The Dynamic of Law-making for the Cosmetic Industry: A Study of the Regional Blocs — the EU and ASEAN and of the US and China

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ภูมิภาคเอเชียแปซิฟิคเป็นตลาดที่ใหญ่ที่สุดสำหรับธุรกิจเครื่องสำอาง และโดยบังเอิญยังเป็นภูมิภาคที่เศรษฐกิจเติบโตเร็วที่สุดในโลกอีกด้วย มากกว่าอเมริกาเหนือและยุโรปตะวันตก อย่างไรก็ตามการออกกฎหมายและบังคับใช้กฎเกณฑ์ที่กำกับดูแลอุตสาหกรรมเครื่องสำอางยังเต็มไปด้วยหลากหลายอุปสรรคทั้งสำหรับฝ่ายนิติบัญญัติ ผู้สร้างนโยบาย และธุรกิจ และกระบวนการต่าง ๆ นั้น ก็ไม่ยังค่อยถูกบันทึกไว้เป็นลายลักษณ์อักษรเท่าที่ควร ในขณะที่ปริมาณการค้าเพิ่มขึ้นทำให้ผลิตภัณฑ์เครื่องสำอางที่มีความหลากหลายมากขึ้นกระจายตัวไปสู่ผู้บริโภค มาตรฐานความปลอดภัยและกรอบการกำกับดูแลในภาพทั่วไปยังคงมีความแตกต่างอย่างมากเมื่อเปรียบเทียบระหว่างประเทศต่าง ๆ ในภูมิภาค บทความนี้มุ่งวิเคราะห์ความเชื่อมโยงระหว่างกระบวนการจัดทำกฎหมาย ความต้องการของภาคธุรกิจ และความปลอดภัยและข้อมูลของผู้บริโภค บทความนี้จะฉายภาพกระบวนการจัดทำกฎหมายในความสัมพันธ์กับอุตสาหกรรมที่กำลังเติบโตอย่างรวดเร็ว และคำนึงถึงบริบทของความพยายามในระดับนานาชาติที่จะสร้างกฎหมายกำกับเครื่องสำอาง อีกทั้งนำเสนอแผนภาพกระบวนการเพื่อทำความเข้าใจกฎเกณฑ์กำกับดูแลผลิตภัณฑ์เครื่องสำอางสำหรับกลุ่มภูมิภาคสองกลุ่ม คือสหภาพยุโรปกับอาเซียน และสหรัฐอเมริกากับจีน นอกจากนี้ ยังประเมิน

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กลุ่มพลังอำนาจที่มีผลต่อกฎเกณฑ์ที่กำลังเปลี่ยนแปลง รวมไปถึงประเด็นทางจริยธรรมและการเติบโตของกลุ่มธุรกิจที่เน้นการดูแลแบบธรรมชาติ (natural care segment) และอิทธิพลที่มีต่อกรอบกฎเกณฑ์ด้วย

คำสำคัญ : ธุรกิจเครื่องสำอาง กฎหมายเกี่ยวกับเครื่องสำอาง กฎเกณฑ์เกี่ยวกับเครื่องสำอาง การค้าระหว่างประเทศ

Abstract

The Asia-Pacific region is the biggest market for cosmetics and incidentally; the world economy's fastest-growing region, followed by North America and Western Europe. However, the adoption and implementation of cosmetics regulations have presented several challenges to legislators, policy-makers and the industry alike; and the overall processes are under-documented. While increasing trade flows boost cosmetic product's diversification and distribution and their access to consumers, safety standards and more generally; regulatory frameworks remain vastly different from one country to another. This article will proceed to analyze the nexus between law-making processes, the industry's requirements, and consumer safety and information. It will shed some light on law-making processes in relation to a fast-growing industry, with the backdrop of the internationalization efforts of cosmetic laws on a worldwide level. It will offer a process-mapping exercise aiming to understand the cosmetic regulations for two regional blocs: the EU and ASEAN, and for the USA and China. It will also assess the forces at play influencing ever-changing regulations, including ethical concerns and the growth of the natural care segment and their afferent impacts on regulatory frameworks.

Key Words : Cosmetic Industry, Cosmetic law, Cosmetic regulations, International Trade

Amongst the myriad of consumption products used daily, besides electronic items, clothing; cosmetics have found a place of choice in our homes. Cosmetics have existed for a very long time. Archeologists have found red clay sticks for coloring the body with ocher presumably used by the Homo erectus, who occupied the African savannah between 300,000 and 1.5 million years ago.[1] Early cave paintings of 30,000 years ago depict the use of body adornment (i.e. rudimentary cosmetics) in the rituals of mating and hunting.[2]

The word "cosmetic" is derived from the Greek *Kosmtikos*, meaning "having the power to arrange, skilled in decorating giving", "*kosmein",* "to adorn," and "*kosmos*", "order, harmony".[3] Throughout the recorded history of man, cosmetics have been used with essentially the same three goals in mind, namely to enhance personal appeal through decoration of the body, to camouflage flaws in the integument, and to alter or improve upon nature.[4] Whether or not this is a pleasant concept; beauty and physical attractiveness are, constantly emphasized as desirable and admirable characteristics[5] in our contemporary societies. Today, the global beauty market is usually divided into five main business segments: skincare, hair care, color (make-up), fragrances and toiletries. Beauty products can be also subdivided into premium and mass production segments (according to the brand prestige, price and distribution channels used). The cosmetics industry has been met with profound structural changes over the past decade, whilst laws and regulations framing manufacturers and traders' practices have known an uneven pace of development and followed different trajectories across various nations. Ever expanding, the beauty and personal care industry boasted a steady 5% growth in 2016.[6] For the second consecutive year, the premium segment outperformed its mass counterpart, with nearly 6% growth.[7] Yet, for all products' segments, industry-

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[1]Brannan, Daniel K. (1997) "*Cosmetic Microbiology: A Practical Handbook",* CRC Press.

[2]Butler H. (1993) "*Historical background*", in Butler H. Ed. *Poucher's Perfumes, Cosmetics and Soaps*, 9th ed. London: Chapman and Hall, 639-692

[3]Butler H. (1993), *ibid.*

[4]Romm S. (1992) "*The Changing face of Beauty*", St. Louis: Mosby-Yearbook, Inc.

[5]Apaolaza-Ibáñez, Vanessa; Hartmann, Patrick; Diehl, Sandra and Terlutter, Ralf (2011) "*Women satisfaction with cosmetic brands: The role of dissatisfaction and hedonic brand benefits*", Journal of Business Management Vol. 5(3), pp. 792-802, 4th February 2011.

[6]Euromonitor International's 2017 edition.

[7]Ibid.

specific legal literature tends to be scarce and scattered, while stakeholders in the public and private sectors continue to operate under dynamics that deeply affect consumers worldwide. The Asia-Pacific region is the biggest market for cosmetics and incidentally; the world economy's fastest-growing region, followed by North America and Western Europe as largest cosmetic markets. However, the adoption and implementation of cosmetics regulations has not followed as rapidly. The regulation of cosmetics has presented several challenges to legislators, policy-makers and the industry alike due to a relative lack of scientific data and evidence of health effects from long-term the use of cosmetics, and pressure coming from the lucrative industry itself. As a result, the overall processes are under-documented. While increasing trade flows boost cosmetic product's diversification, distribution and their access to consumers, safety standards and more generally; regulatory frameworks remain vastly different from one country to another. Products on offer, their modes of production and safety standards vary from a country to another, from a region to another. This article will proceed to analyze the nexus between law-making processes, the industry's requirements, and consumer safety and information. This study will shed some light on law-making processes in relation to a fast-growing industry, with the backdrop of the internationalization efforts of cosmetic laws at the worldwide level. It will offer a process-mapping exercise aiming to understand the cosmetic regulations for two regional blocs: the EU and ASEAN, and for the USA and China. It will also assess the forces at play influencing ever-changing regulations, including ethical concerns and the growth of the natural care segment and their afferent impacts on regulatory frameworks.

I. LEGAL TERMINOLOGY AND REVIEW OF THE MAIN REGULATIONS ON COSMETICS: A REVIEW PER COUNTRY: THE USA AND CHINA AND BY REGIONAL BLOCS: EU AND ASEAN

I.1 America's main regulations on cosmetics

I.1.1 The Federal Food, Drug, and Cosmetic Act (FD&C), 1938 and the Fair Packaging and Labeling Act (FPLA) (1966)

It is the U.S. Congress, as the legislative branch of the federal government that enacts federal laws including those pertaining to cosmetics. The Food and Drugs Administration (FDA) is the main consumer protection agency of the US government. Its origins can be traced back to the 1850s. The FDA, overlooking the fields of drugs, food, medical devices, etc. was given authorization by the Congress to help put the laws into effect by creating and enforcing various regulation on cosmetics. The FDA plays therefore an important role in the day to day working of federal laws, defining the contours of the law, whilst the regulations are adopted under the authority of the laws.

The two most important laws for cosmetics marketed in the USA are the Federal Food, Drug, and Cosmetic Act (or FD&C Act, which predecessor was by the 1906 Pure Food and Drugs Act[8]) and the Fair Packaging and Labeling Act (FPLA).[9] This current regulatory framework is intended to ensure that cosmetics are safe, and that the packaging and label statements are truthful and informative. “Adulterated” and/or “misbranded” cosmetics are prohibited.

I.1.2 Products categories and classification in the USA

When it comes to the definition of cosmetics, a first distinction in the USA is made between “drugs” and “cosmetics” and there exists a distinct definition for both. The definition of cosmetics relates strongly to their “intended use” and goes as follows: “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body…for cleansing, beautifying, promoting attractiveness, or altering the appearance.”[10] Among the products included in this definition are skin moisturizers, perfumes, lipsticks, nail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance *intended for use* as a component of a cosmetic product.[11] The FD&C Act defines drugs, in part, by their

[8]Gabriella Baki, Kenneth S. Alexander (2015) Introduction to Cosmetic Formulation and Technology, Wiley Eds.

[9]Moreover, the Toxic Substances Control Act (TSCA, pronounced “Tosca”) enacted in 1976 gives the EPA the ability to track close to industrial chemical substances produced in or imported into the United States.

[10](FD&C Act, sec. 201(i)).

[11]FDA website, https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm, accessed on the 5th January 2017

intended use, as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals”.[12] Therefore, in the USA, there exists a certain degree of overlap in the product categories. A product can be clearly a cosmetic, clearly a drug, or be both at the same time, This differs from other definitions of cosmetics such as that of the EU or ASEAN, where a product is either a cosmetic or a drug, but cannot be both or part of a third category, as the one that exists *de facto* in the USA. China has adopted the concept of special use cosmetics, for products which have claims making them it more susceptible to present a health risk, while a drug will retain its own set of characteristics. Furthermore, despite the distinction between cosmetics and drugs; there is no definition for products which fall between the two types although some products may be considered as both a cosmetic and a drug. The key to determining whether a product of a drug or a cosmetic, or both; is the “intended use” of that product, as determined by the claims or representations made for the product in its advertisement or labelling. A product may very well have two “intended uses” and may be called “cosmeceuticals” although the term has no legal meaning, or an “over the counter” (OTC) drug or product. For example, all products claiming a sun protection factor, even if this is not their main purpose, are considered as both drugs and cosmetics. An antidandruff treatment will be considered to be a drug because its intended use is to treat dandruff, while an antidandruff shampoo also falls within the definition of a cosmetic.[13] Such products will have to follow the regulatory requirements of both categories: adhering to labeling requirements for both cosmetic and drugs,[14] as well as complying with additional requirements for drugs such as pre-market approval, good manufacturing practice regulations and registration. This standard may be confusing to a non-US based manufacturer, for

[12][FD&C Act, sec. 201(g) (1)].

[13]Among other cosmetic/drug combinations are skin lighteners, toothpastes that contain fluoride, and moisturizers and makeup marketed with sun-protection claims. OTC drugs in the US: these are topical acne treatments, antiperspirants, products for the protection of chapped skin or mucous membranes, sunscreens

[14]The drug ingredients must appear according to the OTC drug labeling requirements and the cosmetic ingredients must appear separately, in order of decreasing predominance. If a Cosmetic is also a drug, then the ingredients statement must list the active ingredient first, followed by the inactive ingredients in descending order of predominance.

his product shall be treated as a cosmetic in its home country, and then classified as being a drug in the USA because of the labelling claims. For clarification purposes, the FDA has published OTC monographs.[15] OTC products do not need medical prescription.

I.1.3 Pre-market approval in the USA

In the United States, the FD&C Act does not subject cosmetics to any form of pre-market approval (PMA) by the FDA; except for color additives. PMA, as an FDA process designed to evaluate the safety and effectiveness of products destines to the use by the public; will apply to medical devices, and drugs, but not to cosmetics. Neither the law nor the FDA regulations require any form of specific tests to demonstrate the safety of individual products or ingredients. The FDA has, in fact, no legal authority or mandate to require pre-market safety assessment, as it does with drugs. Moreover, under the current law, manufacturers are not required to register their cosmetic establishments or file their product formulations with the FDA. As regard to the import of cosmetics into the USA, no registration number is required.

The FD&C Act regulates products only after they are placed on the market. A number of ingredients are prohibited by the regulations, or restricted. The legal responsibility of ensuring the safety of the cosmetic products is borne by the companies or individuals who manufacture or market cosmetics. All in all, with an *a posteriori* system of compliance, active after the products have been placed on the market; one may assert that cosmetic products are among the least regulated products in the market in the USA. In comparison, pharmaceutical and medicine manufacturing are highly regulated industries, along with industries such as petroleum, coal products and motor vehicle manufacturing.

[15]Monographs are regulatory instruments for each specific category of OTC products, provide product definitions the approved active ingredients and permitted combinations, their maximum and minimum permitted concentrations, the labelling requirements (statement of identity, indications for use, warnings and directions).

I.1.4 Manufacturing, ingredients, and safety requirements for the USA

As seen above, the FD&C act does not require cosmetic companies to register manufacturing establishments with the FDA nor does it require an inventive of ingredients or formulations. The industry, however, through its trade association, the Cosmetic, Toiletry, and Fragrance Association (CFTA), has set up a voluntary registration system in cooperation with the FDA using an approved form for stakeholders to report the raw materials used in finished products and the formulation for finished products. It is the manufacturer or the supplier who may provide the information on raw materials and then the manufacturer, packer or distributor who may furnish information on the formulation. The information provided remains a trade secret not to be divulged. The number received does not equate to a formal approval on the formulation by the FDA; its use being more for registration purposes.

In terms of restriction on ingredients, the USA does not have a positive or negative list system as such. With the exception of color additives and a few prohibited substances, the manufacturer is free to use any raw material as a cosmetic ingredient. There are only seven colors that are on the FDA's approved list. Artificial colors usually contain other unnatural chemicals, such as sodium lauryl sulfate or parabens, so the potential toxic effect on humans – which has been a subject for decades - is a strong possibility. The law does require however that color additives be tested for safety by the FDA for their intended uses. All in all; there are only eleven ingredients which are specifically forbidden or restricted for use in cosmetics.[16] Formaldehyde is not one of them, for example, while this

[16]The 11 ingredients that have been banned by the FDA are ingredients of proven toxicity. These are: bithionol (adverse effect: photocontact sensitization), chlorofluorocarbon propellants, chloroform (it has a carcinogenic effect; however, the regulation makes an exception for residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient); halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide) (adverse effect: : may cause serious skin disorders); hexachlorophene (a preservative that has a toxic effect and ability to penetrate human skin; but HCP may be used only when no other preservative has been shown to be as effective, with a concentration in a cosmetic may not exceeding 0.1 percent; however HCP cannot be used in cosmetics that are applied to mucous membranes, such as the lips); mercury compounds (these are readily absorbed through the skin on topical application and tend to

ingredient is banned in the EU for example. As a comparison, governments in the European Union have banned upward of 1,300 ingredients from use in cosmetic The FDA regulations do not ensure or request that the cosmetics are made with chemicals that may have carcinogens, endocrine disrupting and mutagens effects. However, the industry has been active in establishing its own safety guidelines. Finally, the FDA remains responsible for assuring that cosmetics are safe and properly labeled. If the FDA finds non-compliance with the relevant regulations, it can take various regulatory actions.

Following the system described above, one can assert that the USA has a self-regulatory system for cosmetics. Self-regulation is considered a common arrangement in developed jurisdictions. This system's proponents contend that particular industries have greater expertise and knowledge of technical practices within their relevant area than the regulators. The merits of the system may also include the saving of costs traditionally associated with formalities and registration procedures with the relevant authorities; instead, the companies may invest in their own safety procedures and guidelines. It could also be argued that self-regulation helps define or adjust areas of law in which the government would not otherwise interfere, and at minima introduce some specific topics that are subject to debating. On the other hand, self-regulation poses the problem of "information dissymmetry". In the presence of such asymmetric information, it is difficult for all companies to be informed, and consumers may justifiably so doubt unverified claims made by the manufacturers.

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accumulate in the body and may cause allergic reactions, skin irritation, or neurotoxic problems; methylene chloride (it is carcinogenic in animals and is likely to be harmful to human health; prohibited cattle materials (so as to protect against bovine spongiform encephalopathy (BSE), also known as "mad cow disease); sunscreens in cosmetics (since the product's labelling generally causes the product to be subject to regulation as a drug or a drug/cosmetic, depending on the claims. However, sunscreen ingredients may also be used in some cosmetic products to protect the products' color); vinyl chloride (its use is prohibited as an ingredient of aerosol products, because it causes cancer and other health problems); and finally, zirconium-containing complexes. The use of zirconium-containing complexes in aerosol cosmetic products is prohibited because of their toxic effect on lungs of animals, as well as the formation of granulomas in human.

I.2 China's main regulations on cosmetics

China's regulations combines some elements that are similar to US practices, in that there is not necessary safety validation for the products that are placed on the market; except for special domestic cosmetics and foreign imported cosmetics product. These categories require the stakeholder to obtain a market permit, guaranteeing safety tests have been carried out. The distinction between ordinary and special cosmetics is particular to China. The regulations, whilst China is amending a number of provisions to bring them at par with EU and US ones, may still seem rather daunting in terms of complexity and bureaucracy to the foreign exporter. The country has aligned its import tariffs with the requirements by the WTO. However, consumption taxes, that are levied on manufacturing, processing, importing and selling cosmetics are particularly high (30%) remain another concern for companies willing to enter the otherwise booming and attractive Chinese market. The non-implementation of AAT (anti-animal testing) methods remain a concern to foreign companies too.

I.2.1 Chinese laws on cosmetics, including the Regulations concerning the hygiene supervision over cosmetics, 1990

Chinas current cosmetic regulatory system rests upon the overarching "Regulations concerning the Hygiene Supervision over Cosmetics (1990)", which are supported by a series of subsidiary rules, standards and guidance documents issued by the former regulator, the Ministry of Health (MOH) and the current competent authority i.e. the China Food and Drug Administration (CFDA). [17]

The CFDA regulates cosmetic ingredients through rules gathered in the "Cosmetic Hygienic standards" that lists prohibited and restricted ingredients, preservatives, colorants, dyes and UV filters; while the Inventory of Existing

[17]They are completed by Detailed Rules for the Implementation of the Regulation on the Hygiene Supervision over Cosmetics (2005); Hygienic Standard for Cosmetics (2007), The Measures for the Administration of Hygiene License for Cosmetics (revised in 2010); Guideline for Risk Evaluation of Substances with Possibility of Safety Risk in Cosmetics(2010); Standard Chinese Names of International Cosmetics Ingredients Inventory (2010); Cosmetics Technical Requirement Standard(2011);Guidelines for the Registration and Evaluation of New Cosmetic Ingredient (2011); AQSIQ Order No. 143 of 2011 - The Administrative Measures on the Inspection, Quarantine and Supervision of Chinese Imported & Exported Cosmetics (2011).

Cosmetic Ingredients in China (IECIC) provides the list of allowable ingredients to be used, and the determinant for new ingredients.

I.2.2 Products categories and classification in China

According to the Article 2 of China's cosmetic regulation (1990), a cosmetic product is "an industrially produced chemical product subject to daily use, which are intended to be placed in contact with any external parts of human body (skin, hair system, nails, lips and oral cavity) by spreading, rubbing, spraying, sprinkling etc., with the purpose of cleansing, correcting body odors, protecting, maintain function or changing their appearance." The definition was broadened to include the "products which can be spread on the outer surface of human body (e.g. skin, hairs, and nails. lips etc.), the teeth and oral mucosa for the purpose of cleaning, protecting, beautifying, deodorizing and keeping in good condition, by way of smearing, spraying or other similar means."

Furthermore, China has established a distinction between "special cosmetics" and "ordinary cosmetics". The special cosmetics refer to the products that are considered having a special function, including hair growth products, hair dye, products for waving or straightening hair, hair removal products, beauty breast products, products for body fitness (e.g., slimming cream), deodorants, products for anti-spot or UV protection. In other words, special-use cosmetic correspond to the cosmetics used for "special purpose" under Chinese standards. Possibly presenting a greater health risk than "ordinary cosmetics", they are naturally subjected to more inspections and tests.

The definition of ordinary cosmetics is a definition by default and refers to any products other than special cosmetics and that comply with Article 2 on the definition of cosmetics.

I.2.3 Pre-market approval in China

The 1990 umbrella law has established a pre-market review scheme whereby all imported cosmetic products are subject to a pre-market review by CFDA. Despite the fact that China has been revising its framework statutes for drugs, devices, food and cosmetics for over three years and has been expected to soften the rules; the pre-market assessment system for all imported cosmetics as of now implies that a local responsible agent must be identified and then submit the pre-

market application dossier and be there to hold the market permit on behalf of the foreign importer. To be able to sell in the Chinese market, all foreign cosmetic product manufacturers through their agent must successfully complete a safety and health quality test, and obtain a hygiene permit for their products. Only laboratories designated by the CFDA shall perform the test; the list of laboratories is available on the CFDA website. The laboratory test report, issued together with other required documents for the application of the Hygiene Permit will be examined by the CFDA. A hygiene certificate, valid for 4 years, will be issued by the CFDA. Foreign manufacturers are required to renew the hygiene certificate at least four months before it expires. These constitute one-off formalities that shall become obsolete in the near future. The current pre-market application for imported ordinary cosmetics will be removed. Instead of the notification carried out by a local responsible agent, a system of post-market compliance will be created. The forthcoming system shall include adverse effect monitoring, product traceability, and redesign of label of the Chinese market.

Domestically manufactured for the nine categories of special use products (i.e. products for hair growth, hair dye, hair perm, hair removal, breast shaping, fitness, deodorizing, spots removal (whitening) and sun block) are also subject to a pre-market review by CFDA.

I.2.4 Manufacturing, ingredients, and safety requirements for China

After an overhaul by the CFDA of the regulations in 2014, three principles for the management of cosmetics were laid down, modelled after European regulations[18]. The first principle that was established is concerned with the notion of “responsibility” that rests upon the cosmetic manufacturer and the operator. The second principle is that of “self-regulation” for the cosmetics industry. The third one is that of “social supervision”, presumably laying down foundations for up keeping standards and getting feedback by civil society and consumer groups. The compulsory market permit obtained by the agent for

[18]China had signed a Memorandum of Understanding with the European Commission on the topic of trade and cosmetics in 2010. China has been willing to consider alternative means of safety assessment for cosmetics and a regulatory convergence with the EU supports an increase of trade exchanges between the two blocs.

imported cosmetics, and for domestic special cosmetics provides the safety validation for the products to be circulated on the market.

However, there exists no official guidance for the safety evaluation of cosmetic products in China. A draft Guidelines on Safety Risk Assessment of Cosmetic Products (GUIDELINES) exists, and has been compiled based on the Guidance for Safety Evaluation of Cosmetic Products in Europe. Toxicological tests for domestic non-special cosmetics may be waived on the condition that the risk assessment result is deemed sufficient to verify the safety of products.

Regulations also foresee that the Ministry of Health, under the State Council, must ratify any new "cosmetic ingredient" that is intended to be used in the production of cosmetics.[19] A dozen new ingredients have been approved since 2004. The evaluative approach for the new ingredients is based on risk management, with the competitive but not incompatible concerns of consumer safety on one side, and industry competitiveness, on the other. The CFDA released an amended version of the "Inventory of Existing Ingredients" in 2016, and the update includes the addition of nine ingredients. [20] In total, there are more than 8,000 approved cosmetic ingredients in China, and the 2016 update to the existing inventory shows that getting approval for a new ingredient is not an easy task.

I.3 EU main regulations on cosmetics

European regulations establish a clear distinction between cosmetic products and drugs, and include no intermediary third category like in the US. Regulations on cosmetics were created following the rules for the freedom of trade in goods and services in the European market Regulations also introduced the notion of the "responsible person" [21], not to be confused with the "responsible agent" in China.

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[19]The definition of new cosmetics ingredients corresponds to either natural or artificial raw materials that shall be used to produce cosmetics for the first time in China.

[20]Harungana madagascariensis extract, undeceth-3, decyl isostearate, tris(PPG-3 benzyl ether) citrate, chondrus crispus (carrageena) raspberry ketone glucoside, hesperidinase, PEG-50 hydrogenated palmamide.

[21]The person is in charge of ensuring the compliance with safety and good manufacturing practice for the cosmetic products, and usually is the EU manufacturer or EU importer, but it can also be a contractually assigned representative.

I.3.1 EU legislation, including Regulation (EC) N° 1223/2009 on cosmetic products

It has been just over forty years since the EU (named the European Economic Community at the time) adopted its first regulation on cosmetics, the EU Cosmetic Directive 76/768/EEC (safety of cosmetic products for human use). It was indeed in 1976 that the then nine member states (Germany, France, Italy, the Netherlands, Belgium, Luxembourg, Denmark, Ireland and the United Kingdom) adopted a directive aiming at harmonizing their national cosmetic regulations, to ensure a free circulation of cosmetics in the internal community market, with the requisite level of consumer safety therein. The "Cosmetic directive" was adopted against the backdrop of dramatic events due to the inclusion of hexachlorophene in adult products (soaps, facial lotions) and particularly; its accidental inclusion in baby products (talc), leading to 36 deaths and over 200 babies poisoned in France in 1972.[22] Member states agreed upon the safety standards that needed to be laid down to ensure the proper regulation of the fast-moving consumer products that are cosmetics, in the broad context of the free market. The Directive, which was to be transposed into each national system due to its nature as a legislative act; included rules on the composition, labeling and packaging of cosmetic products. With technological advances and research by the cosmetic industry, leading to the introduction of new products, rose the need to greater governance and the adoption of new texts. The creation of a free trade area in the EU (not unlike that of a region like ASEAN with its AEC i.e. the ASEAN Economic Community) provided the impetus for regulations eliminating unjustified barriers to trade.

It is important to note that however, beyond the benefits of the common market, regulations pursue the objective of higher level of protection for health and consumer rights. In 2009, was adopted by the European Union, a regulation aiming at increasing the level of safety of cosmetic products for the consumers. The EU Cosmetic Directive 76/768/EEC was thus replaced by the EU Cosmetics Regulation (EC 1223/2009) which entered into force on 11th January 2010

[22] L'affaire Du Talc Morhange, newspaper « La CROIX L'EVENEMENT (LA) » [No 27348] du 13/12/1972

and took full effect on 11th July 2013.[23] Each country in the EU has a competent authority that is responsible for upholding compliance. The EU' s framework of chemical and cosmetics regulations became therefore binding on all Member States and enforced at the national level.

I.3.2 Products categories and classification in the EU

According to the European Commission Dir. 93/35/EEC, Art. l, a cosmetic product is defined as "any substance or preparation intended to be placed in contact with the various 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 and/or correcting body odors and/or protecting them or keeping them in good condition." This definition gives an indication on the target site of application of a cosmetic product and on its allowed functions.[24] Thus, products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, soap products, shampoos, permanent waves, hair colors, toothpastes, deodorants, fall under the category of cosmetic products in the EU. More questionable product types such as sun tanning preparations, antiperspirants and antidandruff shampoos are also considered cosmetics within Europe, whereas this may differ in other parts of the world,[25] such as in the USA, as seen above, where those may also be considered as drugs. The EU definition of cosmetics really establishes only one possible category of cosmetics; there is no overlap or possible confusion between a drug and a cosmetic, unlike with the US system. ASEAN has followed suit and clearly circumvented the definition of cosmetics without creating an intermediary category between cosmetics and drugs. This system ensures allows, from the EU's perspective that cosmetic products do not make any type of medical or health benefit related claim.

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[23]Contrary to a directive, a regulation imposes rules that are to be immediately followed as it has binding legal force throughout every Member State. All it may need is a translation into the national language for its direct enforcement.

[24]Guidelines on Stability Testing of Cosmetics - Colipa-CTFA – 2004.

[25]Pauwels M. and Rogiers V. "How to improve the quality of a European cosmetic ingredients' dossier?" Oral presentation given during the Scientific Forum of the COLIPA (The European Cosmetic Toiletry and Perfume Association) General Assembly 2004, Amsterdam, 24/06/2004.

I.3.3 Pre-market approval in the EU

A "responsible person"[26] is designated by the EU Cosmetics Regulation with the responsibility to ensure that cosmetic products are safe for consumer use. This responsibility is placed upon the manufacturer or his authorized agent or any other *person responsible* for placing the product on the Community market.[27][28] Safety of cosmetics and their ingredients is guaranteed through a safety assessment mechanism, and for that purpose a unique dossier (Product Information File) needs to be composed, by a qualified safety assessor, holding a specified diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline, or a course recognized as equivalent by a Member State[29] to undersign the safety assessment of the cosmetic product under consideration and guaranteeing the safety of the product when applied under reasonably foreseeable conditions of use.

Overall, the responsible person has several roles: prior to placing a cosmetic product on the market, she/he must ensure that the cosmetic product has undergone a safety assessment. She/he is responsible for maintaining a product information file. She/he shall submit electronically, the notification of the cosmetic to the Commission. She/he is also responsible for the compliance with restrictions for substances listed in the Annexes of the Regulation and other substances (such as CMR, nanomaterials, or traces of prohibited substances). She/he is also in charge

[26]The designated Responsible Person (or EU Brand Owner) is required to submit certain information about cosmetic products and their product specifications to the Cosmetics Products Notification Portal (CPNP) , an online notification platform; they intend to make them available on the EU Market.In ASEAN, the responsible person corresponds to the person responsible for placing the cosmetic products in the market. In China, exists the notion of « responsible agent », which is different. This agent only undertakes the registration of the product. His main task is to make sure that the cosmetics complies with all the requirements of the regulations. He is however, not responsible for the product's safety once it is approved and released on the Chinese market. Tellingly, he does not have its name and address printed on the primary container and secondary packaging. The distributor, importer or a regulatory affairs consultant can take up the role of a responsible agent.

[27]EU, 1993a

[28]The responsible person may be a natural or a legal person. His/its name and address must be printed on the primary container and secondary packaging of each product for which he/it takes responsibility.

[29]EU Cosmetics Regulation (EC 1223/2009), Art. 10.2 on safety assessors of cosmetics

of ensuring the respect of both labelling and product claims. Finally, she/ he must communicate to the Member State serious undesirable effects.

I.3.4 Manufacturing, ingredients, and safety requirements for the EU

Companies that import into the EU should ensure that the responsible companies, down the supply chain, hold the information they require in order to fulfill any registration obligations. Importers and manufacturers of substances in(to) the EU must take direct responsibility for their substances, unless responsibility is taken by another link in the supply chain.[30]

By means of a post-marketing surveillance system, the EU Member States are expected to take all necessary measures to ensure that only cosmetic products which conform to the provisions of Dir. 76/768/EEC and its Annexes may be placed on the European market.[31] Nevertheless, the ultimate responsibility for the safety of a cosmetic product resides with industry. Inspectors appointed at national level may visit retailers selling cosmetic products to check these products. If necessary, these inspectors may take any product from the market to official laboratories to be tested for compliance with EU regulations. The official testing of cosmetic products carried out by laboratories of any kind (national, control, etc.) has to be done in accordance with the European official methods of analysis.[32]

The 2009 Cosmetics Regulation prohibits the placing on the market of cosmetic products, or products containing ingredients, which have been tested on animals to meet the requirements of that regulation using a method other than a validated alternative method.

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[30]Regulation (EC) No 1907/2006 (abbreviated REACH) governs the registration, evaluation, authorisation and restriction of chemicals in the European Union. With respect to ingredients used in cosmetic product, the responsibility to comply with REACH is placed on companies (legal entities) manufacturing or importing substances (on their own or as part of finished cosmetic products) in quantities exceeding 1 tonne, per legal entity, per year. Companies using substances to manufacture cosmetic products are known as “downstream users”. The supplier's is on the other side to this issue of “obligations”.

[31](Art. 3) (EU, 1993a).

[32]http://ec.europa.eu/growth/sectors/cosmetics/assessment_en

I.4 ASEAN's main regulations on cosmetics

The ASEAN Cosmetic Directive (ACD) has been adopted with a view of reducing trade barriers for the trade of cosmetic products without compromising on product safety and quality. The directive's objective is also to make ASEAN more competitive in the region for this sector. ASEAN countries with little or inexistent cosmetics laws and regulations, such as Singapore have the possibility to implement the entirety of the directive.

I.4.1 The ASEAN Cosmetic Directive, 2003

The ASEAN Harmonized Cosmetic Regulatory Scheme was adopted in 2003with the view of removing technical barriers to trade by harmonizing regulatory and technical requirements across ASEAN. Composed of two Schedules, it became the standard scheme for regulating cosmetic products among the ASEAN countries. The objective of free trade inside the region is not yet fulfilled, to the extent of a fully integrated economic system such as that of the EU. Nonetheless, the Regulatory Scheme paves the way for more trade exchanges due to the lowering of barriers in the ASEAN region. ASEAN may be looking at the EU as a successful model of economic integration and emulate some of its regulatory principles insofar they fit the market model of ASEAN countries. The first principle for the management of cosmetics laid down by ASEAN

Schedule A, relating to "The Mutual Recognition Arrangement of Product Registration Approval (MRA)" enabled a product for which registration is processed and issued by one country to be recognized by the ASEAN countries signatories to the MRA. MRAs serve the objectives for the signatories parties to mutually recognize or accept some or all aspects of one another's conformity assessment results such as test reports.

Schedule B corresponds to the ASEAN Cosmetic Directive (ACD). It essentially provides a system of notification.

I.4.2 Products categories and classification in ASEAN

According to the ACD, a "cosmetic product" refers to "any substance or preparation intended to be placed in contact with the various 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 for the purpose of cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition".[33] All cosmetic products marketed in the ASEAN member countries shall conform to the provisions of the ACD as well as its Annexes and Appendices including safety, ingredients, labeling and claims requirements and GMP.

I.4.3 Pre-market approval in ASEAN

The Schedule B of the ACD stipulates that the manufacturer or the person responsible for placing cosmetic products on the ASEAN market needs to notify the cosmetic regulatory authority of the Member(s) State(s) where the product will be marketed of the place of production, or of the origin of the imported product, before it is placed on the ASEAN market. This system marks the transition from a pre-market approval (registration) system to post-market surveillance, and is already effective in most ASEAN countries.

I.4.4 Manufacturing, ingredients, and safety requirements for ASEAN

The ASEAN Ingredient Listings is the reference document of all ASEAN Member Countries in the review of formulations of cosmetics. It also provides the list of ingredients that are banned or restricted for use, the positive list of colorants, preservatives and UV filters that are allowed for use in cosmetic products marketed in ASEAN.

II. THE PROCESS OF LAW-MAKING AND THE ADOPTION OF REGULATIONS ON COSMETICS IN THE USA AND CHINA AND THE REGIONAL BLOCS: EU AND ASEAN

II.1 Towards an international harmonization of cosmetic regulations?

The hygiene and beauty products have developed into a highly expert and profitable industry, with a steady acceleration in the course of the last century. Along with scientific progresses and the affordability component, a broad scale

[33]The ASEAN 's definition is almost word-for-word the European definition of a cosmetic product.

distribution of the products was made possible. To ensure safety and efficacy, cosmetic products are regulated and controlled worldwide.

However, an international harmonization of laws dealing with cosmetics is far from being achieved as regulatory frameworks vary greatly between countries; making it practically impossible for a company to sell the same product on all markets following the exact same manufacturing methods and registration techniques. Precisely because the regulatory requirements of different countries vary considerably, a harmonization of cosmetic regulations among countries is a worthy goal. As we move toward a global economy with more countries placing an emphasis on imports and exports, harmonization would assist in the reduction of barriers to trade.[34] Regulatory complexity is an obstacle to the global competitiveness of the cosmetics and personal care industry and the current fragmented regulatory framework can generate additional cost, complexity and duplication, and limit market access. Harmonization may also be pursued not merely for freer trade objectives, but also for ensuring better consumers' safety worldwide, increasing both the accountability from the part of cosmetic manufacturers and facilitating access to information for the public.

The two regulatory frameworks of significance for the cosmetics industry (namely its stakeholders: the manufacturers, traders and consumers) have traditionally been the frameworks developed by the EU and that of the USA. The main law for finished cosmetic products when placed on the EU market is the 2009 regulation (EC) N° 1223/2009 on cosmetic products while the FD&C Act and the FDA guidelines continue to exert a strong influence over the cosmetic industry across the world, bearing in mind that North America is one the main markets for the cosmetic industry. A number of regulations, notably about labeling and marketing are based on EU standards in many countries and regions of the world, and legislators and regulators have emulated the EU regulations, through the adoption of legal texts transposing parts of the EU legal provisions into their own national systems. In September 2003, the countries of ASEAN approved the cosmetic directive, which was directly modelled after the 6th amendment of the EU directive.

[34]Hendrick BS, Horton I-R. "International Harmonization of Cosmetic Regulation", in: Paye, Marc, Barel, André O; and Maibach Howard I. (2005) "*Handbook of Cosmetic Science and Technology*" Second Edition, CRC Press. (Chapter 14).

The ACD provides an authoritative (by the way of the hierarchy of laws) and collective regulatory framework, similar to that of the EU, so that each member state country needs to transpose all the provisions into their national legal frameworks.

But legal and regulatory differences remain for the four geographical zones and countries of this study; a potent example being that of the "intermediary categories" of cosmetic products such as the OTC cosmetic drugs in the USA and the special use cosmetics in China. Caution is required when selling products belonging to these intermediary categories in those countries; as there are ingredients that are not approved for cosmetics but are approved for intermediary categories such as hair dyes or perming agents.[35] In the EU and ASEAN, ingredients that are prohibited for cosmetics but are approved for intermediary categories are categorized as restricted ingredients (Annex III) and their use is limited to specific cosmetics. Manufacturers and sellers must be acutely aware of regional differences regarding cosmetic ingredients and comply with each country or region's regulations and laws, for they do not want encounter glitches with local authorities and risk having their products quarantined.

General requirements for cosmetic products, whether sold in the US or the EU, China or ASEAN, are that they must be safe, effective, stable, and have the same quality over batches.[36] This is a worldwide consensus that has been well translated in the regulations and laws of the regions and countries of this study. But for instance, in the USA, there is no official mandatory quality assurance system for cosmetic manufacturing. The FDA highly recommends cosmetic manufacturers to follow the Good Manufacturing Practices (GMP) and issued a guidance for the industry to this effect.[37] In the EU, all cosmetic products placed on the market must be manufactured according to the Cosmetic GMPS described in the ISO 22716 standard. Therefore, all non-European markets importing to the EU are concerned since they have to meet the European standard to be able to enter their products

[35]Sakamoto, Kazutami; Lochhead, Robert; Maibach, Howard; Yamashita, Yuji (2017) "*Cosmetic Science and Technology: Theoretical Principles and Applications*", Elsevier.

[36]Baki, Gabriella; Alexander, Kenneth S. (2015) "*Introduction to Cosmetic Formulation and Technology*", Wiley Eds.

[37]Ibid

into the market. To keep up with the EU regulations, many companies follow the GMP outside the EU as well, even if they do not want to import to the EU. Following cosmetic GMPs is a decision that need to be made by manufacturers according to their business plan for the foreseen geographical distribution of their products, in accordance with their principles, and budgetary capabilities. But the example aforementioned shows that following GMP or for that matter, other types of standards, is not always a necessary requirement for selling products on a given market.

II.2 Ethics and the cosmetic industry: different approaches

II.2.1 Animal-testing

The use of animal-testing methods has been controversial and pointed at negatively by media and non-governmental organizations alike. Cosmetic companies have historically tested ingredients, as well as finished products, on animals (typically rabbits and mice) to check their safety levels and these practices have been -if not endorsed-, well known by the public for decades. Although there is a move to phase out animal testing in the industry, it is likely to be many years (if not decades) before a global ban is introduced and then enforced.[38]

Europe introduced its own "Testing Ban", i.e. the prohibition to test finished cosmetic products and cosmetic ingredients on animals on finished cosmetics, in 2004. The "Testing ban on ingredients or combination of ingredients" followed suit and has applied since 2009 with the "EC Regulation 1223/2009 on cosmetics". Imported cosmetics ingredients tested on animals were phased out for EU consumer markets in 2013 by the ban, but can still be sold to outside of the EU.

For China, cosmetic products manufactured by foreign companies and exported to China are currently required by regulations to undergo animal testing prior to approval for the Chinese market. Nevertheless, some changes have occurred. Cosmetics which are not used for special purposes may, under certain circumstances, receive approval without the use of animal testing. In 2014, the CFDA introduced a simplified filing scheme for domestically manufactured general

[38]Sahota, Amarjit (2014) "*Sustainability: How the Cosmetics Industry is Greening Up*", Wiley Eds.

cosmetics and subsequently removed mandatory animal testing requirements.[39] Furthermore, cosmetics intended solely for export are exempt from the animal testing requirement. However, animal testing is still mandated by law for Chinese-made "cosmeceuticals" (cosmetic goods which make a functional claim) which are available for sale in China. It is important to add that any cosmetic sold on shop shelves in China may also be subject to post-market testing. Such testing may be conducted regardless of whether pre-market animal testing had been conducted. This testing may include animal testing and is conducted either randomly or in response to consumer complaints by provincial authorities, whether at random or in response to consumer complaints. Tellingly, the tests are often conducted without a company's knowledge, demonstrating the actual ideological stance – or lack thereof- on the testing of cosmetic products on animals.

The USA are somewhat at the other end of the spectrum. Although the US FDA does not require animal safety testing for cosmetics, animal tests are still used.

For the ASEAN area, as is the case in the United States, there are currently no regulations or laws banning animal testing of cosmetic products and ingredients or the importing of those tested elsewhere. A safety assessment of all cosmetic products is compulsory for the region. However, there is no mandatory requirement as to what method to use, which leaves the door open to animal-testing methods. The responsibility for the method used lies with the company. A decision has recently been made proposing a ban on finished cosmetics product testing on animals in Korea, and other countries and maybe ASEAN may follow suit.

II.2.2 Sustainability concerns

Apart from the ethical issues surrounding animal testing, the industry is often criticized for its selection and use of raw materials, environmental impacts and safety issues of finished products. The industry sources raw products that may have detrimental effects on natural environments and animals' habitat. One of the biggest user of palm oils, the industry has negatively affected rainforests in Indonesia and Malaysia. The company Unilever, has, in a favorable move, decided

[39] A temporary and similar measure in place from 1 March 2017 through 21 December 2018, was adopted, targeting products imported through Shanghai to undergo a simplified filing system.

to source only sustainable palm oil after being named an unethical buyer of palm oil by Greenpeace in 2009.

The industry is closely linked to the chemical industry. Worrying examples of cosmetic products residue contamination include triclocarban and triclosan. In soaps, disinfectants and sanitizer, anti-microbial ingredients of both components are present. They get into fresh waterways from waste treatment plants after entering sewers from consumer households and pollute the soil. Micro-beads used in cosmetics products for their exfoliating and texturizing properties have also come under the spotlight recently. Slow to biodegrade, they accumulate in water and are ingested by marine life and create long term damage.

Environmental pollution stemming from the production of cosmetic products has also raised many concerns over the years. The excessive use of plastic and not biodegradable materials by the industry is also a worrying trend. Skin care products and perfumes are typically housed in layers of packaging.

As environmental issues have gained momentum in public affairs over the past decades, the area of environmental law steadily found its rightful place in national laws as well as international law. Industries have had, with more or less reluctance, to adapt their practices and adopt more sustainable modes of production, even though there is discrepancy at the implementation level across industries and geographically. Evermore, informed consumers have welcomed friendlier environmental company practices. Their requirements for products issued from sustainable based practices with more ethical-based sourcing modes have in turn paved the way for stricter regulations.

These factors marked the seemingly irreversibility of a greener age in production and in related legislation. The cosmetics and personal care industry is taking initiatives to strive toward greener processes and products but more work needs to be done. If a product can be designed with little or no waste, using low-energy techniques, from renewable resources and if it will biodegrade when appropriate and not persist in the environment, then it will not only be successful in the marketplace but will also contribute to a sustainable future.[40] The public

[40]Lintner, Karl (2009) *"Global Regulatory Issues for the Cosmetics Industry",* Vol. II, William Andrew Eds.

needs education about sustainability issues, so as to be more empowered in the choices they make when choosing a particular cosmetic product, with a full knowledge of the potential risk to the environment. Over time, consumers may adopt products for which the manufacturing process has less adverse impact on the environment and the planet. While this may come at a cost, for both the consumers and the industry, it is one of the essential way[41] forward to preserving the humanity's resources.

II.3 Is the future "organic"?

The wide range of products and the complexity of their composition present a formidable challenge to the analytical chemist, as well as to the toxicologist and the formulation scientist; indeed, a glance at the very complicated mixture of ingredients listed on the label of a popular sunscreen liquid gives a good indication of how challenging is the analysis of such a product and how important it is to employ officially validated methods.[42] This complexity is now proven as a cause for worries. The search for products performance and efficacy is more and more questioned in the light of health concerns raised by the levels of chemicals used in the formulation of cosmetic products and the potential adverse effects they may have on human's health. After all, we are a part of nature, not apart from nature. All our qualities spring forth from an organic "soil". Nature always rises again, bringing forth new life. Perhaps, the very nature of chemical cosmetics does not bode well with our essence as natural beings who may choose complex chemical formulations for healthcare, rather than the pursuit of beauty or even hygiene. Decades of ignorance about the potential adverse effects of the long-term use of cosmetics on human's health, coupled with promotional campaigns by the brand and a relative passivity by the public, have not yet threatened the cosmetic industry in the form we know and use today. But awareness about the dangers linked to the utilization of cosmetics, along with the emergence of new brands of natural and organic cosmetics may well soon totally "change the face" of the industry.

[41]Many other industries are concerned with the issues of sustainability and should follow suit.

[42]Chisvert Alberto; Salvador, Amparo (2007) "*Analysis of Cosmetic Products*", Ed. 2011, Elsevier.

As with the issue of sustainability raised above, a continued education of the public on the dangerous effects on health provoked by the repeated use of some chemical substances shall lead to consumers to make more informed choices about the cosmetics they wish to purchase and use. This, in turn, shall influence the multi-billion dollar industry to revise its practices and turn to greener methods of sourcing and producing. The governments and international organizations championing free trade also have a part of responsibility, arguably; by default or omission. The cosmetic industry has indeed been let to grow with less regulatory barriers than would have been desirable, considering the overwhelming issues related to the public and environment's interests.

II.3.1 The legal definitions

Legal definitions are fundamental instruments that the lawmaker uses to try to reduce the interpretative freedom of the interpreter and forge a technical language through the re-use of terms belonging to ordinary language.[43] It is thus important to differentiate between the terms "green", "natural" and "organic" cosmetics .Their definitions have evolved over time and continue being reframed within legislations; and whilst it is important to distinguish between these three notions, distinctions must be made from what they mean from a geographical area to another. It is necessary to approach the definitions of the three concepts "green", "natural" "organic" per regional bloc and per country studied, so as to be able to understand the basic definitions underpinning cosmetic regulations . Definitions help us limit the interpretative discretion of a sentence to a legal norm . However, legal definitions need to go through a process of meaning attribution[44] The very notions under scrutiny have different meaning and the differences underpin and illustrate the various routes taken by various stakeholders when it comes to the adoption of cosmetic law. As the world increasingly transitions to a global economy, the jurisdiction of national laws has diminished. Nongovernmental standards present a mechanism for establishing common rules of marketing across borders. Such standards have emerged for organic and natural personal care products. The world is rife with brands making false natural and organic marketing claims, with some placing fake logos and symbols on product packs. As a

[43]Garavelli Mortara, Bice (2001) « *Le parole e la giustizia* », Piccola Biblioteca Einaudi Ns, p.11.

[44]Tarello, Giovanni (1980) "*L'interpretazione della legge*", Giuffré, p.155.

consequence, there is a high level of consumer confusion about natural and organic cosmetic ingredients.

II.3.2 "Green cosmetics"

Green cosmetics seem to have the least legal existence in cosmetic laws, or at least a conspicuous absence in terms of definitions in legal texts. Green may therefore refer to processes that are either environment friendly, or to products that may contain natural or organic ingredients. More than a textual definition, green would be an intuitive word with an almost all encompassing-meaning for cosmetics that would have been made in an "environmentally friendly manner" or with "natural ingredients."

II.3.3 "Natural cosmetics"

The word "natural", as often used by cosmetic manufacturers, does not have any legal basis *per se*. It does not rest upon legal texts or regulation . Therefore, a legal claim that a cosmetic is "natural" would lack legal grounds .Only general rules apply, such as a prohibition against misleading consumers and an obligation to justify the truthfulness of claims .

In the USA, the term "natural "has not been defined by the FDA. Furthermore, there exist no regulatory definition for this term in cosmetic labeling .

In China, concerns have been raised over the increase of the production and subsequent online sale of homemade cosmetics (DYI or "do it yourself" production process) called "natural" by their manufacturers. The authorities have deemed these products not conform to the existing Regulations concerning the Technical Safety Standard for Cosmetics.[45] There would also be in almost all cases, an absence of the licenses and authorizations required to sell cosmetic products on the market.

In the USA, terms of using the word "natural" on the label, the current "regulations on the issuance of cosmetics named after notice and naming guidelines" deal with the greatest caution regarding the use of the word by

[45]China, Regulations Concerning the Hygienic Standard of Cosmetics) Version 2007 (Replaced by the Technical Safety Standard for Cosmetics, 23rd December 2015, effective since 1st December 2016 http//:www.sda.gov.cn/WS01/CL0781/126540.thml

producers.[46] The claim that the product is "natural" needs to be substantiated by justifying documents, and it cannot be claimed that the product is, for instance "absolutely natural" unless being capable of providing the irrefutable proof of this.

Today, there is no European harmonized standard which sets criteria for natural and organic cosmetics.[47] Nonetheless, any claim must be capable of substantiation and must not be misleading. The Directive on Unfair Commercial Practices (2005), and prevents manufacturers from making false claims on products that are of natural or organic nature.

II.3.4 "Organic" cosmetics

A growing number of organic brands are going for official "organic" certifications for their products. Nonetheless, due to the lack of an official regulatory definition, there has been a proliferation of private standards providing certifiable definitions to reassure thousands of consumers in contrast to "green washed" or "nature-inspired" products.

In the USA, there exists no definition of the term "organic" in either of FD&C Act or the FPLA, or the regulations that FDA enforces under their authority . However, the USDA regulates the use of the term "organic" under the National Organic Program[48], which has been developed for organically grown food. As per the Board of the National Organic Standard, "The principal guidelines for organic production are to use materials and practices that enhance the ecological balance of natural systems and that integrate the parts of the farming system into an ecological whole."[49] If a cosmetic, body care product, or personal care product contains or is made up of agricultural ingredients, and can meet the USDA/NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations.[50] A manufacturer wishes to oppose a

[46]Regulations on the issuance of cosmetics named after notice and naming guidelines, State Food and Drug Administration (2010).

[47]Clarification of the absence of European harmonised standard for natural and organic cosmetics (2012) available at :file///:C/:Users/User/Downloads/organic_standard_en.pdf

[48]National Organic Program, 7 CFR Part 205; available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=a520b30a1496ffe597447c8f1858d469&mc=true&node=pt7.3.205&rgn=div5

[49]On the United States Department of Agriculture, National Agricultural Library website at:https://www.nal.usda.gov/afsic/organic-productionorganic-food-information-access-tools

[50]Ibid

label featuring the word "organic" on his products, he needs first and foremost to seek the certification granted by the USDA under the NOP programme. Under the scheme, "cosmetics, personal care products, and body care products are eligible for the same 4 organic labeling categories as all other agricultural products, based on their organic content and other factors."[51] The standards are notoriously hard to meet for manufacturers of cosmetics. For instance, the standards do not allow the use of synthetic preservatives. Only surfactants derived from organic sources may be used, excluding the use of no petrochemicals.

International certifying bodies for organics are not officially recognized in China, but there are no official standards for organic cosmetics in the country. A certification by the Certification and Management for Organic Products (CNCA) used to operate but has been cancelled by the state a few years ago. What is more, well-established international organic cosmetic brands shy away from the Chinese market due to the animal testing requirements for the registration of the products, which could hamper their reputation.

Not unlike China, in the ASEAN region, the demand for organic cosmetics is perceived as having a lot of potential, spearheaded by a growing demand in Thailand and Indonesia. The ASEAN Cosmetic Directive (2008) does not provide a definition of "natural" or "organic cosmetics. Rather, it stipulates in its article 7 that Member States shall be responsible for ensuring that product claims comply with the guidelines. The directive provides a broad approach that allows countries to adapt their legislation to their national specificities. Unfortunately, the current absence of official uniform certification and the false claims made by many a brand have somewhat deterred the niche market from blossoming the way it could.

In the EU, any claim that a product is organic must be capable of substantiation. Five founder members (COSMEBIO, BDIH, Ecocert, ICEA and Soil Association) have developed the European COSMOS standard, theoretically applicable worldwide and that has become mandatory for all organic cosmetic products to obtain prior to being launched on the EU market after the 1st January 2017.

[51] Ibid, p.1

An even more ambitious project in terms of geographical scope has been developed. Scheduled to be finalized and introduced later this year, hope has been vested in the upcoming "ISO 16128: the technical definition and criteria for natural and organic cosmetics" currently being developed by the International Organization for Standardization (ISO), a well-established and respected organization. Expected to come out this year, will this be the global standard the industry has been calling out for? A harmonization of standards on organic cosmetics is desirable for the public, which would be able to trust and rely on the claims made on the products' labels. Non-conforming products or firms would face legal problems and eventually, the industry would want to comply with the standards in an effort to answer the growing demand for organic cosmetic products.

Conclusion

The cosmetic industry is growing, and the business models are changing in the light of recent demands by consumers for more natural and safe products. However, the current overall regulatory model for the cosmetic industry has many more successful days ahead; and the demand for cosmetic products shows no signs of slowing down, with ever growing market, notably in the Asia-Pacific region and Africa. National laws and regulations are impacted by international agreements and supranational norms; yet, there are many existing conflicting standards and regulations that vary from a geographical area to another.

As the industry is moving towards greener and more sustainable practices, one can imagine more international harmonization of cosmetic laws. WTO members regularly meet as a Technical Barriers to Trade (TBT) Committee, to discuss challenges and experiences on how to apply product regulations and standards without causing undue obstacles to trade, and consumer products have been on and even dominated the agenda of the discussions that took place last May in the last Committee meeting. Further regulatory cooperation on cosmetics is expected, but the motor for cooperation in this particular forum is the lessening of trade barriers, rather them the promotion of more sustainable and greening practices by the cosmetic industry. Ideally, it is the triad of consumer safety, environmental protection, and economic sustainability for producers that would mostly fuel international regulatory progress. The article 20 of the General Agreement on Tariffs

and Trade (GATT) allows governments to act on trade in order to protect human, animal or plant life or health[52]. This paves the way for the strengthening of national legislation on organic cosmetics for example. With an ever growing flux of international trade in cosmetics, the need for increased harmonization shall also grow. Initiatives such as the ISO 16128 follow this principle. It is high time that regulations catch up with industries whose actions pose threats to human health and the environment, and act in impunity.

[52]There are two specific WTO agreements dealing with food safety and animal and plant health and safety, and with product standards in general.