.37 of the Chinese Regulation provides that

> 第三十七条 化妆品标签禁止标注下列内容：
> （一）明示或者暗示具有医疗作用的内容；
> （二）虚假或者引人误解的内容；
> （三）违反社会公序良俗的内容；
> （四）法律、行政法规禁止标注的其他内容。[111]

The Chinese regulation expressively prohibits medical function claims, expressed or implied medical properties and any misleading or false wording. Moreover, as mentioned in the

[109] Pira International Ltd., *Packaging Legislation and Regulations for Cosmetics and Toiletries*, iSmithers Rapra Publishing, 2012. p.33
[110] "Art.22 Efficacy claims of cosmetics shall be supported by sufficient scientific basis.
Cosmetics registrants and notifiers shall disclose the summary of the document literature, research data or product efficacy evaluation document on which the efficacy claims are based on the special website prescribed by the NMPA of the State Council, and accept social supervision." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)
[111] "Art.37 Cosmetics labels are prohibited from being indicated with the following contents:
(I) The expressed or implied contents related to medical effects;
(II) The false or misleading contents;
(III) The contents that violate social public order and good customs;
(IV) Other contents prohibited by laws and administrative regulations." (Translation available at: https://cosmetic.chemlinked.com/epublication/cosmetic-supervision-and-administration-regulation)

Administrative Provisions on Cosmetic Labelling[112], the Chinese label cannot include false information, exaggerated words, medical terms, doctor's names, and foreign letters, numbers, or symbols, apart from brand names and ingredient codes.[113] Some claims on imported products are explicitly forbidden for example "whitening" or "spot removing", "hypoallergenic", "dermatologically tested" or "100% natural", while others are acceptable such as "anti-spot".[114]
On the contrary, the EU has not provided specific prohibited contents but has just set common criteria for product claims. These criteria are listed in the Annex of the *Commission Regulation (EU) No 655/2013*[115] and additional guidelines and practical examples are provided by the *Technical document on cosmetic claims agreed by the sub-working group on claims*[116], a non-binding document that supports the Commission Regulation.
These examples are not exhaustive, they are just illustrative and provide general guidance to companies giving them more freedom to adjust their product claims, implement creative marketing strategies and distinguish themselves from competitors. Instead, China provides stricter requirements and does not leave much freedom of expression to companies.

[112] It is one of the integrative regulations that support the new Chinese Regulation. It states all requirements on cosmetic labelling and product claims. Recently, the NMPA published a new version on June 3, 2021; the new Administrative Measures on Cosmetic Labelling will enter in force in 2022. (Draft available at: https://members.wto.org/crnattachments/2020/TBT/CHN/20_7026_00_x.pdf, 03/06/21)
[113] Demi Ding, "Prepare for Cosmetic Registration and Notification under China's New Regulations", p.14, on "chemlinked.com", April 13, 2021, https://cosmetic.chemlinked.com/new-webinar/prepare-for-cosmetic-registration-and-notification-under-chinas-new-regulations (03/06/21)
[114] ChemLinked Cosmetic Team, "China Mainland Cosmetic Regulation", on "cosmetic.chemlinked.com", March 15, 2021, https://cosmetic.chemlinked.com/cosmepedia/china-mainland-cosmetic-regulation (03/06/21)
[115] European Commission, *Commission Regulation (EU) No 655/2013 Laying Down Common Criteria for the Justification of Claims Used in Relation to Cosmetic Products*, July 10, 2013, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R0655 (03/06/21)
[116] Full text available at: https://ec.europa.eu/docsroom/documents/24847 (03/06/21)

To sum up and provide a clear overview on increasing similarities and major differences existing between the EU and the Chinese regulatory framework on cosmetics, we provide the following tables, which highlight the most important points discussed in this chapter.

	SIMILARITIES	
	EU	**China**
Definition	Similar definition of "cosmetics" Now, products for toothcare are included in both definitions Clear distinction between cosmetics and products with medical functions	
Responsible person	Similar definition of "responsible person" as a legal entity on the domestic territory directly in charge of the products and fully responsible for their safety	
Import procedure	Centralized notification system for all imported cosmetic products	Centralized notification system but just for general imported cosmetics
Market surveillance	Strict in-market surveillance over product safety and compliance, performed by authorities through on-site inspection and additional testing Companies must constantly monitor the safety and compliance of their products on the market	
Market surveillance	Notification system of Serious Undesirable Effects (SUEs)	Notification system of adverse reactions to cosmetics
Testing requirements	Full ban on animal testing	Ban on animal testing for general cosmetics
Ingredients	Similar lists of prohibited, restricted, and allowed ingredients (since the Chinese lists are based on the EU model)	
	Uniform ingredient names based on the International Nomenclature of Cosmetic Ingredients (INCI)	
	Mandatory approval of new ingredients by competent authorities before they can be placed on the market	
Labelling requirements	Similar labelling requirements in terms of mandatory information on labels Prohibition of any misleading or false information on labels	

Table 4: Similarities between the EU and the Chinese regulatory framework on cosmetics

	DIFFERENCES	
	EU	**China**
Definition	One single definition for all cosmetic products. More clear and detailed definitions of several additional terms (e.g., “substance”, “undesirable effects”, “preservatives”, etc.).	Further distinction of products in two categories: special and general cosmetics. Lack of additional detailed definitions that leaves room for ambiguity and misinterpretation.
Responsible person	Further distinction of responsible person in “manufacturer”, “importer” or “distributor”.	General definition of responsible person. He can be either a manufacturer, an importer, or any other person responsible for the products, but there is not a clear distinction between these terms.
Import procedure *Import procedure*	Same notification procedure for all products, both domestic and imported. Only general information about the products is required for notification. Then, companies need to prepare and keep for themselves a complete Product File Information (PIF).	Notification process for general cosmetics and registration procedure for special ones. Mandatory submission of a detailed and cumbersome product dossier before importation.
Market surveillance	Specific guidelines on how to report Serious Undesirable Effects (SUEs) caused by cosmetics. Advanced and efficient notification system of SUEs which ensures both product safety on the market and protection of companies’ confidential information.	No specifics on how and to what extent to report adverse reactions to cosmetics. The report system is not advanced and does not ensure the complete protection of confidential information nor does it prevent leaks of misleading information.
Safety requirements	Safety assessment is performed by companies to prepare a “cosmetic safety report” (included in the PIF). Specific guidelines on how to prepare a “cosmetic safety report”. Safety assessment results are included in the PIF and kept by the responsible person; they are consulted by authorities only in case of need or reported problems.	Safety assessment is performed both by Chinese authorities and by companies (to prepare mandatory documents for notification or registration). Mandatory submission of safety assessment reports for notification or registration, but no clear guidelines on how to prepare these documents. Public disclosure of assessment results, often causing leaks of misleading information, consumers’ panic, and damages to companies’ reputation.

Safety requirements		Companies are now required to hire specific professional figures with ad hoc knowledge and expertise in charge of safety and quality management of products.
Testing requirements	Companies can freely choose the EU institution that will perform safety assessment tests on products. Successful implementation of full animal testing ban. Many advanced alternative testing methods available and recognized at the European level. New alternative testing methods are constantly evaluated and validated by the ECVAM.	Tests are performed by the NMPA, or other authorized labs on the Chinese territory. Mandatory animal testing for special cosmetics. Few recognized alternative testing methods, many of these are only for single ingredients, not for finished products. Lack of a scientific and systematic approach to validation of new alternative methods. Lack of advanced technology to develop and perform new alternative testing methods.
Ingredients	Specific lists of prohibited and restricted ingredients with full details for each ingredient category included in the Regulation. Innovative elements are included in the EU lists such as requirements on nanomaterials and CMR substances.	Chinese lists are not as advanced and complete as the EU ones. Great difference in the number of ingredients included in Chinese lists compared to the EU, and lack of requirements on many existing substances. No mention of nanomaterials or CMR substances, which makes the approval of innovative products difficult.
	Same approval process for all new ingredients. New ingredients are periodically evaluated by the SCCS according to market developments. Companies cannot apply for ingredient approval; new ingredients are constantly evaluated by the SCCS and if they are deemed as prohibited, they cannot be used under any circumstance.	Two different approval processes for new ingredients according to the level of risk: registration for high-risk ingredients and notification for low-risk ingredients. Companies must independently apply for registration or notification of new ingredients before importation.
Labelling requirements	Guaranteed minimum product durability of 30 months, which must be explicitly stated only if it does not exceed 30 months. Mandatory Period after Opening (PaO) on labels.	Mandatory generic product lifespan regardless of product durability or category.

Labelling requirements	Use of specific symbols to better suit the label size. Specific guidelines on how to display label contents to make them visible and legible. Allowed omission of some ingredient names through a confidentiality agreement. Common criteria and illustrative examples on product claims but no explicitly prohibited contents. No need for additional tests for assessing efficacy claims since the EU relies more on corporate social responsibility.	List of mandatory information on labels, but no further guidelines on how to display them to be compliant. Mandatory disclosure of full ingredients list without any exception. Explicit prohibited contents and wordings which are forbidden to be displayed on labels. Mandatory submission of scientific proofs and required additional tests to support any efficacy claim.

Table 5: Differences between the EU and the Chinese regulatory framework on cosmetics

In conclusion, we can state that at present, although China is gradually implementing changes that are pushing its regulation and requirements on cosmetics to increasingly align with those of the EU, there are still major differences that make the two regulatory frameworks incompatible on crucial aspects. These critical points often have a strong negative impact on EU companies that aim at importing their products in the Chinese market.

The existing differences between the Chinese and the EU regulation on cosmetics often constitute actual trade barriers for EU companies working in the field and trying to enter the Chinese cosmetic market. These companies must invest huge resources, time, and efforts to prepare documents, engage in complex registration processes, perform relevant tests, and comply with all Chinese requirements.

During the past few years, the importation process in China has become slightly easier for European companies thanks to the implementation of new measures and provisions increasingly in line with the EU requirements. But what are China's real intentions? Does it share the same aim as the European Union?

The EU has provided an emblematic example of regulatory standardization between different countries, and it has become the advocate for international harmonization in order to ensure the safety of citizens and environment and allow international trade and free movement of goods between different countries. On the contrary, considering differences still existing in the Chinese regulations and legal requirements, China seems to aim at increasing safety and quality on its domestic market mainly to improve its internal market in terms of technology, quality standards and innovation. The fact that the importation process has become a bit easier is just a side effect.

After years of unregulated trade of cosmetics products which has damaged the Chinese reputation at international level, China now aims at getting in line with international standards in order to enhance its image and economic power. The fact that this process of alignment can also help foreign companies enter the Chinese market is just a secondary aspect. Taking this into account, it may seem reasonable to suppose that some differences will continue to exist in order to obstacle foreign invasion of the Chinese market.

At this point, our question is: is China going to completely align its regulation and legal requirements on cosmetics to the EU? Is it going to follow the EU in the path of international harmonization? We will specifically discuss the above-mentioned aspects and try to answer to these questions in the following chapter.

5. Future developments: is China going to align with European regulations?

5.1 China's real intentions: foster international trade or protect its domestic market?

In the view of what we have discussed and analyzed up to this point, we can argue that, in the last decade, China has engaged in a path of modernization and improvement of its regulation and legal requirements on cosmetics, showing a tendency to gradually align with international standards and regulations of other developed countries, especially with the EU that is considered the pioneer of cosmetics regulation worldwide.

However, the analysis on similarities and differences between the Chinese and the EU regulatory frameworks on cosmetics discussed in the previous chapter has highlighted a contradictory tendency from the Chinese part. On one hand, the new Chinese regulation showed increasing alignment with the EU on several important points demonstrating a general stronger attention toward product safety and quality.

These common points can be summarized as follows:

- Increasing responsibilities on companies, defined as "responsible persons", who are directly accountable for safety and quality of products placed on the market.
- Introduction of a notification process through a centralized online system at national level which has made the importation of general cosmetics easier and faster since products do not have to wait for pre-approval before being launched on the market.
- Implementation of a strong system of in-market surveillance and monitoring of cosmetics adverse reactions in order to ensure control over product safety.
- Update of allowed, prohibited, and restricted ingredient lists and improvement of labelling requirements in line with the latest developments on the international market.
- Enforcement of animal testing ban on general cosmetics and increasing research on alternative testing methods based on the EU model.

On the other hand, several major differences still exist between China and the EU, and they often represent important trade barriers for foreign cosmetic companies that operate on or aim at the Chinese cosmetic market.

The most important differences highlighted in the previous chapter are:

- Mandatory registration for imported special cosmetics before entering the Chinese market. In the EU, the importation process is managed through a uniform system of notification that facilitates international trade. Instead, while general cosmetics are subject to a notification process in China, special cosmetics are still subject to pre-approval, and this is an uncertain process completely under Chinese authorities' judgement and outside companies' control.

Chinese registration is a lengthy procedure with several steps and strict requirements, often resulting in delays, additional costs, and a high degree of uncertainty for foreign companies due to ambiguities, legislative voids, and heavy bureaucracy.

- Stricter requirements in terms of safety, from stronger in-market surveillance performed by the Chinese authorities through random invasive inspections to full mandatory submission of safety assessment and testing results.
- No clear guidelines on how to report adverse reactions or how to prepare safety reports in China.
- Lack of completeness and specificity in terms of prohibited and restricted ingredient lists and safety standards in China.
- Underdeveloped technology for cosmetic safety assessments and alternative testing methods compared to the EU.
- Mandatory full disclosure of product ingredient lists, endangering companies' business secrets and confidential information, and public disclosure of inspection results without previous review, often resulting in leaks of misleading information that jeopardize companies' reputation.
- Stringent requirements on labeling and efficacy claims in order to prevent unfair competition. The EU does not require extensive proofs for efficacy claims nor explicitly prohibits specific wordings displayed on the label, it just provides general guidelines. Instead, China requires additional tests and complete proofs supporting any efficacy claim and it explicitly prohibits specific contents and expressions on product labels leaving companies little freedom to express and distinguish themselves from competition.

As we can see, differences seem to outnumber similarities. Therefore, important questions arise at this point: what are China's real intentions? Is China going to completely align with the EU regulation and legal requirements on cosmetics?

After our in-depth analysis, we can draw the following conclusions. China is gradually aligning with EU requirements primarily with the aim of improving its domestic market in terms of safety and quality standards. By improving safety and quality requirements, China wants to foster domestic innovation and technological development in order to foster its economic growth, improve its reputation and increase its influence on the international market.

By increasingly aligning with some EU requirements, it is inevitable that the importation process is going to become easier on some aspects, but this is just a side effect. It is not China's primary focus to allow international trade and ease foreign entry into the Chinese market. On the contrary, international trade is a secondary aspect on China's political agenda.

As regards the Chinese cosmetic market, foreign presence is considered a threat for emerging domestic companies. China is willing to grant some advantages to foreign companies in order to attract investments, foreign know-how and advanced technology, and a wider choice of innovative products. However, its main focus remains its own internal market development and every measure is taken in order to improve the conditions on the domestic market and to foster internal economic growth. Indeed, foreign know-how and technology is instrumental in order to foster the technological development on the domestic market and improve the internal competitive environment, while foreign products are fundamental to satisfy an increasing national consumer demand for safe and high-quality products which Chinese companies are not completely able to provide.

As a result, several trade barriers are still in place and, in the view of the above considerations, it is reasonable to suppose that they will not be completely lifted in the future. This way, on one hand, China will be able to engage in international trade and take the related advantages coming from it, and, on the other hand, it will continue to protect its market from a "foreign invasion" through strict legal requirements and lengthy procedures that slow down the importation process and limit competition.

The development of the Chinese cosmetic market is part of a bigger political and economic plan for the continuous economic growth of the country and the growing enhancement of its international influence. Indeed, by looking at the developments in terms of Chinese cosmetics regulation from a wider perspective, our above-mentioned hypotheses about China's real intentions are supported by the general national policy adopted by China after Xi Jinping's political rise.

The so-called Xi Jinping Thought[1], introduced by the Chinese president during the 19th National Congress of the Communist Party in 2017, provides a series of policies and ideas developed by Xi Jinping himself and adopted by the Chinese Communist Party. Xi Jinping Thought includes several points and some of them are in line with the latest developments in Chinese regulations and supportive of our thesis.

For instance, one of the fundamental principles of Xi Jinping Thought is "adopting a new vision for development".[2]

[1] Short for "Xi Jinping Thought for Socialism with Chinese Characteristics for a New Era" (in Chinese, 习近平新时代中国特色社会主义思想 *xi jinping xinshidai zhongguo tese shehuizhuyi sixiang*). It is a political philosophy developed by the President Xi Jinping between 2012 and 2017. Now it is an integral part of the Constitution of the Chinese Communist Party, and it provides the basis for the entire policy that China has been carrying on in the past few years.

[2] Xiang Bo, "Backgrounder: Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era", *Xinhua*, March 17, 2018, http://www.xinhuanet.com/english/2018-03/17/c_137046261.htm (08/06/21)

As President Xi said in his speech "发展必须是科学发展，必须坚定不移贯彻创新、协调、绿色、开放、共享的发展理念".[3] China aims at engaging in a new path of development based on the pursue of scientific innovation. This aspect is also reflected by the latest developments on the Chinese market. China is pushing for technological and scientific innovation in several fields and domestic companies are encouraged to engage in R&D, to draw from technology, expertise and standards taken from other countries, to develop new innovative ideas, and to contribute to the Chinese market development and economic growth.

China wants to improve its technological environment in order to be able to compete with other world economic powers and Chinese domestic companies are the standard bearers of the Chinese objective.

As we have discussed in Chapter 2 of this thesis, after years of "foreign invasion" on the Chinese market, many Chinese companies are finally emerging and constantly growing on the domestic market, so that they could become a threat for well-established foreign companies.

This is the so-called phenomenon of *Guo Chao* 国潮 (which literally means "National Trend"), that is to say the rise of Chinese domestic brands and companies that perfectly bring together developed technologies taken from abroad and Chinese traditions and customs to create innovative products specifically aimed at satisfying the growing consumer demand on the domestic market. This growing phenomenon has invested several market sectors, including the cosmetic market.[4]

China is adopting a more scientific and systematic approach to the management of several aspects of the cosmetic market such as management of cosmetic ingredients, market surveillance, safety and risk assessment, review of mandatory documents for registration or notification, and development and acceptance of new alternative methods to animal testing. This scientific approach is the only way to promote market development, to increase safety standards and to encourage innovation with the final aim of keeping up with the international community and finally becoming a leader at the international level.

This new path of development is also necessary to support another point of Xi Jinping Thought that is "ensuring and improving living standards".[5]

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[3] "Development must be a science-based development, and must firmly carry out the idea of an innovative, coordinated, green, open and shared development" (my translation)
Ren Yilin 任一林, Yan Yan 闫妍, "Xi Jinping xinshidai zhongguo tese shehuizhuyi sixiang xuexi gangyao" "习近平新时代中国特色社会主义思想学习纲要", *Renmin ribao*, 6, August 2, 2019, http://theory.people.com.cn/n1/2019/0802/c40531-31271315.html (08/06/21)

[4] This is evident by looking at some examples of emerging Chinese cosmetic brands such as Perfect Diary, Florasis, or Little Dream Garden, which are increasingly growing in the last few years. For more information, please refer to paragraph 2.3 about the competitive scenario in the Chinese cosmetics industry.

[5] Xiang Bo, "Backgrounder: Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era", *Xinhua*, March 17, 2018, http://www.xinhuanet.com/english/2018-03/17/c_137046261.htm (08/06/21)

By using Xi's words, "增进民生福祉是发展的根本目的。必须多谋民生之利、[…]促进社会公平正义，[…] 学有所教、劳有所得、[…], 必须保证全体人民在共建共享发展中有更多获得感，不断促进人的全面发展、全体人民共同富裕".[6]

Technological and economic development is instrumental for improving Chinese people's lives, ensuring that people are satisfied with their standard of living and granting social harmony and stability. China has experienced an unprecedented economic growth in the last decades, people now have more resources and are willing to spend more in order to satisfy their needs.

Therefore, the development of the Chinese cosmetics industry is crucial for satisfying Chinese people's desire for higher living standards and it is an important part of China's political agenda. As we have discussed in Chapter 2, cosmetics are deeply linked to increasing desires and people's well-being since they are not only used to make one look better, but also to improve one's well-being and self-esteem. As a result, with China's economic growth and Chinese people's growing spending power, cosmetics have shifted from luxury goods to common daily-used products, fundamental means not only to show off their social status but also to improve their own appearance and satisfy one's need for higher living standards and improved well-being. This is why there is such a strong demand for cosmetic products on the Chinese market.

The huge potential of the Chinese market has attracted many foreign companies that have conquered huge market shares, especially in the cosmetic market, because they have been able to provide innovative products with high safety and quality standards. Meanwhile, Chinese domestic companies were left behind because of an unbridgeable technological gap.

Moreover, as consumer demand has become more sophisticated and diversified, foreign companies have been able to provide a wider range of products in line with major market trends. An emblematic example is given by one of the latest market trends: sustainable, natural, and cruelty-free products. Since China did not possess the technology to produce this kind of products nor did it have proper expertise and advanced assessment methods to evaluate their safety, foreign companies quickly conquered this market segment. In order to protect its domestic market, China has raised important trade barriers in terms of strict safety assessment and mandatory animal testing. These barriers have hindered foreign import of natural and cruelty-free products. However, due to pressures coming not so much from other countries, but rather from increasing consumer demand,

[6] "Improving people's livelihood and well-being is the primary goal of development. We must seek more benefits for people's livelihood, […] promote social fairness and justice, […] learn and work, we must ensure that people have a greater sense of gain from shared construction and development and continuously promote people's overall development and common prosperity". (My translation)
Xinhuawang 新华网, Xinshidai zhongguo tese shehuizhuyi sixiang sanshijiang kejian 新时代中国特色社会主义思想三十讲课件, on "xinhuanet.com", http://www.xinhuanet.com/politics/xjpsxkj/20.html (08/06/21)

China has begun to lower some of these barriers by gradually aligning with international standards and regulations. On this matter, an important milestone was the ban on animal testing for general cosmetics, which finally allows cruelty-free products to reach the Chinese market.[7] This provides a great advantage to foreign cruelty-free companies; however, we must stress that this is just a side effect and China's real intention is not to allow foreign entry, but primarily to satisfy a growing internal demand for this kind of products and enhance the national economic growth.

China wants to take back the control on its domestic market, it is aware of the economic potential of its market and wants to protect it from foreign monopoly. On one hand, China is willing to grant partial access to foreign companies and products in order to satisfy internal needs, on the other hand, it continues to implement significant trade barriers on other relevant aspects in order to contain the "foreign invasion", as we have discussed several times in previous chapters.

China is aware of the fact that it needs to make some concessions in order to promote its economic growth and to cooperate with other countries for its market development. As stated by Xi Jinping, "这个世界，各国相互联系、相互依存的程度空前加深，人类生活在同一个地球村里，［…］越来越成为你中有我、我中有你的命运共同体"[8], therefore every country needs that "各国人民同心协力，构建人类命运共同体，建设持久和平、普遍安全、共同繁荣、开放包容、清洁美丽的世界"[9]. However, Xi Jinping does not hesitate to underline that China "［…］要坚持走和平发展道路，但决不能放弃我们的正当权益，决不能牺牲国家核心利益。任何外国不要指望我们会拿自己的核心利益做交易，不要指望我们会吞下损害我国主权、安全、发展利益的苦果".[10]

International trade plays an important role because, on one hand, it allows China to attract foreign innovation and technology that the Chinese market lacks, and, on the other hand, it allows domestic companies to engage in trade with other countries enhancing China's international influence.

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[7] For more information about the ban on animal testing, please refer to Chapters 3 and 4 of this thesis.

[8] "In this world, the degree of interconnection and interdependence between countries has increased unprecedentedly. Human beings live in the same 'global village'. […] (we) have increasingly become a community with a shared destiny". (My translation)
Xinhuawang 新华网, Xinshidai zhongguo tese shehuizhuyi sixiang sanshijiang kejian 新时代中国特色社会主义思想三十讲课件, on "xinhuanet.com", http://www.xinhuanet.com/politics/xjpsxkj/26.html (08/06/21)

[9] People of all countries work together to build a community with a shared future for mankind, and build a world characterized by long-lasting peace, universal safety, common prosperity, openness, tolerance, transparency and beauty". (My translation)
Xinhuawang 新华网, Xinshidai zhongguo tese shehuizhuyi sixiang sanshijiang kejian 新时代中国特色社会主义思想三十讲课件, on "xinhuanet.com", http://www.xinhuanet.com/politics/xjpsxkj/26.html (08/06/21)

[10] "[…] must adhere to the path of peaceful development but must never give up our legitimate rights and interests and must never sacrifice the core national interests. Any foreign country should not expect us to trade our core interests, nor expect that we will accept anything that could harm our country's sovereignty, security, and development interests."
Xinhuawang 新华网, Xinshidai zhongguo tese shehuizhuyi sixiang sanshijiang kejian 新时代中国特色社会主义思想三十讲课件, on "xinhuanet.com", http://www.xinhuanet.com/politics/xjpsxkj/26.html (08/06/21)

In order to achieve its goals, China aims at "promoting the building of a community with a shared future for humanity"[11], which is another fundamental point of Xi Jinping Thought. However, this does not mean that it will completely open up losing control over its own domestic market and economic development. Allowing international trade is not the Chinese final objective, it is rather a mean to achieve its end.

This is the political background behind the latest developments in Chinese regulation and legal requirements on cosmetics, and it helps us to explain China's real intentions and to envision future developments in the cosmetics industry. China is getting in line with some international standards and with some aspects of the EU regulatory framework, firstly, to ensure safety and quality on its domestic market and to promote technological innovation in the field; secondly, to satisfy a growing consumer demand for safe, high-quality, natural and cruelty-free products; and lastly, to maintain good trade relationships with other countries which is fundamental for a country's economic growth and international prestige in a globalized society as the one in which we are living.

Increasing alignment has made the importation process of cosmetics slightly easier and faster for foreign companies. However, while China is willing to give some ground to foreign companies on its market, it is not willing to completely open up to a "foreign invasion". Therefore, it will continue to keep some trade barriers to limit foreign import and to favor domestic companies' development and growth.

After years of bad reputation in the cosmetics industry, China aims at improving its image abroad. Therefore, developing safety, quality, and technological standards for cosmetics is a key element in order to compete with other countries at international level and finally enter the forefront of world economic powers also in the cosmetics field, as in many other market sectors.

5.2 Attempts for international regulatory harmonization: is it an achievable goal?

Although China's intentions and objectives do not directly take into consideration international interests, its increasing alignment with EU regulations has also been indirectly influenced by international pressures exerted by world's economic powers to reach international harmonization with the ultimate goal of fostering international trade. Indeed, the increasing convergence of regulations and standards among different countries all around the world is the result of globalization and increasing international trade.

[11] Xiang Bo, "Backgrounder: Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era", *Xinhua*, March 17, 2018, on "xinhuanet.com", http://www.xinhuanet.com/english/2018-03/17/c_137046261.htm (08/06/21)

By looking at the major markets at the international level, we can notice a wide range of similar regulatory elements among different countries, these similarities fuel expectations for a promising future international alignment.[12]

Throughout our thesis we have mentioned some of these international similarities that can be encountered in many regulatory frameworks, from the EU to China. For instance, the manufacturer responsibility for product safety, the introduction of a notification processes, the required compliance with Good Manufacturing Practices (GMP) standards, the management of ingredients through positive and negative lists, the widespread use of the International Nomenclature of Cosmetic Ingredients (INCI), common basic labelling requirements and mandatory safety assessment of products.[13]

Nonetheless, considering what we have discussed so far, major differences continue to exist at the international level making a complete international harmonization difficult to achieve. On this matter, we have provided an emblematic example by comparing the EU and the Chinese regulatory framework on cosmetics in Chapter 4 of this thesis. The same major differences identified between China and the EU can also be found in other countries around the world, suggesting that there is still a long way to go for international harmonization.

Nevertheless, in the past few decades, there have been several attempts to foster harmonization at the international level, from the set-up of international organizations to the adoption of international standards and common guidelines for the management of cosmetics.

For example, in 2007 Canada, the EU, Japan and the US established a voluntary group called International Cooperation on Cosmetics Regulation (ICCR)[14], which meets every year to discuss international convergence of national cosmetic regulations.

Its aim is to discuss common issues on cosmetics regulation, remove regulatory obstacles and minimize international trade barriers while ensuring the highest level of protection of consumers' health.[15] The ICCR made a great contribution to the development of GMP standards, guidelines on nanomaterials, alternative methods to animal testing, and common criteria for safety assessment of ingredients worldwide. Throughout the years, many countries and international associations have joined the ICCR, for example, China has also showed an interest in cooperating with the ICCR, and it has attended the yearly meetings as observer since 2012.

[12] Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017, p.4
[13] Ibidem
[14] For further information: https://www.iccr-cosmetics.org
[15] Alberto Chisvert, Amparo Salvador, *Analysis of Cosmetic Products (2nd edition)*, Oxford, Elsevier Science, 2017, p.19

Another important international organization is the Personal Care Products Council[16] which made an important contribution to international harmonization thanks to the development of the International Nomenclature of Cosmetic Ingredients (INCI). As we have mentioned in different sections of this thesis, it is a set of harmonized cosmetic ingredients names that has been adopted by other legislations throughout the world, for example in the EU, Japan and now also in China. However, each country presents some discrepancies in cosmetics nomenclature and adopts their own version of the INCI.

As regards international standards, the most successful example of internationally recognized standards is the so-called Good Manufacturing Practices (GMP), common guidelines and best practices for the manufacture of cosmetic products. We have already mentioned the GMP in Chapters 3 and 4 of this thesis, indeed, compliance with this kind of standards is required both by the EU and China.

The most important recognized GMP standard is the ISO 22716:2007 proposed by the International Organization for Standardization, adopted by the EU, and recognized in many countries.

Even though common standards exist, there are not uniform mandatory provisions, some GMP standards are not recognized in some countries[17], and many other countries, including the EU and China, let companies choose which set of GMP standards to apply.

Moreover, an important element for international harmonization is international cooperation and bilateral agreements between countries.

For example, an important contribution is given by the EU which, as pioneer of cosmetics regulation and advocate of international harmonization, cooperates with several international partners in order to foster harmonization and promote international trade.

The European Commission is in close contact with the US Food and Drug Administration (FDA) since they jointly signed an agreement in 2007. And it has also established relationships with Chinese authorities, particularly with the State General Administration for Quality Supervision and Inspection and Quarantine (AQSIQ) and the China Food and Drug Administration (CFDA).[18]

The efforts showed by the EU in promoting international cooperation for regulatory harmonization are another supportive example of what has already been discussed in paragraph 4.1 of this thesis. The EU is considered to be a leader in cosmetics regulation, and this is proven by the fact that its regulation and legal requirements have influenced the regulatory framework of other countries, also

[16] For further information: https://www.personalcarecouncil.org

[17] As we have already mentioned in Chapters 3 and 4, this is a major problem for foreign companies that import in China.

[18] European Commission, "International Cooperation", on "ec.europa.eu", https://ec.europa.eu/growth/sectors/cosmetics/international_en (09/08/21)

outside of Europe. Since the EU regulation and standards provided clear, detailed, and complete guidelines with a high degree of accuracy and innovation to ensure product safety and promote trade, many countries have implemented changes in their regulations in line with the EU ones, and, as we have discussed in Chapter 4, China has also showed increasing similarities with the EU framework.

Its international influence is also due to the fact that the EU provided the first successful example of regulatory harmonization between different countries. It was able to overcome differences in national regulations and establish a common regulatory framework for all Member States. This way it removed many trade barriers represented by different requirements and standards and it enhanced trade among EU countries without overlooking safety and quality of products on the market.

Aware of its strong influence, the EU has become an advocate of international harmonization and it is trying to push other countries to follow this path of regulatory convergence, for example China. However, even though many countries, from the EU to the USA, push for international harmonization, this long-awaited regulatory harmonization is not included in some countries' plans, especially in the Chinese ones. As we have discussed in the previous paragraph, although China has showed an increasing alignment with the EU regulation and an interest in engaging in international trade, it does not share the same objectives of the EU.

After its opening to the outside world, China has taken part to many international organizations and meetings. In particular, China's entry into the WTO was a milestone in Chinese history since it marked its international recognition among other world economic powers and its opening to international trade. After this event, China has implemented changes in its laws and regulations to meet the WTO's requirements and lower trade barriers. However, China has always looked at its internal market and its own interests first. Even though China lowered tariffs and reduced some requirements, it has never completely lifted crucial trade barriers in order to protect and keep control over its domestic market.

As regards cosmetics, we have mentioned before the Chinese interest in taking part to the Personal Care Products Council for the discussion of cosmetics regulation worldwide. Nonetheless, in the light of what we have discussed up to this point, it is evident that China is trying to establish and keep relationships with other countries, not to foster international trade or to promote regulatory harmonization, rather to engage in international trade and exploit it for its own interests and economic development.

China aims primarily at developing its own economy and secondarily at enhancing its international influence and prestige. In order to achieve its goals, China needs to cooperate with other countries because, in a modern globalized society, it is impossible to act independently and overlook

international trade. Economic growth is deeply linked to international exchanges and diplomatic relationships, it is not just a matter of financial resources and profits but is more and more about the so-called “soft power”, which is the underhanded influence exerted by one country over others. Therefore, China is playing both sides, it has adapted some regulations and requirements in line with international ones as a sort of “favor” to other countries but expecting a favorable economic return. At the same time, it is not willing to compromise on other aspects in order to keep control over its domestic market and internal affairs. China’s interest in international affairs is just a mean to achieve its own ends and international harmonization is not included in its economic plans and political agenda. Consequently, as long as divergent approaches to international trade and different national aims exist, international harmonization will continue to be an unattainable goal.
Nowadays too many different national interests are in place, and regulations are inevitably deeply rooted in different historical, economic, and cultural backgrounds. Unless there is convergence of interests, as in the case of EU countries, international regulatory harmonization will continue to be an unattainable goal.

5.3 Benefits of increasing harmonization for both the EU and China

Differences in cosmetic regulations undoubtedly affect international trade and the creation of a global cosmetic market. Therefore, international harmonization, however difficult to achieve, could provide important benefits to companies, that want to engage in trade in other countries, and to countries, that want to enhance their economic growth.
Differences in registration, safety assessment, labelling, and prohibited ingredients and other legal requirements between countries mean that a company cannot import its products in other countries without having to undergo cumbersome procedures and pay high costs. These differences represent important trade barriers for companies, but they also affect other aspects of the cosmetics industry at the international level. For example, there is not a uniform degree of product safety within different countries, there is not a homogenous level of innovation and technological advancement among different markets, and consumers suffer a limited choice of products due to trade barriers. A system of harmonized regulations and standards is, thus, seen as the only way to remove these barriers and foster international trade. Moreover, it also creates a more efficient cosmetics industry in which companies take full responsibility for the safety of their products and are encouraged to constant self-monitoring and engage in R&D fostering innovation and technological advancement on the market. All involved parties can benefit from international harmonization: companies are not affected by trade barriers and are encouraged to trade, as a result, countries benefit from trade exchanges that foster domestic economic growth, while consumers enjoy a wider choice of products

to fulfill their desires.

As we have already discussed in the central chapters of this thesis by taking the example of trade between China and the EU, different regulations and legal requirements have always negatively influenced trade of cosmetics between these two regions and have affected companies, consumers and the whole cosmetics industry. China's increasing alignment with the EU regulations has provided some advantages to foreign companies, therefore, increasing harmonization could bring even more benefits for trade of cosmetics between the EU and China. The benefits coming from increasing regulatory harmonization could be enjoyed by all the parties involved, from companies to consumers, from the cosmetics industry to countries themselves.

Companies will surely benefit from the removal of important trade barriers. European companies that aim at importing their products into the Chinese market have to fulfill strict requirements and make important adaptations to their products in order to get approval from Chinese authorities, thus suffering high costs and even great losses in case of rejection due to small mistakes or discrepancies emerging during the import procedure. Moreover, the importation of many products is often hindered by other elements such as the complex registration procedures that increase the administrative and financial burden on companies; the uncertainty of approval processes due to unclear guidelines leaving companies at high risk of non-compliance and to the arbitrary judgement of Chinese authorities; the strict requirements and mandatory proofs for efficacy claims which increase business costs, and many other aspects discussed in more details in Chapter 4 of this thesis. The removal of the above-mentioned barriers will provide great advantages to foreign companies and will encourage import in the Chinese market. More import will result in increasing trade and sales, thus fostering competition on the Chinese market. Therefore, China could take advantage from increasing international trade as a driver of economic growth. Not only foreign companies will benefit from increasing harmonization, but also Chinese companies, consumers, and the whole Chinese cosmetics industry.

Major differences between the EU and China that have always negatively affected Chinese companies are the different degree of technological advancement and the animal testing issue. Many Chinese companies have not been able to compete with EU ones because they lacked a strong brand image, technology, and know-how. These elements have affected the performances of Chinese companies not only on their domestic market but also at the international level since they were not able to fulfill the sophisticated and advanced EU requirements in terms of testing and safety assessment. Moreover, China still lacks the knowledge and technology to perform the advanced tests required by the EU, and this has always been an important trade barrier for Chinese export to the EU.

Chinese backwardness has also affected the performance of domestic companies on their own market since their products could not compete with the innovative characteristics and high quality of the EU ones. Therefore, EU companies managed to conquer most of the Chinese cosmetic market.

EU companies not only possess a strong brand image, since they are worldwide popular and they are symbols of a certain social status in China, but they have also been able to provide the best products in terms of quality and safety.

Increasing alignment with EU standards would mean, on one hand, finally getting in line with the EU technological and regulatory advancement, and, on the other hand, attracting EU companies into the Chinese market, which will bring their cutting-edge technologies and extensive experience in quality management and safety assessment. As a result, competition and cooperation between Chinese and European cosmetic companies will not only ensure that the domestic market becomes stronger through exposure to competition but will also encourage R&D and innovation in the Chinese cosmetics industry. Chinese companies will be pushed to innovate and invest resources to developed new safe and high-quality products able to increasingly compete with the EU, thus increasing their ability to compete not only on their domestic market but also at the international level.

Chinese companies have been affected not only by underdeveloped technology and know-how but also by the different requirements on animal testing.

A survey carried out on 42 companies in the area of Shanghai between 2011 and 2016 has shown that these companies have suffered considerable losses in terms of rejection or destruction at customs or returns of many products after the full implementation of EU ban on animal testing. These losses were estimated around 560,000 US dollars.[19] This happened because those products had already been tested on animals prior to the ban and companies were not prepared to provide proofs or perform alternative testing methods.

Other costs suffered by these companies were linked to additional certifications, tests, and approval procedure that they had to perform after the first rejection of their products in the EU. These indirect losses were equal to 2.12 million US dollars.[20]

These losses were also due to the fact that China was not prepared for alternative testing methods. Research and studies in the field were quite inexistent, there was no qualified institution able to

[19] Li Xiaolin, Wang Wei, Xi Jie, Chen Ruili, Zhong Yan, Ye Li et al. 李小林, 王伟, 奚杰, 沈瑞丽, 钟燕, 叶理 et al. Oumeng huazhuangpin shiyan yunwu jinling dui shanghai huazhuangpin chukou qiye yingxiang de diaocha 欧盟化妆品实验动物禁令对上海化妆品出口企业影响的调查, (Survey on Effects of EU Cosmetics Animal Testing Ban on Shanghai Export Cosmetics Enterprises), *Jianyan jianyi xuekan* 检验检疫学刊, *27*, 2, 2017, p.71

[20] Ibidem

perform alternative tests and Chinese recognized methods and technology were underdeveloped compared to the EU ones.

The whole import procedure of Chinese products in the EU became more time-consuming, costly, and almost impossible for Chinese companies due to the huge gap in animal testing requirements. Since the EU represents one of the most important target markets for Chinese products, the ban on animal testing resulted in huge direct and indirect losses.

Considering the strong influence of the EU at the international level, other countries gradually introduced the ban in their regulation. Since China could not afford to lose other important target markets, it was indirectly forced to consider and introduce a partial ban on animal testing.[21]

China should consider to completely lift animal testing requirements since it will not only benefit trade between the EU and China and provide advantages for both European and Chinese companies, but it will also enhance its national image abroad.

Moreover, if Chinese companies manage to develop products that can compete in terms of quality, safety, and innovation with the EU ones, while ensuring their safety without performing any animal tests, they will be able to satisfy an increasing demand for cosmetic products on their domestic market.

Considering that China has a thriving cosmetic market characterized by an increasing consumer demand, increasing harmonization could bring several benefits also to consumers, fulfilling their desires and boosting their demand at the same time.

Since increasing harmonization means reduction of trade barriers, a wider variety of products will be able to reach the market and satisfy the increasing Chinese consumer demand, which is constantly more sophisticated, diversified, and exigent.

In the last few years, a new trend has emerged from the Chinese market. As we have discussed in Chapter 2 of this thesis, Chinese consumers are increasingly interested in cosmetics that are not only safe and high-quality, but also natural and cruelty-free. Therefore, ensuring a complete ban on animal testing could benefit the development of the Chinese market and increasingly fulfill Chinese consumers' desires.[22]

Moreover, as we have mentioned in previous lines, increasing competition between Chinese and European companies will push for more product innovation and stronger control over product safety in order to offer the best competitive products on the market.

[21] In China, animal testing ban was directly influenced by the increasing internal consumer demand for cruelty-free products, as we have discussed in the previous paragraph. But it was also indirectly influenced by international pressures to keep up with developments on the cosmetic market and remain competitive at the international level.

[22] As we have mentioned in the previous paragraph, this is also one of the main points of Xi Jinping's political agenda. Therefore, a complete ban of animal testing can also be instrumental to attain China's political and economic goals.

More detailed harmonized guidelines on safety and labeling in line with the EU ones and stronger self-monitoring on products due to increasing responsibilities of companies will ensure that consumers are more protected from potentially harmful or not properly labelled cosmetics. In addition, more clear indications and warnings on labels will allow a well-informed and conscious use of cosmetic products.

Apart from providing benefits to Chinese companies and consumers, increasing harmonization will ultimately benefit the whole Chinese industry.

Harmonized standards on ingredients, clearer guidelines on safety assessments and an improved report system of adverse reactions will strengthen product safety on the internal market. Companies will be obliged to prevent the marketing of cosmetic products that do not comply with the harmonized requirements in order to maintain their presence on the market and to stay competitive. Increasing competition on the market between EU and Chinese companies will push innovation and development of new advanced technologies on the market.

Until now, even though Chinese consumers are increasingly interested in this kind of products, the rigid approval procedures have hindered the introduction of new cosmetic ingredients on the Chinese market and have prevented innovative products on the international market from reaching China. This limit can be overcome through increasing harmonization with the EU, as we have discussed up to this point.

The development of the Chinese cosmetics industry will inevitably enhance Chinese economic growth and enable China to increase its international prestige and influence and to reach its ultimate goal: being at the forefront of world's economic powers and becoming an influential leader able to compete at international level.

In conclusion, increasing alignment between the EU and China in terms of cosmetics regulation and legal requirements is a win-win situation since it can provide advantages to both parties and further speed up their economic growth.

It does not only benefit EU companies by lifting trade barriers and allowing them to freely import their products in the Chinese market, but it also provides several benefits to China.

More competition on the Chinese market will foster advancements in terms of technology and safety and it will result in growing trade exchanges and increasing economic growth.

Chinese companies will be pushed to invest in innovation, and they will be increasingly able to compete at the international level. A wider choice of cosmetic products on the market will be able to satisfy the increasing consumer demand, while advancements in product safety and quality will fulfill Chinese consumers' desires for more safe, natural, and cruelty-free products.

In general, it will foster international trade between the EU and China and become a driver for their

own economic growth.

Considering the above-mentioned aspects, it is evident that the benefits provided by a regulatory harmonization between the EU and China are deeply in line with China's aims, namely fostering its domestic market development, satisfying Chinese people's desires, promoting innovation on the market, and becoming a leader able to compete at the international level.[23]

Therefore, the increasing alignment with the EU showed by the new Chinese regulations as highlighted in this thesis is further justified by the above-mentioned benefits provided by an increasing regulatory harmonization. However, China is not willing to completely align its regulations and to further lower its guard when it comes to protecting its domestic market and interests.

China should understand that its protectionist approach is just preventing it to achieve its ultimate goals and it is holding back its own development. China should continue on the path of harmonization with EU regulations and requirements in order to fully enjoy all the advantages coming from it and accelerate its own development.

In the contemporary globalized era, the crucial element for a country's economic development is to be able to maintain relations with other countries all around the world. Diplomacy and international trade are the key drivers for enhancing national economic growth and influence.

In order to allow international trade, what is mainly important for companies is to be able to use a similar set of regulation and requirements and consequently get rapid market access in different regions and countries.[24]

Nowadays all countries provide requirements on the same regulatory elements, such as notification, safety assessment, market surveillance, labelling, etc. But what countries really need is a set of common regulatory models and standards that can be transposed in different legislations[25] in order to ease the administrative burden on companies that suffer additional costs in order to adapt to different national requirements, thus fostering international trade of cosmetic products.

Regulatory harmonization is increasingly becoming a key element in international trade, since as long as important trade barriers remain, international trade cannot achieve its greatest potential. Nowadays, protectionism does not work anymore, and international trade is the actual driver of economic development. Therefore, if China wants to finally reach its goals, it should take these aspects into consideration and reconsider its position.

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[23] For further information about China's aims please make reference to paragraph 5.1 of this chapter.

[24] Lucy Whitehouse, "Is global regulatory harmonization possible for the beauty industry?", on "cosmeticdesign-europe.com", May 30, 2018, https://www.cosmeticsdesign-europe.com/Article/2018/05/30/Is-global-regulatory-harmonisation-possible-for-the-beauty-industry?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright (10/06/21)

[25] Ibidem

Conclusion

Nowadays the cosmetic market is one of the most promising and thriving markets worldwide, particularly driven by online sales and by the renewed interest of young consumers toward skincare and make-up.

Cosmetic products are widely commercialized and used all over the world, this is the result of an increasing globalization phenomenon that has made similar products available in different markets at the same time. Worldwide popularity of cosmetic products is also supported by similar consumer behaviors and preferences that emerged in different countries in spite of cultural and social differences. Similar trends can also be identified at the international level.

Increasing environmentalism, interest toward more natural and cruelty-free products and ingredients, and greater concerns for product safety are highlighting the need for global regulatory changes. Therefore, countries are gradually updating their regulations on cosmetics pushing toward a regulatory convergence among different countries, not only to facilitate international trade, but also to strengthen product safety, to satisfy an increasing consumer demand, and to stay competitive at the international level.

The EU was a pioneer in cosmetics regulation, and it seems to be the only one to implement and abide by consistent and detailed regulations and standards on the international cosmetic market. Therefore, the EU is trying to leverage its strong position to influence other countries in improving their regulations. Indeed, in recent years many countries are implementing new regulations, safety assessment requirements and testing methods in line with the EU, including China.

This is the background on which this thesis was elaborated, as introduced in Chapter 1.

Throughout our discussion, we first investigated the current state of the Chinese cosmetic market and we specifically focused on Chinese regulation and legal requirements on cosmetics and their impact on foreign companies that operate or aim at importing in the Chinese market. Then, through an in-depth analysis on the increasing similarities and major differences between the EU and the Chinese regulatory framework, we finally tried to answer to some important questions raised throughout this thesis: is China going to align with European regulations? What are its real intentions? Does it want to foster international trade or to further protect its domestic market?

We will now retrace some important steps of our discussion to draw final conclusions.

After introducing a general framework about cosmetics at international level in Chapter 1, we provided an analysis of the Chinese cosmetic market in Chapter 2, highlighting its increasing economic growth and relevance on the international level.

The Chinese market has experienced an unprecedented growth after its period of reforms in 1980s. Demand and consumption of several products, including cosmetics, skyrocketed fostering Chinese

economic growth. Nowadays the Chinese market is the second most important market for cosmetic products at the international level. Therefore, it has rapidly become the most sought-after market for many foreign companies, especially European ones, who easily ended up conquering major market shares because of an initial lack of regulations and controls on the market.
In the last few years, even though foreign companies and imported cosmetic products have dominated the Chinese market, they have constantly been challenged. On one hand, they are threatened by the constant growth of Chinese cosmetic companies that aim at competing with other companies at the international level. On the other hand, they are constantly challenged by the complex import procedures and the strict legal requirements that represent significant trade barriers to foreign entry.
Nonetheless, huge developments have been occurring in terms of regulations and legal requirements on cosmetics with the entry into force of the new *Cosmetic Supervision and Administration Regulation* (CSAR). This new regulation has resulted in the revision of several other related regulations and measures and has shown a tendency from the Chinese part to align its regulations with international ones, especially with the EU.

In Chapter 3, we went on analyzing the latest developments in terms of regulations and legal requirements on cosmetics in China and the actual impact of these regulatory changes on foreign companies and foreign import into the Chinese market.
The new regulation and legal requirements have shown a greater attention toward ensuring safety and quality of cosmetic products circulating on the Chinese market, in line with international safety and quality standards. Moreover, regulatory changes and increasing alignment with the EU allowed the import process to become gradually more efficient and faster.
However, many critical issues remain in place. Bureaucracy is heavy and requires the preparation of many documents, while the import process continues to be complicated, costly, risky, and subject to the arbitrary decisions of Chinese authorities that are intransigent and do not leave room for mistakes and negligence nor do they hesitate to adopt punitive measures even for the smallest discrepancy.
Moreover, the non-implementation of alternative testing methods and the requirement for animal testing for special cosmetics and new ingredients registration create marketing problems for companies and pose trade problems with countries that banned this kind of testing methods.
On one hand, China has increased some requirements which are becoming more stringent and costly for companies so that they are still major trade barriers for foreign companies. On the other hand, China is increasingly improving and updating its regulation and legal requirements in line with other countries, especially with the EU, this way apparently facilitating foreign import.

But what are China's real intentions? Is China going to completely align with EU regulations and legal requirements?

In order to answer to the above-mentioned questions, we proposed a comparison between the EU and the Chinese regulatory framework on cosmetics in Chapter 4.
Since the European Union was a pioneer in cosmetics legislation on the international level, it exerted a strong influence on regulations and standards implemented by other countries, including China. Therefore, in order to better understand the latest developments in terms of Chinese regulation and legal requirements, it is important to highlight increasing similarities and major differences between China and the EU.
From the comparison between the EU and China, two main points emerged.
Firstly, although China is gradually implementing changes that are pushing its regulation and requirements on cosmetics to increasingly align with those of the EU, there are still major differences that make the two regulatory frameworks incompatible on crucial aspects.
The existing differences between the Chinese and the EU regulation on cosmetics often constitute actual trade barriers for EU companies working in the field and trying to enter the Chinese cosmetic market. These companies must invest huge resources, time, and efforts to prepare documents, to engage in complex registration processes, to perform relevant tests, and to comply with all Chinese requirements.
Secondly, the import process in China has become slightly easier for European companies during the past few years thanks to the implementation of new measures and provisions increasingly in line with the EU requirements.
The coexistence of increasing similarities and major differences between the Chinese and the EU regulatory framework on cosmetics further highlights a contradictory tendency from the Chinese part. On one hand, the new Chinese regulation showed increasing alignment with the EU on several important points facilitating foreign entry into the Chinese market. On the other hand, several major differences still exist between China and the EU, posing important trade barriers for foreign cosmetic companies that operate on or aim at the Chinese cosmetic market.

After this in-depth analysis, we tried to answer the main questions raised throughout our discussion in Chapter 5.
Firstly, we clarified China's real intentions. The latest developments on the Chinese cosmetic market in terms of regulations and legal requirements are deeply in line with China's overall political and economic plans. China is getting in line with some international standards and with some aspects of the EU regulatory framework, firstly, to ensure safety and quality on its domestic

market and to promote technological innovation in the field; secondly, to satisfy growing consumer demand for safe, high-quality, natural and cruelty-free products; and lastly, to maintain good trade relationships with other countries which is fundamental for a country's economic growth and international prestige in a globalized society as the one in which we are living.
These three points are in line with Xi Jinping's Thought: technological and economic development on the Chinese market is part of the "scientific development" at which China aims; allowing a wider variety of foreign products to reach the Chinese market is to "improve people's livelihood and well-being"; and maintaining international trade relationships with other countries is fundamental for the creation of a "shared community" and for the "peaceful development" of China's economy and international influence.
Increasing alignment has made the importation process of cosmetics slightly easier for foreign companies, but this is just a side effect. China is not willing to lose its sovereignty over its domestic market, therefore, it will continue to keep some trade barriers to limit foreign import and to favor domestic companies' growth. International trade is just part of a larger Chinese plan for its own economic development and for the enhancement of its international influence.

Secondly, we tried to envision future developments on the international cosmetic market and answer to an important question raising in the field: is future international harmonization possible? China's increasing harmonization with the EU is a direct result of its political and economic plans, however, it has also been indirectly influenced by international pressures.
Increasing convergence of regulations and standards is a phenomenon that can be observed in several countries all over the world. Significant signals of increasing harmonization are international organizations such as the ICCR, the adoption of INCI, the required compliance with GMP standards, and the international cooperation among countries and national authorities.
However, taking into consideration that national differences are still in place, international harmonization has still a long way to go. As in the case of China and the EU, our analysis on similarities and differences and the consequent conclusions drawn on China's aims have highlighted the fact that the Chinese interest in international trade is just a mean to achieve its own ends and international regulatory harmonization is not included in its economic plans and political agenda.
Therefore, as long as divergent approaches to international trade and different national aims exist, international harmonization will continue to be an unattainable goal.

Lastly, we explained why international harmonization is an important issue on the cosmetic market. Increasing international harmonization could provide important advantages to all parties involved, from companies to consumers, from countries to the whole cosmetics industry.
Increasing alignment with EU requirements will allow China to fill the technological gap in terms of product safety and quality. It will attract more foreign companies into the market fostering competition and pushing for increasing innovation inside the domestic market, as a result, Chinese companies will be increasingly able to develop new safe and high-quality products able to compete with foreign ones, both on their domestic market and at the international level.
A wider range of new products, both foreign and domestic, will reach the market satisfying and fostering a strong Chinese consumer demand for safe, natural, and cruelty-free products.
Ultimately, the increasing alignment with EU regulations will benefit the entire Chinese cosmetic markets in terms of safety and innovation. The development of the Chinese cosmetics industry will inevitably enhance Chinese economic growth and enable China to increase its international prestige and to reach its ultimate goals.

In conclusion, increasing alignment between the EU and China in terms of cosmetics regulation and legal requirements is a win-win situation since it can provide advantages to both parties and further speed up their economic growth.
From our analysis, it is evident that benefits provided by regulatory harmonization between the EU and China are deeply in line with China's aims, namely fostering its domestic market development, satisfying Chinese people's desires, promoting innovation on the market, and becoming a leader able to compete at the international level. This also explains why China is showing an increasing alignment with the EU regulation and legal requirements on cosmetics.
However, China is not willing to completely align its regulation and to further lower its guard when it comes to protect its domestic market and its own interests.
The Chinese protectionism is just preventing it to fully take advantage of international trade and it is holding back its own development.
Regulatory harmonization is increasingly becoming a key issue in the contemporary globalized era, since as long as important trade barriers remain international trade as a driver of economic development cannot achieve its greatest potential. Therefore, China should not only strengthen relationships and trade with other countries, but also consider aligning with the EU regulations and legal requirements on cosmetics to finally achieve its goals.

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