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Review

Overview of Cosmetic Regulatory Frameworks around the World

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Abstract: To ensure safety and efficacy, cosmetic products are regulated and controlled worldwide. However, the regulatory approaches of each country may be significantly different and impact the competitiveness and economic viability of the industry. This work presents an updated review and comparison of regulatory requirements from the European Union, United States of America, Canada, Japan, People's Republic of China and Brazil. It outlines contents such as the definition, classification and categorization of cosmetics, pre-market requirements, ingredients management, general labelling requirements, regulation of claims concerning advertisement and commercial practices, increase of animal testing and marketing bans on cosmetic products. Furthermore, it weighs the impact of regulatory differences on the safety and accessibility of these products in the mentioned regions.

Keywords: cosmetics; regulation-based framework; standard-based framework; harmonization

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1. Introduction

The cosmetic industry is a global, everchanging growing sector. Over the past decades, the industry innovation was immense, resulting in a wide range of new products and increase of sales. In 2020 alone, the global cosmetic market was valued at USD 341.1 billion and is expected to hit USD 560.50 billion by 2030, with a compound annual growth rate of 5.1% from 2021 to 2030 [1].

Because it is a highly innovative, fast-paced and complex sector, the cosmetic industry must be regulated to ensure the safety and quality of cosmetic products, thus avoiding adverse impacts on the consumer health. However, regulatory frameworks differ between markets/countries and are far from being harmonized, which greatly challenges the possibility for a global industry to sell the same product on all markets [2]. The major markets follow broadly similar regulatory elements; however, the existing differences are enough to impact the industry, by restricting innovation and reducing the potential growth of the market. Additionally, such differences can also affect international trade and hinder the role of the regulatory authorities that ensure every product complies with the regulations used by each country [3].

For these reasons, it is essential to find solutions that can lead to the alignment of cosmetics regulatory frameworks, to encourage innovation, enhance the market growth and eliminate restrictions to trade. To achieve this objective, several international organizations have been making concerted efforts in this direction. One example is the International Cooperation on Cosmetics Regulation (ICCR), established in 2007, which is a voluntary group of cosmetic regulatory authorities from Brazil, Canada, Chinese Taipei, the European Union (EU), Japan, the Republic of Korea, and the United States of America (USA), which meet on an annual basis to discuss several topics related to cosmetic safety and regulation

(e.g., alternatives to animal testing, nanotechnology, microbiological limits) [4]. Other examples include the Organization for Economic Co-operation and Development (OECD) [5] and the International Organization for Standardization (ISO) [6], which have a key role in the mutual acceptance of testing methods guidelines and in the development of international standards on cosmetics. However, much can still be done to support the ongoing dialogue and to strengthen the existing cooperation efforts between the different countries.

This review presents an overview of the regulations for cosmetic products in the EU, the USA, Canada, Japan, the People's Republic of China and Brazil, which represent some of the main markets across the globe. In particular, it discusses the current regulatory frameworks, definitions and classifications, product registration requirements, regulations related to ingredients, general labelling requirements, and advertising and claim substantiations applicable to cosmetic products in these countries. Furthermore, the consequences of these cosmetic industry regulatory differences are also discussed.

2. Current Regulatory Framework

The cosmetics industry is a global sector that has experienced a significant global growth over recent years. It is a very competitive field in which marketing plays a fundamental role, especially nowadays with social media and online commerce, which greatly facilitate the advertisement of products on a global scale. International trade is also crucial for the cosmetics industry, contributing to its growth and innovation, and ensuring that consumers' demands are met and that everyone has access to the same products. However, this can be a challenge since cosmetic products are regulated differently in different regions of the world, making it difficult to ensure compliance in all countries. To surpass these problems, several efforts have been made to harmonize regulatory frameworks worldwide and facilitate international trade. For instance, in the EU, all member states follow the same legislation. The cosmetic regulatory framework is provided by Regulation (EC) No. 1223/2009 of the European Commission, which has the overall responsibility for cosmetic legislation, and is then enforced by the competent authority of each member state. This Regulation, which replaced the previous Directive 76/768/EC, adopted in 1976 [7], was a step towards a regulatory harmonization across all EU states and also an adaptation to much-needed technical progress. However, such progress has not yet been observed in other regions. For example, in the USA, the two most important laws related to cosmetic products and regulated by the Food and Drugs Administration (FDA)—the Federal Food, Drug and Cosmetic Act (FD&C Act), and the Fair Packaging and Labeling Act (FPLA)—have been enforced, respectively, since 1938 and 1966, and have remained essentially unchanged with just a few amendments [8]. A similar situation is observed in Canada, where regulations—the Cosmetic Regulation Act (1977) and Food and Drugs Act (1985)—have undergone only a few amendments over the years [9].

In contrast, Japan and China have undergone recent modifications. In Japan, since 2014, cosmetic products are regulated under the Pharmaceutical and Medical Devices Law (PMDL) by the competent authority, the Ministry of Health, Labor and Welfare; this replaced the previous Pharmaceutical Affair Law (PAL), dating from 1960. Likewise, China is undergoing a large institutional reform that started in 2018. Currently, there are three major competent authorities in the cosmetic sector: the State Administration for Market Regulation (SAMR), the National Medical Products Administration (NMPA) and the General Administration of Customs (GAC). The new cosmetic regulation, Cosmetic Supervision and Administration Regulation (CSAR), was implemented on 1 January 2021, replacing the former Cosmetics Hygiene Supervision Regulations (CHSR), from 1990. As a follow up to this general regulation, several subsidiary regulations have been announced, notably related to the registrations and notification process, good manufacturing practices (GMPs), and monitoring of adverse reactions, among others [10,11].

In Brazil, cosmetic products/sector are regulated by three authorities, the Ministry of Health, the Brazilian Health Regulatory Agency (ANVISA) and the Hygiene, Perfume, Cos-

metics and Sanitizing Products Management (GHCOS), through a number of resolutions, which have been amended over the years [12].

3. Definition and Categorization of "Cosmetic Product"

Although similar, the definitions for "cosmetic product" differ slightly in the six markets discussed herein (Table 1). Mostly, such definitions are based on the functions of the product, parts of the body where it is applied, mode of application, indication of use, claims and consumers' perspectives. However, in reality, depending on the country, products have different regulations and classifications.

Table 1. Definition of "Cosmetic Product" by country or region.

Region or Country	Definition of "Cosmetic Product"	References
EU	"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 odours"	[13]
USA	"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"	[14]
Canada	"Includes any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes"	[15]
Japan	"Articles with mild action on the human body, which are intended to be applied to the human body through rubbing, sprinkling or other methods, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition"	[16]
China	"Daily chemical products intended to be applied on the external part of the human body (such as skin, hair, nails, lips, etc.) by spreading, spraying, or other similar ways for cleansing, protecting, beautifying, or grooming purposes"	[17]
Brazil	"Preparations made from natural or synthetic substances, for external use in various parts of the human body, skin, hair, nails, lips, external genitals, teeth and mucous membranes of the oral cavity, with the sole or principal purpose of cleaning, perfuming, altering and correcting bodily odors and/or protecting or keeping them in good condition"	[12]

In the EU, the definition is based on the site of application and intended functions, and borders a range of other categories such as medicinal products, biocides and medical devices. However, each product can only fall into one category. This rule does not apply worldwide. In the USA, for example, a product can simultaneously belong to two categories; for example, an antidandruff shampoo is classified as both a cosmetic and a drug because it has two intended uses, to clean the hair (cosmetic) and to treat dandruff (drug). In these cases, the product must meet the requirements of both sets of regulations [18].

The borderline between categories and legislations is a concern common to all regions. It is a problem because the same product might be classified into different categories depending on the region or country where it is being marketed and, therefore, be subjected to requirements different from those applicable to cosmetics. For example, there are products that generally require pre-market approval and are subjected to limitations on composition and manufacturing processes, which reduces flexibility whilst not necessarily increasing safety. This, together with the aggravating factor that some of those categories do not even exist in some countries, may prevent international trade.

For instance, in the USA, the FD&C Act defines two main categories of products: cosmetics and drugs, the latter including a sub-category of over the counter (OTC) drugs which can be sold without prescription [19]. Identically, in Canada, besides cosmetics,

products can be categorized as OTC or natural-health products (NHP), the latter being considered a subset of "drugs" [20].

Japan is also a market with a unique categorization system, as beauty products are divided into two categories: cosmetics and quasi-drugs (Table 2). Cosmetics are further classified into other six categories—perfume and eau de cologne, makeup products, skin care products, hair care products, special purpose cosmetics and cosmetic soaps [16,21]. Quasi-drugs are defined as:

Table 2. Examples of cosmetic and quasi-drug products in Japan.

Category		Examples
Cosmetics	Perfume and eau de cologne	Perfume, eau de cologne, etc.
	Makeup products	Foundation creams, lipstick, etc.
	Skincare products	Skin lotion, essence, cleansing cream, etc.
	Haircare products	Shampoo, hair treatment, etc.
	Special-purpose cosmetics	Sunscreen, shaving cream, etc.
	Cosmetic Soaps	Soaps for cosmetics
Quasi-Drugs		Deodorants, hair growth treatment, depilatories, hair dyes, bath products, dentifrice, medicated cosmetics (anti-dandruff products; shaving products; anti-acne products)

> "*articles for the purpose of preventing nausea and other discomfort, preventing heat rash, soreness, etc., encouraging hair growth or removing hair or exterminating and preventing mice, flies, mosquitos, fleas, etc.*" [16].

The categorization systems of China and Brazil are more similar to that of the EU, but both countries further divide cosmetics into more specific categories. In China, under the new CSAR, cosmetics are divided into special cosmetics and general cosmetics. Special cosmetics include hair dyes, hair perming products, (hyper)pigmentation removing (whitening) products, sunscreen, anti-hair loss products and a new category, "cosmetics with new efficacy claim", while the remaining products are classified as general cosmetics. It is also possible for a product to fall under more than one category, as in the case of hair growth products that are subdivided into three categories for supervision: general cosmetics (products that prevent hair breakage by improving hair quality), special cosmetics (products that prevent hair loss by improving the condition of the scalp) and drugs (products that promote hair growth by being involved in human physiological activities) [17]. Additionally, the NMPA specifies a coding system for the classification of cosmetics. The system has five sub-categories:

1. Efficacy claims, which includes 28 kinds of claims such as cleaning, makeup removing, moisturizing;
2. Application area, which includes 10 different areas where the product can be applied, for example, hair, skin, head, face;
3. Dosage form, which lists a total of 14 different product forms such as creams, liquids, gels, pastes;
4. Target users, which comprises 3 different age groups: infants, children and adults;
5. Application methods, including rinse-off and leave-on categories. Each layer is represented by a 2-digit number or letters which are arranged together to form a code for a specific product. For example, a hair shampoo made especially for infants can get a code of 01-01-03-02-01, which means "clean-hair-liquid-infants-rinse off" [10].

Likewise, in Brazil products are classified into grade I and grade II according to their risk to consumers (Table 3):

Table 3. Examples of cosmetics in Brazil, according to risk.

Grade I	Grade II
Face cleansing creams; Lotions; Gels and oils (except for skin acne); Perfumes, lipsticks (without sunscreen); Fingernail polishes; Cleansing shampoos and hair conditioners; Eye and facial makeup preparations (without sunscreen).	Children's products; Sunscreen lotions and creams; Products for wrinkles; Antiseptic soap; Insect repellent products; Products for straightening, curling and/or dyeing hair.

Grade I: Products with basic or elementary properties, that do not require detailed information on their labelling regarding their mode of use and their restrictions of use [22].

Grade II: Products with specific indications that require proof of safety and/or efficacy, and more information on their labelling, concerning their mode of use and restrictions of use [22].

Some of the products that can illustrate this divergency between categorization systems in different markets are listed in Table 4. For example, soap is considered a cosmetic in the EU, Japan, Canada, and Brazil; however, in the USA, soap is a product that needs special attention since the regulatory definition differs from the common definition of soap used by most people. The definition of soap in the FDA's regulations is based on three criteria: composition, intended use and what ingredients are responsible for the cleaning action. If a product meets the regulatory definition of soap, it is considered a consumer product and regulated by the Consumer Product Safety Commission (CPSC), instead of by the FDA; otherwise, it is either considered a cosmetic, a drug, or both, depending on the relevant criteria [18,23]. Furthermore, in China, soaps are free of supervision by CSAR, except those that claim to have special cosmetic efficacy (e.g., whitening) [10].

Table 4. Examples of product categorization in the six regions (EU, USA, Canada, Japan, China and Brazil).

Product	EU [13]	USA [14]	Canada [15]	Japan [16]	China [17]	Brazil [22]
Soap	Cosmetic	Consumer product, Drug or Cosmetic	Cosmetic	Cosmetic	Cosmetic (w/exceptions)	Cosmetic
Lipstick	Cosmetic	Cosmetic	Cosmetic	Cosmetic	Cosmetic	Cosmetic
Sunscreen	Cosmetic	OTC	NHP or OTC	Cosmetic	Cosmetic	Cosmetic
Anti-acne lotion	Medicinal Product	OTC	NHP or OTC	Quasi-Drug	Cosmetic	Cosmetic
Anti-caries toothpaste	Cosmetic	OTC	NHP	Quasi-Drug	Cosmetic [1]	Cosmetic
Anti-perspirant	Cosmetic	OTC	Cosmetic	Quasi-Drug	Cosmetic	Cosmetic
Hair dye	Cosmetic	Cosmetic	Cosmetic	Quasi-Drug	Cosmetic	Cosmetic
Antidandruff shampoo	Cosmetic	Drug and Cosmetic	NHP or OTC	Quasi-Drug	Cosmetic	Cosmetic

[1] In China, toothpastes are not defined as cosmetics but they are regulated with reference to general cosmetic regulations. Claims like "anti-caries" are permitted, given that their efficacy was evaluated according to national and industry standards.

Sunscreen is another example of a product with distinct classifications in different countries. In the EU, Japan, Brazil and China sunscreens are classified as cosmetics. However, in the USA, sunscreens and any other products labelled with SPF values intended to protect consumers from the sun, are regulated as OTC drugs. This means that moisturizers, foundations, or any kind of products with this type of claim are also categorized as OTC drug products by the FDA [18,24]. In addition, in Canada, as in the USA, sunscreens include products intended to be applied on the face or skin, as makeup or skincare, which also carry sunscreen claims. These can be classified as NHPs or non-prescription drugs, depending on their ingredients [25].

4. Pre-Market Approval and Notification of Products

In the EU, the responsible person (RP), usually the manufacturer or the importer, must ensure the safety of the product before placing it on the market [8]. For this purpose, the RP must guarantee that the cosmetic product undergoes a safety assessment on the basis of the relevant information and that a cosmetic product safety report (CPSR) is established [13].

The safety assessment is carried out by the safety assessor (SA), which, according to Regulation (EC) 1223/2009, is a person, appointed by the RP, qualified in pharmacy, toxicology, medicine or a similar discipline, or a course recognized as equivalent by a Member State [13]. This is the only requirement specified in the regulation for the SA; there are no other conditions or even a definition. Therefore, even though the same regulations are followed within the country, the CPSR can be different because it is written by specialists with different academic backgrounds, experience, and knowledge.

The CPSR can be found in the product information file (PIF) of the cosmetic and is divided in two parts:

- Part A: Cosmetic product safety information, consisting of all the information necessary for the safety assessment of the product and comprising ten sections, 1. quantitative and qualitative composition; 2. physical/chemical characteristics and stability; 3. microbiological quality; 4. impurities, traces and information about the packaging material; 5. normal and reasonably foreseeable use; 6. exposure to the cosmetic product; 7. exposure to the substances; 8. toxicological profile of the substances; 9. undesirable effects and serious undesirable effects; 10. information on the cosmetic product [13].
- Part B: Cosmetic product safety assessment, which is the cosmetic safety assessor's opinion on the safety of the product and consists of four sections, 1. assessment conclusion; 2. labelled warning and instruction of use; 3. reasoning; 4. assessor's credentials and approval of part B [13].

On the other hand, the PIF contains the following information: a description of the cosmetic product; the cosmetic product safety report; a description of the manufacturing method and a statement of compliance with GMP; proof of the effect claimed for the cosmetic product and 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 [13].

Both the CPSR and PIF must be kept updated, and modified every time there are any changes to the product or new information becomes available. For example, when the recipe is changed by the manufacturer, there may be new information on stability as well as ingredients. Similarly, when the supplier of the ingredient(s) or the packaging that is in direct contact with the cosmetic changes, the documents must be updated. Additionally, the RP also needs to provide some information through the cosmetic products notification portal (CPNP), such as the product category and identification, foreseeable exposure conditions, and the frame formulation [13,26].

The notification process is the same for all cosmetic products except for those containing nanomaterials, which are subject to an additional procedure. According to Article 16 of Regulation (EC) 1223/2009, in addition to the above-mentioned notification, the RP needs to notify, via a separate module on the CPNP, cosmetic products containing nanomaterials six months prior to being placed on the market. These provisions are applicable to all nanomaterials, except those used as colorants, preservatives, or UV-filters, listed in Annexes IV, V and VI of the cosmetic regulation and those in conformity with the requirements set out in Annex III of the same regulation, since these ingredients undergo an authorization process as per Article 14 of the regulation [13,27]. The FDA does not require pre-market approval of cosmetics, except for color additives (other than coloring materials used in coal-tar hair dyes) that need to be approved for the specific intended use. Therefore, the manufacturers or distributors of the product have the responsibility of ensuring that the product is safe. Additionally, as opposed to the EU, product filing and establishment registrations are not

mandatory in the USA. The manufactures or distributers may voluntarily submit online information to the agency under the Voluntary Cosmetic Registration Program [28–30].

In Canada, the manufacturer has the responsibility of ensuring the safety of the cosmetic product. All cosmetics sold in Canada must be notified to Health Canada. Manufacturers also need to submit a Cosmetic Notification Form (CNF) for each product, within ten days after they first sell the product. This online notification form includes information such as the address and contact details of the manufacturer, the function and form of the cosmetic and the concentration of each ingredient. The notification does not constitute approval for sale or any type of agreement that the product complies with all legal requirements, as those are the responsibility of the manufacturer [31].

In Japan, to register a cosmetic product, it is necessary to first obtain a Cosmetic Manufacturing License and a Cosmetic Marketing License. Each has their own requirements. However, Marketing License holders need to comply with two standards: the Good Quality Practice (GQP) standard, to maintain the quality of products, and the Good Vigilance Practice (GVP) standard, to undertake appropriate actions for safety management. After obtaining the required licenses, the manufacturers need to submit a cosmetic marketing notification to the same prefecture that granted the Cosmetic Marketing License. Lastly, after all the requirements mentioned previously have been implemented, the product can then be placed on the market [32].

Under China's new regulations, special cosmetics need to be registered and approved by NMPA before production while general cosmetics can be directly put on the market after a notification. However, since 1 January 2022, before registration or notification, the registrant or notifier shall either perform a self-assessment safety evaluation or entrust this task to a professional agency, and submit the product safety assessment documents during registration and notification [10].

In Brazil, the registration procedures depend on the product. Some of the products classified as Grade II cosmetics and listed in Annex VIII of Resolution RDC 07/2015 are subjected to pre-market approval procedures. These procedures are valid for five years from the date of their publication in the Brazilian Official Gazette and can be renewed for equal and successive periods. Those cosmetic products not included in Annex VIII of Resolution RDC 07/2015 are exempt from premarket approval and only need to be notified to ANVISA. The notification procedure is performed online, via the Cosmetic Automation System (SGAS System), is valid for five years from the date when the online protocol is finalized and can be renewed for equal and successive periods [22].

5. Ingredients Regulation

All six markets have similar ingredients regulatory approaches, accomplished by the establishment of positive and negative lists, the main difference being the amount and type of substances included in those lists. For example:

- Contrary to the EU, the USA and Canada only have negative lists, partly because some of the products positive-listed in the EU (e.g., UV-filters) are not regulated as cosmetics in North America;
- The EU bans more than 1400 dangerous chemicals from cosmetics while the USA bans less than 20 chemicals [11];
- The EU has more than 25 ingredients approved for use as sunscreens, while the USA has only 2 ingredients fully approved and 12 ingredients provisionally approved, providing additional safety data is supplied [11].

More thoroughly, in the EU, cosmetic regulations are "ingredients risk-based". The Scientific Committee on Consumer Safety (SCCS) regularly revises and updates the "Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation", which provides guidance to public authorities and the cosmetic industry about the safety of cosmetic ingredients. This guideline includes toxicological test procedures, such as basic toxicity tests, to evaluate different human health-related toxicological endpoints. For SCCS safety evaluation, the systemic doses obtained (mostly) after oral administration are used.

For local toxicity endpoints, normally only hazard identification is performed. Safety evaluation is done for intact skin. For safety purposes, only validated non-animal methods are required for the evaluation of cosmetic products [33].

Taking into consideration the opinions of the committee, the EC and the Member States decide on the addition or removal of substances from the ingredients list established in Regulation (EC) 1223/2009 [34]. The regulation establishes two negative lists, for prohibited and restricted substances, and three positive lists, for colorants, preservatives, and UV-filters [8]. The safety of the Annex substances is evaluated by the SCCS while the safety of cosmetic products is evaluated by the industry [33].

Regarding nanomaterials, colorants, preservatives and UV-filters, these can only be used in cosmetic products if included in the specific positive lists (Annexes IV, V and VI of the regulation). To date, only five nanomaterials have been authorized for use in cosmetic products: carbon black (nano), as a colorant, and methylene bis-benzotriazolyl tetra-methylbutylphenol (MBBT), titanium dioxide, zinc oxide and tris-biphenyl triazine, as UV-filters [27].

To use a new nanomaterial as a colorant, preservative or UV-filter in a cosmetic product, an authorization must be requested from the EC, which will then request the SCCS to carry out a full safety assessment. If the ingredients are allowed to be used as nanomaterials, this must be explicitly mentioned in the Annexes; otherwise, they cannot legally be used in their nano form. Moreover, all ingredients present in a cosmetic product in nano form must be clearly indicated as such in the labelling of the product, by the ingredient's name followed by the word "nano" in brackets [27].

Additionally, according to Article 16 (a) of the regulation, the Commission needs to publish a catalogue of all nanomaterials used in cosmetic products placed on the market. The catalogue must indicate the categories of cosmetic products and the foreseeable exposure conditions and must be regularly updated and made publicly available [13].

In addition to these lists, Article 15 of the Regulation prohibits the use of substances classified as CMR substances (substances classified as carcinogenic, mutagenic, or toxic for reproduction) of categories 1A, 1B or 2. These are listed under Part 3 of Annex VI of Regulation (EC) No 1272/2008, which regulates the classification, packaging and labelling of hazardous substances in the EU. Nevertheless, a substance classified as category 2 may be used in cosmetic products if it has been evaluated by the SCCS and considered safe for use [13].

The regulations of Brazil, Japan and China follow a similar approach, establishing negative and positive lists for the control of ingredients in cosmetics, i.e., lists for prohibited ingredients and restricted ingredients, as well as positive lists for preservatives, UV filters and colorants. However, China goes one step further and also distinguishes between "existing" and "new" cosmetic ingredients. New cosmetic ingredients refer to natural or artificial ingredients used in a cosmetic for the first time in China. An ingredient is considered "new" if it is not included in the Inventory of Existing Cosmetic Ingredients in China (IECIC). Ingredients are also divided into different risk levels. Those considered to be relatively high-risk (preservatives, UV filters, colorants, hair dyes and (hyper)pigmentation removal or whitening agents) require a registration with NMPA to obtain approval while the others can be immediately used after notification to NMPA [10].

Both the FDA and Health Canada, similarly to the EU, have some available lists for the control of cosmetic ingredients, but they are not as comprehensive as the EU ones. Canada has an available Cosmetic Ingredient Hotlist, which is a document that is reviewed and updated periodically and lists the substances that are prohibited or restricted for use in cosmetics [35]. The FDA has a similar approach, only listing a small number of prohibited and restricted ingredients, and the only substances that need to be approved are color additives, except coal-tar hair dyes, as previously mentioned [36]. Additionally, the FDA considers the Cosmetic Ingredient Review (CIR) reports when evaluating the safety of cosmetic ingredients. The CIR is an industry-funded panel of scientific and medical experts that review and assess the safety of numerous ingredients used in cosmetics [29,37].

6. Labelling, Packaging and Claims

6.1. Labelling and Packaging

Cosmetic product packaging is a versatile medium designed not only to attract the consumer and provide information about the product's content, but also to protect, carry and store the product. Therefore, to prevent misleading and misbranded labels and to ensure the safety of the packaging, each country has implemented a set of regulations.

Regarding the labelling, there are broad similarities between the requirements. For example, all the countries have identical label displays and information requirements and all have adopted the International Nomenclature of Cosmetic Ingredients (INCI) in the labelling of ingredients (although with some variations, e.g., in the USA the most significant differences rely on the labelling requirements and permitted claims for specific ingredients (e.g., SPF)).

As stated before, the packaging not only provides information about the product but is also extremely important for its protection, transport and storage. Packaging must provide compliance against climatic conditions and biological, physical, and chemical hazards, ensure adequate stability, etc. [38]. For these reasons, in the EU, the cosmetic packaging is an important part of the cosmetic safety assessment.

According to Regulation (EC) 1223/2009, packaging evaluation is mandatory to guarantee the cosmetic product's safety; hence, the CPSR must contain explicit information about the characteristics of the packaging material, in particular purity and stability [13]. In addition to the requirements of the cosmetic regulation, there is other legislation to which the packaging must conform. Examples are: Directive 94/62/EC, which establishes requirements regarding REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) and packaging/packaging waste [39]; Regulation (EC) 1935/2004 which sets out general principles of safety for food contact materials [40]; Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food [41]; and Directive 87/357/EEC which is a general product safety directive which prohibits the marketing of products, such as cosmetics, which are not edible, but could be easily mistaken for foodstuffs due to their appearance, smell or packaging [42].

6.2. Claims

A cosmetic claim can be a text, image, symbol or any sign that is present on the product packaging, the brand website, in an advertisement, on social media, etc., and informs the consumer about the product's characteristics and benefits. These claims are used by cosmetic companies as marketing tools to differentiate their products from the competitors, thus stimulating innovation and competition between companies. For this reason, claims play a considerable role in advertising and thereby in the cosmetic industry. Many areas must be considered when developing a marketing campaign, such as the market itself, the scientific progress, and the consumers' diversity and demands. However, all these areas must be regulated in order to protect the consumer from being misled.

In the EU, article 20 (1) of the EU Regulation clearly states that:

> "*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.*" [13].

Accordingly, in 2013, following the release of Regulation (EC) 1223/2009, the EU published a separate regulation—Commission Regulation (EU) No 655/2013—with the purpose of establishing common criteria for the justification of claims concerning cosmetic products. With the main objectives of ensuring consumers' protection from misleading claims, establishing a common approach at the EU level and enhancing the cooperation between the national authorities of each Member State, six common criteria were established: (i) legal compliance; (ii) truthfulness; (iii) evidential support; (iv) honesty; (v) fairness; and (vi) informed decision-making [43]. Additionally, in 2017, a sub-working group released a non-legally binding document—the Technical Document on Cosmetic Claims—to provide

guidance for its application. The document contains in depth-descriptions and examples of the six criteria, as well as two additional annexes, one on "free from" claims and other on "hypoallergenic" claims [44]. Although there are standard principles that must be respected in the EU, the common criteria do not specify the wording that should be used for cosmetic product claims. Therefore, the responsible person needs to "ensure that the wording of the message communicated is in compliance with the common criteria and is consistent with the documentation in his possession for supporting the claim" [44].

The current European regulatory framework for claims and advertising of cosmetic products is comprehensive and ensures a high level of consumer protection while simultaneously enabling the industry to be competitive within the EU and the world. Similar to the EU, there are some regions which have available official or semi-official documents to provide better guidance on claims regulation. For example, Japan has implemented a list of 56 allowed efficacy claims for cosmetics [10]. However, in other countries, like the USA, Canada or Brazil, there is not a list of approved/accepted claims for consultation or much available guidance, the only requirements being that the claims must be truthful and not misleading.

Either way, none of the six regions analyzed in this work has any authority to approve cosmetic claims before the product is placed on the market. This often leads to non-compliance, and is the reason why post-marketing surveillance is so important. One of the most common non-compliances is a drug claim on a cosmetic product. This occurs because sometimes it is challenging to determine what type of claims are appropriate for cosmetics, rather than drugs, since some cosmetic products can alter the function of the body (e.g., cosmetics for aging, acne, rosacea). This problem is especially relevant in the USA and Canada because the intended use of a product determines whether it is classified as a drug and/or a cosmetic. For example, in Canada, products that claim to have SPF, even if it is a secondary function, are considered drugs; however, products that contain sunscreen ingredients but do not claim to have SPF, are considered cosmetics. Therefore, when describing the function of a cosmetic product, terms such as "treat", "cure", "heal", "restores", "prevents" should always be avoided [45].

Another issue arising from the lack of legislation is the unfair commercial practices performed by some companies. Although there are legal frameworks to regulate these issues such as the Directive (EU) 2019/2161 in the EU, which aims to protect consumers from unfair commercial practices, these are still common. For example, companies commonly use claims that do not apply to their products in order to appeal to consumers and increase their share in the market. That is the case of hypoallergenic cosmetics, which claim to produce fewer allergic reactions than other cosmetic products. In the USA, there is no legal definition for this claim (contrary to the EU), and since the manufacturers are not required to submit any type of supporting evidence for this claim before including it on the product label, the consumers have no assurance that the product they are buying complies to what its label claims [46]. Another illustrative example of this issue are cruelty-free claims. Nowadays, most consumers want to buy cosmetic products that have not been tested on animals. As a result, companies take advantage of such preference to promote their finished products, even if they contain ingredients tested on animals to assess their safety profile. This might happen in countries in which there is no legal definition for such claims and, simultaneously, cosmetic animal testing/marketing bans are not enforced or, at least, not as restrictively as in the EU.

This problem also highlights the importance of claim substantiation, which was one of the measures covered by China's new cosmetic regulation, which presents new requirements for efficacy claims to protect consumers against misleading and false information. According to the CSAR and the Standards for Cosmetic Efficacy Claim evaluation, efficacy claims of cosmetics need to be supported by scientific evidence, which include literature documents, research data, test reports or efficacy evaluation. For this purpose, the responsible person should publish the summary of evidence on a website designated by NMPA for public supervision [17].

7. Ban on Animal Testing

Animal testing in cosmetics has been widely discussed over the years, and consumers have increasingly become more conscious of this problem, and are progressively demanding animal well-being. Fortunately, the replacement of animal testing in cosmetics by alternative methods is, currently, a high priority for the industry and the list of countries with enforced animal testing bans is growing. However, until very recently, the discrepancies between animal testing and marketing bans between countries would lead to situations such as cosmetics produced in country A not being sold in country B because they had been tested on animals, or the other way around (e.g., EU and China). This is, perceptibly, a significant barrier to trade. The current situation of the six countries discussed herein (Table 5), regarding the ban of animal testing of cosmetic products, is as follows:

- The EU leads this process with a ban on animal testing and related marketing for both finished cosmetic products and cosmetic ingredients. The last ban was implemented on 11 March 2013 and extended the prohibition to repeated-dose toxicity, reproductive toxicity and toxicokinetic studies [47].
- In the USA, as of today, eight states (California, Hawaii, Illinois, Maine, Maryland, Nevada, New Jersey and Virginia) have passed laws banning cosmetic animal testing [48]. As for the rest of the country, even though the FD&C Act does not specifically require the use of animals in safety cosmetic studies, and while the FDA supports the use of alternative methods for the refinement, reduction and replacement of animal testing, it is the manufacturers' responsibility to employ whatever tests are deemed necessary to sustain the safety of their products [49].
- In Canada, there is no ban on animal testing for cosmetic products. In 2015, the Canada's Bill S-214 (the Cruelty-Free Cosmetic Act) was introduced to end the use of animals for cosmetic testing, and the sale of cosmetic products developed using animal testing methods. However, as of today, this bill has not yet been passed into law and therefore the use of such methods is still permitted [50].
- Japan is in the process of phasing out animal testing. Currently, there is no law that bans animal testing in products classified as cosmetics, but they are also not required or mandatory. However, for quasi-drugs, which include products classified as cosmetics in the EU, it is still mandatory to perform animal testing [41].
- China's mandatory animal testing requirement for cosmetics registration has long been a major obstacle for global trade between regions like the EU and countries with "cruelty-free" testing policies. However, as many countries are gradually introducing animal testing bans, China has also started to align its regulations. On 1 May 2021, China officially removed the mandatory animal testing for general cosmetics, whether imported or manufactured in China. However, there are some preconditions and exceptions. In particular, one precondition is to provide a GMP certification, issued by the cosmetic regulatory authority of the country or origin. This requirement is difficult to obtain because many countries do not issue this kind of GMP certification [51,52].
- In Brazil, some states (Amazonas, Mato Grosso do Sul, Minas Gerais, Pará, Paraná, Pernambuco, Rio de Janeiro, São Paulo, Santa Catarina and Federal District) have already banned cosmetic tests on animals. However, tests on animals are still recognized by Anvisa guidelines to assess the dangers of cosmetic products and their ingredients [53].

Table 5. Current prohibitions and/or restrictions in force regarding cosmetic animal testing and marketing, by country or region.

Country/Region	Prohibition/Restriction of Animal Testing and Marketing on Cosmetics
EU	Ban on animal testing and marketing for ingredients and products. Prohibition on repeated-dose toxicity, reproductive and toxicokinetic studies.
USA	Animal testing bans on 8 states (California, Hawaii, Illinois, Maine, Maryland, Nevada, New Jersey and Virginia). For the rest of the country animal testing is not mandatory.
Canada	No bans.
Japan	No bans but in the process of phasing out. Animal testing is mandatory for quasi-drugs (which includes products classified as cosmetics in some countries).
China	Testing is not mandatory, but there are preconditions/exceptions (e.g., GMP certification from the country of origin).
Brazil	Animal testing bans on 10 states (Amazonas, Mato Grosso do Sul, Minas Gerais, Pará, Paraná, Pernambuco, Rio de Janeiro, Sao Paulo, Santa Catarina and Federal District) Testing guidelines are still recognized.

8. Conclusions

The cosmetics industry has been aiming to achieve a global regulatory cosmetic harmonization over the past few decades. Currently, the regulatory frameworks around the world are relatively similar, even if several differences still exist. But rather than asking if global harmonization is possible, the question might be "Is it necessary?" Some answers are suggested by the evidence from this review. The legislative measures of the six regions considered in this work are in fact different, affecting international trade, among other issues. However, it is also true that regulators, formulators and other professionals in the industry have managed to navigate through these differences, and that there is always space for improvement and adaptation, as exemplified by the recent reforms on the Chinese and Japanese regulatory frameworks.

Nevertheless, improvement and adaptation are not enough if the products are not in compliance with the respective legislative measures, since even the most restrictive regulations, if not followed, will not ensure the safety of consumers. With the increasingly demanding and constantly changing global regulatory context, there is a need for extra vigilance of companies and manufacturers, to avoid non-compliance, since not all countries require companies to report problems to regulatory authorities. This shows the importance of post-market surveillance, reporting of adverse effects and non-compliance and the implementation of measures and enforcement actions against the person/entity responsible for a non-compliance (e.g., removing violative products from the markets or financial penalties).

To conclude, it is essential to maintain the ongoing dialogue between countries, to encourage innovation, enhance market growth and eliminate restrictions to trade. In this way, the accessibility of the consumer to safe cosmetic products is ensured.

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