






Review

Regulatory Requirements for Exporting Cosmetic Products to Extra-EU Countries

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Abstract: In this study, an overview of the regulations in force in some extra-EU states belonging to different geoeconomic areas is provided, starting from the current EU legislation on cosmetic products. We focused on their legislative frameworks and the location of the relevant regulatory documentation. Furthermore, for each state considered, our analysis examined the notification/authorization processes, approaches to animal testing, and allowed/prohibited ingredient lists, as these aspects are considered to be among the primary restrictions hindering the cosmetic market. It can be observed that many states are working towards standardising their regulations to promote greater international trade. However, it is essential to recognize that different countries belonging to distinct geoeconomic areas may have unique requirements, and harmonization may not necessarily be the best solution. It is crucial to consider different needs and preferences when approaching the global regulation of the cosmetic industry.

Keywords: cosmetic market; regulatory frameworks; notification; authorization; animal testing; ingredient list



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1. Introduction

The global beauty industry (comprising skin care, colour cosmetics, hair care, fragrances, and personal care) is a multibillion-dollar market that is constantly growing because more consumers are becoming increasingly aware of the importance of health, wellness, and personal care products. Additionally, the cosmetic market is strongly affected by many factors, including the economy: When the economy is strong, people are more likely to spend money on this type of product. On the contrary, when the economy is weak, a decline in sales in the cosmetic industry is unavoidable.

In 2022, the global cosmetic market experienced a growth of over 16 percent in comparison to the previous year. Skincare is one of the most profitable product categories; in fact, it was the leading category in 2021, accounting for about 41 percent of the global market. Haircare products made up a further 22 percent, while makeup accounted for approximately 16 percent.

Focusing on Europe and in line with the general trend, skin care products represent the dominant force in the cosmetic industry, capturing more than 27 percent of the cosmetic market in 2019. Note that, within the European cosmetic market, Germany consumed the largest amount of cosmetics in 2021, valued at approximately EUR 13,600 million. This was followed by France and Italy at approximately EUR 12,000 million and EUR 10,600 million, respectively. The Italian cosmetic industry recorded an increase in the global turnover of 10 percentage points in 2021, going from EUR 10,700 million to EUR 11,800 million. This trend was positively affected by exports, which grew by 13.8 percent with a value of over EUR 4800 million compared to the previous year [1].

The USA, next to Europe, is the world's leading cosmetic market, with an estimated total revenue of about USD 49,000 million as of 2022 [2]. Specifically, for Italy, the USA is the second destination of its exports, surpassed only by France.

Besides the USA and Canada, Mexico is the third North American country with a market size of beauty and personal care which reached, in 2020, about USD 10,000 million and which imported, in 2021, USD 1400 million of products [3,4].

Moving to Latin America, it must be noted that the MERCOSUR/CAN is a huge, booming market. Data on the size of the cosmetic market in Brazil is published periodically on the website of the Brazilian Industrial Association of Personal Hygiene, Perfumery and Cosmetics (ABIHPEC) [5]. The Brazilian cosmetic market is the fourth largest consumer market in the world, with revenues of approximately USD 23,000 million in 2021; it is the second country in the world, after the United Arab Emirates (UAE), to launch new products in the market [6]. The Argentine market represented 10 percent of the Latin American market in 2020 [7]. The cosmetic industry in Ecuador is represented by Procosméticos, whose associates produce 95 percent of the turnover of the cosmetics and household hygiene industry sector, a market of about USD 2300 million. The Ecuadorian government announced that, in 2020, the total sales of cosmetic products would exceed USD 600 million [8,9]. The cosmetic industry in Colombia showed a 7.7 percent increase in its market value in 2021, giving hope for the future of the sector [10]. In 2018, Colombia ranked as the fourth largest market in Latin America for beauty and personal care products [11].

The cosmetic market in the Common Market for Eastern and Southern Africa (COMESA) and Central West Africa is growing [1]. The makeup cosmetic market in Egypt settled on a value of around EUR 85 million, with a growth rate of 18 percent in 2017 [12]. This significant growth was due to the "adolescent spirit" of the country and the high percentage of young people in the population who supported the consumption of cosmetic products, but strong customs duties are limiting imported products [13]. It was estimated that the Cameroonian cosmetic market was worth EUR 194 million in 2018, but, according to many experts, its size would be almost double. The market offer is largely dominated by imports from international groups (70 percent). In fact, 58 percent of mass market cosmetics and 91 percent of premium segment cosmetics are imported; the demand for premium products is constantly evolving, rising by 7.1 percent in the period of 2018–2022 [14]. The indigenous cosmetic market in Nigeria is currently not widely documented, but, according to Euromonitor International and confirmed by the Statista Research Department, in this country, it is growing and is presently worth an estimated USD 3000 million [15].

Southeast Asia is considered to be an important market for the beauty and cosmetic industry due to the growing urban population and the influence of neighbouring regions (e.g., the East Asian market). Considering the entire Southeast Asia Region, the beauty and cosmetics sector was worth approximately EUR 21,360 million in 2020. In particular, the size of the cosmetic market in Malaysia in 2019, as stated by Allied Market Research, practically doubled in six years [16]. The Philippines is the second largest cosmetic market, representing approximately 22 percent of the total sales in Southeast Asia in 2020. According to a published report by Statista (2022), the Philippine beauty and personal care market revenue would reach USD 5790 million in 2023, with an expected annual market growth of 0.90% (CAGR (compounded average growth rate), 2023–2027) [17]. There is no official data on the size of the cosmetic market in Indonesia, but there is data published by the Indonesian Cosmetic Association which indicates that the market size of the cosmetic industry is growing. From the USD 4370 million made in 2019, 80.2 percent was produced by locals, while the other 19.8 percent was imported [18].

Regarding the Central European Free Trade Agreement (CEFTA) region, cosmetic products manufactured abroad are preferred over those manufactured locally. Foreign manufacturers and brands, in particular, hold most of the cosmetic market both in Montenegro and in Serbia and Albania [19–21].

In Japan, data on the import, export, and market share of cosmetic products are made available by the Japanese Ministry of Finance and the Ministry of Economy, Trade, and Industry; they show an increase in both the import and export of cosmetic products [22,23].

Based on the company reports available online, Dubai, considered the hub of business and luxury, held the largest market share in 2019. The second place goes to Abu Dhabi, which has an improving gross domestic product (GDP) and is easily accessible to international brands. According to the estimates, the UAE beauty market will exceed USD 3000 million in 2025 [24].

The National Regulatory Authority (NRA) of India is responsible for the circulation of data relating to the cosmetic market in India. Moreover, it is possible to find many cosmetic market surveys in journals such as *Mordor Intelligence*, *The Economic Times*, and *Techsci Research*. Herbal cosmetic products have seen a huge growth of around 15–20 percent in the last 5 years, as Indians are leaning more towards Ayurvedic, natural, plant-based, and organic products [25–27].

According to the Amman Chamber of Commerce, the exports of the chemical and cosmetic sector in Jordan increased by almost 5 percent in the last 7 months of 2020 compared to the same period in 2019. The sector has a high potential for import/export development in the next period [28].

This review covers the regulatory frameworks of cosmetic product export in regions that are or could be important markets for Italian and European cosmetic products [1]. Table 1 summarises the list of the countries, grouped by their corresponding geoeconomic area, examined in this review.

Table 1. List of the states examined in this review and their corresponding geoeconomic area.

States	Geoeconomic Area
Mexico	USMCA
Brazil, Argentina Ecuador, Colombia	MERCOSUR CAN
Malaysia, the Philippines, Indonesia	ASEAN
The UAE, India, Jordan	Asian strategic countries
Egypt, Cameroon, Nigeria	COMESA ECCAS ECOWAS
Montenegro, Serbia, Albania	CEFTA

Recently, other authors have analysed the cosmetic regulatory frameworks of some significant realities of the non-EU market, namely, the USA, Canada, Japan, China, and Brazil, to evaluate the free trade of cosmetics. In their report, they argue that trade restrictions should be eliminated and that market growth should be improved. As a result, consumers would be able to access safe cosmetic products [29]. The present review examines some significant geoeconomics areas not discussed in the previously cited paper, although it considers and updates some regulatory aspects of Brazil. At first, we evaluate Mexico, belonging to the USMCA area (United States–Mexico–Canada Agreement). Afterwards, attention is paid to Brazil and Argentina, which belong to the Southern Common Market (MERCOSUR) together with Ecuador and Colombia, which are both associate members of the MERCOSUR and also members of the Andean Community (CAN). Then we consider some important Asian countries, such as Malaysia, the Philippines, and Indonesia, which are members of the Association of Southeast Asian Nations (ASEAN), as well as India, the UAE, and Jordan. Finally, we focus on the African continent, analysing Egypt, which belongs to the Common Market for Eastern and Southern Africa (COMESA), and two growing states, Cameroon and Nigeria. Note that Nigeria is the most populous country in Africa and that it is part of the Economic Region—the Economic Community of West African States (ECOWAS). In addition, as well as Serbia, Montenegro and Albania, belong-

ing to the CEFTA, are considered in this study, as, in this geoeconomic area, cosmetics are mainly imported.

This review offers an in-depth analysis of the regulatory frameworks governing the export of cosmetic products in countries that are or could be significant markets for Italian and European cosmetic products. In particular, it covers the regulatory sources for these frameworks, including where to find them and the responsible bodies. In addition, a coverage of the notification/authorization procedures and the approach of each explored country towards animal testing is also presented. Moreover, the presence or absence of ingredient lists is reported, which is an essential factor to consider when exporting cosmetics. All of this information is crucial and helps to identify the potential challenges that companies may face when exporting their cosmetic products to different regions.

2. Regulatory Frameworks

To understand the regulatory situation of cosmetic products in the selected extra-EU countries, it is useful to review some of the highlights of European cosmetic legislation.

Regulation EC 1223/2009 of the European Parliament and of the Council governs cosmetic legislation in Europe, and it is applied in its entirety across all the 27 EU member states. The regulatory body is the European Commission [30]. This legislation is available at Eur-lex in all EU languages [31]. To place a cosmetic product on the EU market, there must be a responsible person who is highlighted on the label and who complies with all the standards as set out in Article 5 of the regulation [32]. According to Article 13, cosmetic products can be placed on the European market after having notified the European Cosmetic Products Notification Portal (CPNP).

In the EU, selling cosmetic products tested on animals is prohibited. The ban on animal testing applies to both the final formulation and the ingredients of the product. This means that validated alternative methods are employed as reported in Article 18.

Regulation EC 1223/2009 also reports restrictions to cosmetic ingredients: Article 14 deals with the basic aspect of production, indicating which substances are banned, which are allowed within certain limits, and which are permitted. These substances are listed in Annexes II, III, IV, V, and VI.

All of these above-mentioned aspects of European regulations are key factors to be taken into consideration when starting an export process (Figure 1) in countries where the regulatory framework is different.

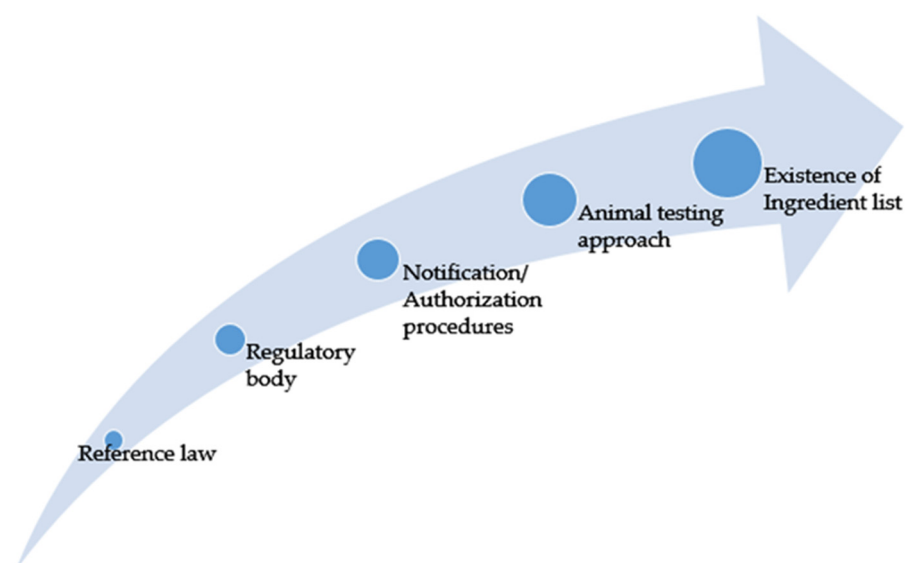


Figure 1. Key points to consider when starting the process of exporting cosmetics abroad.

In the following sections, we examine how these issues are regulated in the extra-EU countries under review.

2.1. Cosmetic Regulation in Mexico

In Mexico, cosmetics are defined by Article 269 of the General Law of Health, which serves as the reference legislation framework for this category of products [33,34]. The regulatory body responsible for a company to place its products on the Mexican market is the Ministry of Health, and this occurs through the Federal Commission for the Prevention of Sanitary Risks (COFEPRIS), a decentralised body with administrative, technical, and operational roles [35]. The documents required to place products on the market include three annexes, according to which procedures and services are disclosed, as well as application forms [36]. By submitting a notice of production, Annex I, the establishment complies with the General Sanitary Law. In particular, the original and a simple copy of the form “Notice of Operation, Health Manager and Notification of Change or Cancellation” must be presented thirty days before starting the activity.

COFEPRIS is responsible for the control and surveillance of cosmetic products from production to marketing. All provisions relating to the legislation are published in the Mexican *Official Journal of the Federation* (DOF), which is in the Spanish language [37]. In the legal framework governed by COFEPRIS, there are three official standards (NOM) which concern the methods for determining the microbial content in beauty products, the labelling of perfumery and beauty products, and the good manufacturing practice (GMP) for cosmetic products [38–40].

Recently, the Mexican Senate has passed a bill banning animal testing in cosmetics. It also prohibits the manufacturing, importation, and marketing of cosmetic products that contain ingredients or combinations tested on animals outside the country [41]. Moreover, there is a list of prohibited or restricted substances in the production of perfumery and beauty products available in the DOF: 21 May 2010 [42].

2.2. Cosmetic Regulations in Brazil, Argentina, Ecuador, and Colombia

In Brazil, the regulation framework of cosmetic products is the Resolução da Diretoria Colegiada (RDC) n. 752/2022, which contains, in the Portuguese language, the definition, classification, and technical requirements of regulating personal hygiene products, cosmetics, and perfumes. All the relevant legislation related to cosmetic products is available on the website of the National Health Surveillance Agency (ANVISA) [43,44]. A summary document of the current regulations can be found on this website [45]. The National Institute of Metrology, Quality and Technology (Inmetro), the government body responsible for certifications, has published an explanatory document in English [46].

RDC Regulation n. 752/2022 governs all three classes of products for external use: hygiene products, perfumes, and cosmetic products. All these products are divided into two categories: grade 1 and 2. The grade 1 category includes products with basic and elemental formulation properties which do not require detailed information and/or restrictions on how to use them; they must not contain UV filters or restricted substances. Grade 2 products, on the other hand, have specific indications whose characteristics require safety and/or efficacy tests as well as information, methods, and limitations of use on efficacy and/or restrictions on the methods of use (for example, sunscreens, antiperspirants, suntan creams/lotions, baby products, dandruff shampoo/conditioner). The criteria for this classification were defined on the basis of the probability of undesirable effects occurring due to the improper use of a product, its formulation, the purpose of its use, the areas of the body which it is intended for, and the treatments to be observed during its use. A complete list of grade 1 and 2 products can be found in Annex I of RDC n. 752/2022 [47].

To produce or import cosmetic products in Brazil, companies must have the authorization of ANVISA and an operating licence (Autorização de Funcionamento (AFE)) from the local health authority, and they must comply with GMP standards. All documents required for marketing must be uploaded electronically on the ANVISA website.

In Brazil, to place a cosmetic product on the market, you must submit the electronic notification for grade 1 products or register for grade 2 products with ANVISA. A document of the assumption of responsibility for the product must be signed by the technical

manager and the legal representative of the company, and the applicant company must be officially registered and legalised in Brazil. The company must comply with the GMP (self-certification), and all the data relating to the dossier for each product that is placed on the market, relating to the quality, safety, efficacy, labelling, and specific technical requirements of the product, must be provided; the fees established by the health authority must be paid [45]. For grade 2 products, such as sunscreens, premarket authorization is required. This authorization corresponds to the registration of the cosmetic product on the ANVISA platform, including the uploading of all the required documentation, to allow the competent authority to view all the documents before placing it on the market. Registration lasts ten years and can be renewed [47].

Since 2014, the state of São Paulo, with Draft Law 777/2013, and, subsequently, other federal states of Brazil have banned animal testing for cosmetic purposes in their territory. With the publication of RDC 35/2015, alternative methods to the use of animals are accepted. [48]. In RDC no. 752/2022, all references to the lists of permitted and prohibited substances in cosmetic formulations are indicated. The main lists can be found in the following directives, which are available on the ANVISA website [43,44].

Argentina's cosmetic market is regulated by Resolution n. 155/1998, issued by the Ministry of Health. This law was followed by various updates on the GMP, cosmetovigilance, labelling, and permitted substances [49]. All legislation is in the Spanish language.

The regulatory body responsible for dealing with a cosmetic product on the market is the National Administration of Drugs, Foods and Medical Devices (ANMAT), an agency under the authority of the Ministry of Health. It is a technical-scientific body that guarantees the quality and safety of cosmetic products [50,51].

This legislation covers all the cosmetic products available in Argentina. Cosmetic products are divided into two categories: grade 1 and 2 products, with formulations compliant with the definition adopted in Resolution no. 110/94. Grade 1 products are characterised by basic or elementary properties; they do not require detailed information regarding their mode of use and their restrictions of use due to the intrinsic characteristics of the product. The list is shown in Annex II to Provision 345/2006—ANMAT, which implements Resolution n. 07/05 of the Common Market Group (GMC). Grade 2 products have specific indications whose characteristics require safety and efficacy tests, methods of use, and restrictions on use. This category includes sunscreens, antiperspirants, antidandruff products, and hair dyes. The list is shown in Annex III to Provision 345/2006 mentioned above [52].

Argentina, with Provision 959/2012, has adopted electronic notification for grade 1 products. The electronic management system, with a digital signature, can be accessed through the ANMAT website, through the “Grade I cosmetics system” before marketing grade 1 cosmetics [53].

To start the registration procedure for a grade 2 cosmetic product, it is necessary to submit “Form R-155”, which is present on the ANMAT website, in person to ANMAT [54]. On this form, manufacturer and product data must be provided, and safety and efficacy tests and stability data must also be provided.

Argentine legislation has not yet banned animal testing for cosmetic products; however, many laboratories are developing alternative methods to the use of animals [55]. There are ongoing discussions in the country about a possible ban on animal testing.

In Legislative Decree 1112/99, on the ANMAT web page, there are lists of prohibited substances, substances of limited uses, dyes, preservatives, and UV filters. These are lists that take into account the European Commission's lists and FDA bans [56].

Ecuador and Colombia belong to the Commission Andean Community (CAN). The reference standard on cosmetic products is Decision n. 833 of 2018 of the CAN “Harmonization of Legislation on Cosmetic Products” [57]. It was carried out to favour the Andean integration and development process, integrating the internal legislation of the member countries on cosmetic products.

Decision 833/2018 establishes the requirements and harmonises the procedures that cosmetic products must comply with for production, storage, import, and marketing in the

CAN as well as for quality control and health surveillance. Resolution 2206/2121 sets out the GMP requirements that all companies that deal with cosmetic products must comply with to obtain health authorization to operate and to obtain a GMP certificate [57].

However, each of the CAN members has its own organisation. Particularly, in Ecuador, the National Agency for Health Regulation, Control and Surveillance (ARCSA) is the technical body responsible for the regulation, control, and health surveillance of cosmetic products. The marketing of cosmetic products in this country is subject to Resolution ARCSA-DE-006-2017-CFMR, available only in Spanish on the websites of ARCSA and Procosméticos [58]. Additionally, cosmetic products require mandatory health notification (Notificación Sanitaria Obligatoria (NSO)) for their marketing in the CAN region. All requirements for the application of the NSO are listed in Chapter III of Decision 833/2018 [57].

Currently, the Ecuadorian government does not prohibit the animal testing of cosmetic products, nor does it have any national legislation; however, it is still a matter of discussion [59,60].

The ingredients allowed in cosmetic products are specified in Articles 3, 4, and 5 of Decision 833. In any case, the cosmetic products marketed must comply with the international lists of ingredients [57]. The restriction or prohibition of the use of an ingredient takes place through the provision of the national competent authority, the General Secretariat of the Andean Community (SGCAN), through technical reports from reference bodies or scientific tests that demonstrate that the ingredient affects or can affect health.

In the case of Colombia, the national legislation consists of general rules such as Decree 219/1998, which partially regulates the health regimes for the quality control of cosmetic products. The legislation framework is only in Spanish and can be found on the official website of the National Institute for Surveillance and Control of Medicines and Food (INVIMA), the Colombian regulatory body. Circular INVIMA 1000-083-19 implements above-cited CAN Decision 833/2018 [61].

To market, manufacture, or import cosmetics into the Colombian market, it is necessary to obtain the relevant NSO authorization from INVIMA before placing them on the market [62]. Marketing must take place after the date of the assignment of the code by the national competent authority of the member country where the notification was made. The request for the issuance of the NSO code must be submitted in the required form [57].

Colombia became the first country in Latin America to ban animal testing in cosmetics through Law 2047/2020, which bans the testing, importation, production, and marketing of products in Colombia cosmetics, their ingredients, or combinations thereof tested on animals. This law will come into effect in 2024 [63].

Colombia has lists of ingredients that may or may not be incorporated into formulations; these lists comply with the Andean Community's regulations on specific ingredients. Cosmetic products marketed in the CAN must comply with the international lists and provisions issued by the FDA, EU, and Personal Care Products Council (PCPC).

2.3. *Cosmetic Regulations in Some Asian Countries*

2.3.1. Malaysia, Philippines, and Indonesia

All ASEAN states are in line with the ASEAN Cosmetic Directive (ACD) directly inspired by Regulation 1223/2009/EC. All materials on the ACD can be found on the ASEAN website, and they are available in English [64]. Under the ASEAN Cosmetics Directive, the manufacturer or responsible person is the one who notifies the product to the competent authority of each member state.

The ACD was developed by the ASEAN member states in collaboration with the ASEAN Cosmetic Association (ACA) to enhance cooperation among the ASEAN member states to ensure the safety and quality of the cosmetic products marketed in the region. Specific legislation on animal testing does not exist in the ASEAN Cosmetics Directive. The ASEAN guidelines for the safety assessment of cosmetic products only state that the testing of finished products does not require animal toxicological testing. As there is not currently

a question on banning animal experimentation in ASEAN countries, neither now nor in the foreseeable future, animal experimentation will not be banned.

In regard to Malaysia, the Control of Drugs and Cosmetics Regulations of 1984 (CDCR) is the legislative framework, promulgated under the Sale of Drugs Act of 1952, that regulates cosmetic products in this country. In agreement with the harmonisation of cosmetics through the ACD, cosmetic products in Malaysia are controlled by a notification procedure that started on 1 January 2008. Information is available on the official website of the government agency, the National Pharmaceutical Regulatory Agency (NPRA). Legislation is promulgated in both English and the national language [65,66].

The CDCR of 1984 establishes, for cosmetics, the control authority; regulates the registration and granting of licences; and regulates the notification and the manufacturing of registered products [67].

The definition of cosmetics includes all products that come into direct contact with the human body; sunscreens, therefore, are included, as they are applied to the skin and contain substances that protect against the harmful effects caused by UV radiation, which is in accordance with the regulation on EU cosmetics [66].

In Malaysia, the Director of Pharmaceutical Services (DPS) is responsible for the control of the cosmetic product placed on the market. Before a company can manufacture, import, possess, or market its product in the local market, the Cosmetic Notification Holder (CNH), the company, or the responsible person must notify the DPS via the National Pharmaceutical Control Bureau (NPCB). This process is mandatory, as it allows the NPCB to collect all the information on the cosmetic products that are placed on the local market [68].

Through the official website of the National Pharmaceutical Regulatory Agency (NPRA), notification can be submitted electronically. Any company wishing to proceed with the notification process must register in the system to access it. The NPRA Quest 3+ System allows the business to complete the notification form for each cosmetic product and to make a payment to the NPRA [66].

In Malaysia, products tested on animals may be considered in cosmetics. Indeed, animal tests are considered to be toxicological tests aimed at ensuring the safety of users.

In 2019, the Chinese National Medical Products Administration approved two non-animal (alternative) tests among the nine accepted methods, namely the Direct Peptide Reaction Assay for skin sensitization and the Short Time Exposure Assay for eye irritation. These tests have been recommended since 1 January 2020 for registering and obtaining the premarketing approval of cosmetic ingredients only but not for the approval of final cosmetic formulations. As a result, Malaysia, a member of the Asia–Pacific Economic Co-operation (APEC) region, including China, will be affected by this important step towards animal-free testing [69].

A list of ingredients that may or may not be used in cosmetic products can be found on the official NPRA website in Annexes II–VII [66]. In this sense, these ingredient lists are similar to the annexes of Regulation EC/2009/1223.

Since more than half of the population is Muslim, the development and manufacturing of halal cosmetics plays a crucial role in Malaysia. However, like in other countries, a cosmetic product must receive halal certification and approval from the Department of Islamic Development Malaysia (JAKIM) or an Islamic body recognized by the JAKIM in order to display the halal logo [66].

The reference legislations for cosmetic products in the Philippines are Republic Act No. 3720 and Republic Act 9711. The first was amended in 1987 with the task of guaranteeing the safety and purity of foods and cosmetics and guaranteeing the purity, safety, efficacy, and quality of drugs and devices [70], and the second, also known as the “Food, Drug and Devices and cosmetic Act of 2009”, aimed to strengthen and rationalise the regulatory capacity of the Bureau of Food and Drugs [71].

In addition, due to its geographical location, the Philippines adhere to the above-mentioned ACD. Therefore, several regulations have also been released by the Food and Drug Administration (FDA) of the Philippines which are related to ASEAN’s streamlining

initiative. The FDA of the Philippines is the main governing body that a company must deal with to market cosmetic products in this country [72]. However, before the products are marketed, the company itself must be registered with the Department of Trade and Industry (DTI) and the Securities and Exchange Commission (SEC). The person authorised to manufacture the cosmetics must also be registered with the Philippines Professional Regulation Commission (PRC).

For a cosmetic product to reach the market, the company must first obtain a licence to operate (LTO) and must then request a product registration certificate. There are several licences for cosmetic establishments authorised by the FDA of the Philippines, as reported in Act. 9711, depending on whether you are an importer, wholesaler, final distributor, or manufacturer of cosmetics. An electronic notification must be made for each cosmetic product via the FDA's e-portal [73]. In agreement with the ACD, Annexes IV, VI, and VII contain the positive list of substances, while Annex II contains the negative list. The substances listed in Annex III are prohibited from being used except under certain situations. Animal testing is not specifically covered by any laws in the Philippines; it is merely stated that toxicological testing on animals is not necessary for testing final products.

The Indonesian cosmetic market is governed by several regulations that are in accordance with the ACD. In addition, it is governed by Act 33 of 2014, concerning halal product insurance. Halal Law, implementing regulations enacted on 17 October 2019, clarified that halal certification started on a voluntary basis and will become mandatory on 17 October 2026 for cosmetics [74,75].

All Indonesian legislation material can be found on the official website of the Indonesia National Agency of Drug and Food Control (NADFC) in the regulatory section and the cosmetics section in the Indonesian language only, and it is not available in English [76]. The NADFC is the responsible regulatory body for protecting public health; it controls and supervises cosmetics and more [77].

The material relating to Act 33/2014 on halal product insurance is available on the website of the People's Representative Council and on the website of the Ministry of Religious Affairs in the Indonesian language only.

The NADFC legislation covered all the aspects related to the technical regulation of cosmetic ingredients, labelling, the GMP and certification guidelines, the monitoring of side effects, the advertising of cosmetics, the cosmetic categories, the monitoring and distribution of cosmetics, contamination in cosmetics, the criteria and guidelines for the withdrawal and destruction of cosmetic products.

The Halal Product Assurance legislation provides the criteria and conditions (the products that can be considered halal or nonhalal according to Islamic law), the guidelines, the certification process, the certification body, and the labelling of the product after certification.

To place a product on the market, notification (Act n. 12/2020) on the NADFC website is mandatory. After the company/importer has been registered and approved, to submit the cosmetic notification, the dossier must be submitted. The notification number that the NADFC provides after approval is valid for three years. The renewal of the notification number can be performed 30 days before the expiry date of the notification number [78–80].

In Indonesia, the manufacturer is eligible to produce the cosmetics only if it has a GMP certificate for cosmetics issued by the Indonesia NADFC as legal proof that the facility and system have met the GMP standards for cosmetics, and there will be an inspection by the NADFC and a certification renewal process; non-ASEAN manufacturers also need to submit a GMP certificate from a government or a recognized body in order to receive notification [78].

As mentioned previously, starting in 2026, it will be mandatory for the company to have a halal certificate for the product, so it will also have to deal with the Halal Product Assurance Organizing Agency and the certification body appointed by the Assessment Institute for Foods, Drugs, and Cosmetics Majelis Ulama Indonesia (BPJPH). To obtain the BPJPH's approval or halal certification, the documents must be submitted as reported

on the website. In the BPJPH Halal Certification/Approval System, a responsible person, called the Internal Halal Supervisor, is required [81].

In Indonesia, animal testing in cosmetics is currently allowed. However, the government has made some efforts to reduce the use of animal testing in the cosmetic industry. In 2016, the Ministry of Health issued a regulation requiring the use of alternative testing methods and reducing the use of animal testing for cosmetic products. Additionally, there have been some calls from animal welfare organisations and the public to ban animal testing in cosmetics in Indonesia. In 2021, the Indonesian Food and Drug Authority reportedly stated that it is considering a ban on animal testing for cosmetic products, although there has been no official announcement of such a ban yet.

It is worth noting that many cosmetic companies have voluntarily stopped using animal testing regardless of whether it is legally required in a particular country. Consumers can look for products that are labelled as “cruelty-free” or “not tested on animals” to support companies that do not conduct animal testing.

The positive and negative lists of ingredients that may be used in a cosmetic product are available on the official NADFC site in the legislation section, which shows the technical regulation of cosmetic ingredients [82].

2.3.2. The UAE, India, and Jordan

The legislation governing the cosmetic industry in the Gulf Cooperation Council (GCC) and thus in the UAE consists of one main regulation, GSO 1943:2021, published in February 2021 in both the English and Arabic languages; that is the latest version of the standard [83]. It replaces the previous version, GSO 1943:2009, and includes updates to reflect the latest developments in the cosmetic industry and to ensure the safety of consumers by reporting the safety requirements of cosmetic and personal care products.

There are several other guidelines that must be taken into account to ensure the safety and quality of the food, cosmetic, and personal care products sold in the UAE as well as to protect the health and well-being of consumers. For example, compliance with GSO 2528:2016 is another Gulf standard specification that covers the mandatory labelling requirements for prepackaged food products, including those sold in the UAE. In addition to the labelling requirements, there are also the GMP and the standards that have been issued by the GCC Standardization Organization. These include GSO ISO 22716:2008, a standard that outlines the requirements for a quality management system for the manufacturing of cosmetics. This standard covers the entire manufacturing process, including raw materials, production, storage, and shipment [84].

Emirates Standardization and Meteorological Authority (ESMA) is the regulatory body identified by Federal Law No. 28 of 2001. It is responsible for drafting regulations and defining their requirements at the federal level, whereas the municipalities (one for each emirate) are responsible for market surveillance and inspections [85].

To market their products in the UAE, cosmetics companies must first obtain certification through the Emirates Conformity Assessment Scheme (ECAS). This request is issued by ESMA. Once ESMA has deemed the products compliant with the required requirements, an ECAS document is issued which describes the quality and safety requirements for cosmetic products. Once an ECAS certificate has been obtained, the cosmetic company must register the products in the relevant municipality before placing them on the market [86–89].

The requirements to be fulfilled to place the products on the market are registration on the ESMA website as a new applicant, the provision of the suitable documents, the completion of the application form, and an assessment of compliance with the ESMA standards [88].

Together with the application, an EAU commercial licence; the report of a recognized and accredited laboratory according to GSO 1943:2021; a certificate issued by the manufacturer with the list of ingredients and relative percentages; a free sale certificate; the label and corresponding graphics of the cosmetic product according to GSO 1943:2021; and, finally, a complete and detailed report on the safety of these products, including microbiological

tests, product composition (qualitative and quantitative), physicochemical characteristics, side effects, stability, etc., must be presented.

To the best of our knowledge, the UAE has not yet implemented a full ban on animal testing in cosmetics. However, recently, the UAE Ministry of Climate Change and Environment announced a draft law that would ban the import and sale of cosmetics that have been tested on animals. Although the law has not yet been published, vegan and cruelty-free cosmetics are available from most retailers in the UAE.

GSO 1943:2021 provides a list of ingredients that are prohibited or subject to restrictions and conditions of use as well as a list of approved colourants, preservatives, and UV filters. Annex VII includes the symbols that are used on cosmetic product packaging and containers.

Most of the annexes in GSO 1943:2021, except for Annex I, are similar to those found in the European legislation for cosmetics, Regulation (EC) No. 1223/2009 and its subsequent updates. Annex III contains a short list of additional substances that cosmetic products should not contain except in specific concentrations [84].

In India, the Drugs Act was enacted in 1940. The Drugs Act regulates the import, manufacturing, and trade of medicines and cosmetic products in India. This law helps to ensure that the cosmetic products available for sale are safe and comply with the quality standards. The Drugs Act 1940 was amended with several subsequent legislations among which was Cosmetic Rules, 2020 [90].

All the information on cosmetic legislation can be found on the website of the Indian Ministry of Health and Family Welfare [91]. All information published by the Gazette Notification of Indian Legislation is in English.

The Drugs and Cosmetics Act is divided into five chapters, I, II, III, IV (IVA), and V, and two lists. It contains the definition of cosmetics, and this includes sunscreens [90,92].

The Central Drugs Standard Control Organization (CDSCO) is the central body that regulates all the activities related to the production, distribution, and importation of cosmetics and that promulgates the related regulations. Upon the submission of documents to the CDSCO, it will licence the product [93].

The Bureau of Indian Standards (BIS), since August 2013, has banned the testing of cosmetics on animals; India is the first South Asian country to completely ban this trial. Any manufacturer interested in testing a cosmetic ingredient must obtain approval from the CDSCO, which will ensure that standard nonanimal testing is performed for the cosmetic ingredient [94].

The BIS provides a list of banned or regulated ingredients in Annexes A, B, C, and D. Annex A shows the list of ingredients that a cosmetic product must not contain, Annex B shows the substances that could be used with restrictions, Annex C is the list of authorised preservatives, and Annex D is the list of UV filters [95]. India, on the other hand, does not have a list of permitted dyes.

In Jordan, the responsible authority for cosmetic legislation is the Jordanian Food & Drug Administration (JFDA), the Department of Cosmetic Registration. Cosmetic products are divided into two categories: beauty products and pharmaceutical cosmetics, i.e., any cosmetic product used externally containing an effective pharmaceutical substance whose use is for cosmetic purposes [96].

The 2016 legislation, the Foundations and Legislations of Cosmetics and Pharmaceutical Cosmetics, regulates cosmetic products. The material, available only in Arabic, can be found in the official gazette published by the JFDA's Department of Cosmetic Registration. The law consists of 17 articles and deals with the requirements for the production and circulation of any cosmetic, pharmaceutical, or beauty product; imported products; the information required for labelling; the analysis of cosmetic preparations; traceability and inspections; and the documents necessary to import/export the beauty products or pharmaceutical cosmetics [96].

The JFDA is the regulatory body for the production and circulation of cosmetics. Companies must follow the steps prescribed according to two reports published on the

JFDA website for the production, registration, and circulation of cosmetic products: the Foundations and Legislation of Good Manufacturing of Cosmetic Materials of 2015 and the Foundations and Legislation of Cosmetics and Pharmaceutical Cosmetics Circulation of 2016 [96].

The JFDA website lists the documents required for the free circulation of cosmetics according to the Foundations and Legislations of Cosmetics and Pharmaceutical Cosmetics Circulation of 2016.

Regulation no. 89 of 2017, Regulation for the Examination of Medicines, Medical Supplies, Sterilizers, Disinfectants, and Cosmetics, issued in accordance with Medicines and Pharmacy Law n. 12 of 2013 and published on the JFDA website, does not mention the use of animal testing for the evaluation of cosmetics [96]. According to the text of the Export Guide to the European Union (EU), the guidelines on the industrial and manufacturing affairs in Jordan, all the cosmetics manufactured in Jordan and exported to the EU must not perform any animal testing [97].

Pursuant to Article 5 of the Foundations and Legislations of Cosmetics and Pharmaceutical Cosmetics of 2016, it is not permitted to sell or distribute any cosmetic product that contains any of the prohibited negative list ingredients listed in the JFDA specifications [96].

There is no direct way to obtain the negative prohibited ingredients list from the JFDA website, and the prohibited materials list must be requested from JFDA; this will ensure that companies that manufacture, import, and export cosmetics know about these prohibited materials to ensure they are not used in any cosmetics.

2.4. Cosmetic Regulations in Egypt, Cameroon, and Nigeria

In Egypt, the regulatory framework for cosmetic products is defined by Ministerial Resolution No. 106 of 1996, which includes a clear definition of these products. The resolution is enforced by the Egyptian Ministry of Health and Population and the Egyptian Drug Authority (EDA). Although this legislation can be accessed on their official websites, it is currently available only in Arabic [98].

The primary regulatory body responsible for registering cosmetics in Egypt is the Cosmetics Registration Department of the Egyptian Drug Authority (EDA). All cosmetics must be registered with this department before they can be sold in the country. Several other regulatory bodies are responsible for ensuring that cosmetics are placed on the market in compliance with the regulations. These bodies include the Egyptian Ministry of Health and Population, the EDA, the National Authority for Drug Control and Research, the General Organization for Export and Import Control (for imported products), the General Administration of Inspections, the Department of Registration of Cosmetics, and the Central Administration for Pharmaceutical Affairs (PACA) [99].

To place the imported products on the Egyptian market, it is necessary to submit the complete documentation of the cosmetic product to the PACA and the EDA through the email address cosm.noneec@edaegypt.gov.eg [99]. The product documentation must include the different documentation reported on the site, and a halal religious conformity certificate is recommended.

There is no Egyptian legislation that prohibits testing cosmetics on animals. Products tested on animals can be marketed in Egypt; however, the raising of awareness and the efforts of animal rights protection societies in Egypt may lead to a possible development in favour of cruelty-free cosmetics [100].

Positive and negative ingredient lists are not available in Egypt; however, the National Drug Research and Control Authority, the General Administration of Inspections, and the Central Administration of Pharmaceutical Affairs carry out extensive testing and inspection on the cosmetic product upon initial registration to ensure consumer safety.

The first Cameroonian Standards for Cosmetics (NCs) were published at the end of 2018 by the National Agency for Standards and Quality (ANOR), thereby establishing the foundations of the legislation on cosmetics in Cameroon. The material is available in the two official languages of Cameroon, French and English, at the ANOR headquarters in

Yaoundé and at its regional agencies. The digital version is still being uploaded on the ANOR website, where the full list of standards is already available [101,102]. The NCs were inspired by European and US legislation.

The regulatory bodies responsible for placing cosmetic products on the market are ANOR together with the National Laboratory for Quality Control of Medicines and Expertise (LANACOME) and the Directorate of Pharmacy, Medicines and Laboratories (DPML). ANOR is the official regulatory agency in Cameroon [101,103]. It is a member of the International Organization for Standardization (ISO) and is tasked with contributing to the development and implementation of government policy in the areas of standardisation and quality. The DPML is a central technical body of the Ministry of Public Health responsible for organising and coordinating regulatory activities in the pharmaceutical sector [104]. Since December 2019, it has also been responsible for developing the official procedure for the approval and registration of cosmetics in Cameroon. The LANACOME checks the quality of the products intended for consumption that are imported or manufactured locally [105].

The DPML at the Ministry of Public Health in Cameroon is currently developing rules that specify the necessary documents for approving cosmetics. Once finalised, these rules are likely to introduce premarketing requirements similar to those in China [105].

Currently, there is no specific legislation or regulation in Cameroon addressing animal testing for cosmetic products.

As of our knowledge, there is not a comprehensive list of allowed and prohibited cosmetic ingredients in Cameroon. However, the Cameroonian standard NC 814 provides a framework for the safety and quality requirements of cosmetic products in the country, including prohibited ingredients such as hydroquinone and mercury compounds. It is noteworthy that Cameroonian standard NC 814 prohibits lightening cosmetics, as they are associated with the practice of the voluntary depigmentation of the skin, a scourge that is rampant in many Sub-Saharan African countries [106].

In Nigeria, the law on foods, medicines, and related products, CAP F33 LFN 2004, defines cosmetics and differentiates them from medicines. It regulates the manufacturing, sale, and advertising of cosmetic products. To comply with the regulations, cosmetics in Nigeria must be registered in accordance with the provisions of CAP N1 (LFN) 2004 of the National Agency for Food and Drug Administration and Control (NAFDAC) and other related regulations. The NAFDAC is the body responsible for registering cosmetics. It is managed by the Nigerian Federal Ministry of Health (FMOH). All information regarding the registration process is available on the NAFDAC website in English [107]. This website reports the guidelines for the registration of imported cosmetics, the NAFDAC Act, CAP N1 LFN (2004), and Cap F33 LFN 2004 [108–110].

To import cosmetics into Nigeria, you need to submit a written application for registration on an online form at <http://registration.nafdac.gov.ng> (accessed on 5 November 2022) [111].

The documentation is reviewed; if approved, an import permit is issued, and the products undergo verification. Once the verification process is completed, the final documentation must be submitted to the Director General of the Registration and Regulatory Affairs Directorate at the NAFDAC. Moreover, a person legally responsible in Nigeria must provide proof of power of attorney from the manufacturer, authorising them to handle all matters related to the products.

There is currently no explicit legislation in Nigeria regarding animal testing in cosmetics, and it does not seem to be a priority of the NAFDAC. However, if a company wishes to conduct a clinical trial for a product in Nigeria, it must obtain valid clinical trial approval from the NAFDAC. This approval process includes a review of the safety and ethical considerations of the proposed trial as well as the qualifications and experience of the investigators involved. It is worth noting that clinical trials in Nigeria are subject to international ethical and safety standards, and any animal testing that may be involved must adhere to the ethical guidelines [112].

In Nigeria, the NAFDAC maintains a list of the essential medicines that are considered necessary for meeting the primary healthcare needs of the population. This list is updated periodically to reflect changes in disease patterns, the availability of new medicines, and emerging health priorities.

The current list of essential medicines in Nigeria includes a range of dermatological products, such as topical antibiotics, antifungal agents, and corticosteroids. The list also includes some sunscreens, such as aminobenzoic acid and titanium dioxide, which are part of Appendix 2. This appendix contains a list of excipients and other substances used in the manufacturing of pharmaceutical products [113].

There are no detailed lists of ingredients (positive or negative) for cosmetics in Nigeria. However, due to the misuse of “bleaching agents” in cosmetic products, the Nigerian government imposed a ban on the production and importation of cosmetic products containing hydroquinone and mercury in 2019. The ban was put in place to protect the public from the harmful effects of these chemicals, which have been linked to skin cancer and other health problems [114].

2.5. Cosmetic Regulations in Montenegro, Serbia, and Albania

Overall, the regulatory requirements for cosmetic products in Montenegro, Serbia, and Albania are similar, with a focus on ensuring product safety, proper labelling, and advertising. As part of the process of becoming EU members, these states are required to align their legislation with EU regulations, including those related to cosmetics. This includes the harmonisation of product safety standards, labelling requirements, and other regulatory measures to ensure that the cosmetic industry in these countries meets the EU standards. In addition, these countries may also adopt the EU regulations related to animal testing, banned substances, and the other aspects of cosmetic products.

Cosmetic legislation in Montenegro is published in the official gazette (OG) of Montenegro and is available on its website. The document was published in 2019 in Montenegrin [115] under the title “Law on Cosmetic Products” (OG n. 24/2019), and it outlines the requirements for cosmetic products in Montenegro. The law is the main regulatory framework for cosmetic products in Montenegro and sets out the rules for the manufacturing, import, and sale of cosmetic products, including a detailed description of the safety considerations to be met and the safety assessments to be performed by the manufacturer.

The body responsible for the implementation of cosmetic legislation in Montenegro is the Ministry of Health [116], which is responsible for ensuring that cosmetic products comply with the regulatory requirements. This includes carrying out inspections, verifying compliance with labelling and advertising requirements, and taking enforcement actions against noncompliant products.

To enter a cosmetic product into the Montenegrin market, the company must submit the required documentation to the Montenegrin Ministry of Health and the European Commission, which is the same as that which is required by the EU. While the legislation does not explicitly mention the need for a responsible national person, companies must still ensure that their products comply with the legal requirements and that they have a local point of contact in case of any issues.

Montenegro has not yet banned animal testing for cosmetic products; therefore, the current Montenegrin legislation allows the use of animal testing data for cosmetic products or their components provided that the tests have not been carried out on EU territory. However, the Montenegrin government has expressed its commitment to gradually align its legislation with EU regulations, which includes the phasing out of animal testing for cosmetic products. In addition, the Montenegrin cosmetic legislation allows products that have not been subjected to animal testing to carry this information on the label, which could encourage companies to move towards using alternative methods to test their products.

Montenegro’s cosmetic legislation does not currently have a positive or negative list of cosmetic ingredients. However, certain classes of ingredients are on a negative list which is not available in the legislation but can be provided by the Ministry of Health.

In Serbia, in April 2019, the Regulation on General Use Items (n. 25/2019) entered into force, and, with it, a new Law on Cosmetic Products (n. 60/2019) emerged, which allowed almost complete harmonisation with EU legislation [117,118].

Law n. 60/2019 provides for new rules and technical requirements for the cosmetic products sold in the Serbian market, such as the need to identify a nationally responsible person, to prepare a product information file, and to provide information on animal testing. The entirety of the material of this legislation is available on the official website of the Ministry of Health, but it is, so far, only available in Serbian.

As Serbia is not yet an official EU member, companies that wish to market their products have to apply to the Serbian Ministry of Health [119].

A responsible person is legally required to place a cosmetic product on the market; this can be either the manufacturer or the importer, or both can designate another person as responsible [117].

In accordance with the legislation, the responsible person must maintain both the product information file (if it is available) and the product documentation for ten years following the date of when the last batch of cosmetic products was placed on the market. The health inspector can access this information electronically or otherwise to the address the information indicated on the packaging [118].

In Serbia the testing of cosmetics or their ingredients on animals is prohibited except in certain limited circumstances, and it requires the use of validated alternative methods [117]. These include cases where the use of alternative methods is not yet possible or where it is required by specific legislation or regulatory authorities. The provision also requires that the use of alternative methods must be scientifically validated and consistent with the principles of the 3Rs (replacement, reduction, and refinement) to minimise animal suffering.

Since Serbia aims to align its laws with those of the EU as part of its efforts to become a member of the EU, the Serbian Law on Cosmetics requires compliance with EU Regulation (EC) No. 1223/2009, which includes a list of prohibited substances and those subjected to restrictions, such as colorants, preservatives, and UV filters. Particularly, Law n. 60/2019 provides several annexes with a detailed list of substances for cosmetic products in the paragraph "Limitations for substances". These lists have been marked as highlights of this new legislation, as the previous legislation (Law No. 18/1991) had very few limitations either on the type or concentration of substances. In addition, the presence of impurities, raw materials, CMR substances, and trace substances has been corrected according to European regulations. The lists of prohibited and restricted substances are given in Annexes II and III, respectively, and the lists of permitted colourants, preservatives, and UV filters are given, respectively, in Annexes IV, V, and VI [118]. All of them are publicly available on the Ministry of Health's website [119].

The current legislation on cosmetics in Albania is governed by Law No. 26/2017 for cosmetic products, which is available on the website of the Ministry of Health and Social Protection or at the Centre of Official Publications [120]. Unfortunately, the law is not currently available in English. The law contains 30 articles that outline the safety and responsibility requirements for producers and importers, with a focus on protecting consumers [121].

The Albanian law on cosmetics is designed to ensure the safety and quality of the cosmetic products sold in the country while also promoting transparency and accountability in the cosmetic industry. The law covers a range of issues, including the definition of cosmetic products, the registration of cosmetic products, the safety assessment of cosmetic products, the labelling and packaging of cosmetic products, and the responsibilities of producers and importers.

Although the law is not available in English, it is understood that the Albanian legislation on cosmetics aligns with the requirements of EU cosmetic regulations, which includes the safety assessment of cosmetic products, the lists of prohibited and restricted substances, and the requirements for the labelling and packaging of cosmetic products. As

Albania seeks to join the EU, it is likely that the country's cosmetic legislation will continue to evolve and become more closely aligned with EU regulations in the future.

Only cosmetic products for which a natural or legal person is designated as the responsible person are placed on the market. For each cosmetic product placed on the market, the responsible person must ensure compliance with the GMP. The responsible person deals with the National Business Centre, the Ministry of Health, and the Cabinet to see the products launched in Albania. Together with the application form, the company must hand over several documents to the relevant regulatory bodies. The documents that are required by Albanian legislation are the product information file and the safety data sheet. The responsible person must keep this information for a period of ten years from the date on which the last batch of the cosmetic product was placed on the market. The product information file must be translated into both the Albanian and English languages.

Overall, the position of Albania on cosmetic animal testing is consistent with that of the EU, and the country has taken steps to ensure the safety and ethical use of cosmetic products without the need for animal testing. Together with the safety data sheet, the Ministry of Health has regulated the list of prohibited substances, those permitted, and the substances subject to restrictions as introduced in EU legislation [121]. Indeed, Law No. 26/2017 contains provisions on the safety and quality of cosmetic products, which include the prohibition of certain substances, the use of substances subject to restrictions, and the safety assessment of cosmetic products. The law requires that the cosmetic products sold in Albania must comply with the same safety standards as those in the EU, which includes compliance with the lists of prohibited and restricted substances in EU cosmetic regulations.

The two following tables summarise the key aspects of cosmetic regulation in the various countries examined in this research. In particular, Table 2 reports the regulatory bodies and reference legislations; meanwhile, Table 3 provides an overview of the presence of the list of ingredients, the animal testing approach, and the market access rules.

Table 2. List of regulatory bodies, reference laws, and languages.

	Regulatory Body	Reference Law	Language
The EU	European Commission [31]	Regulation 1223/2009/EC	UE languages
Mexico	COFEPRIS [35]	General Law of Health, DOF 02-7-1984, and updates	Spanish
Brazil	ANVISA [43]	RDC 752/2022	Portuguese
Argentina	Ministry of Health—ANMAT [50]	Resolution n. 155/1998	Spanish
Ecuador	ARCSA [57]	Resolution ARCSA-DE-006-2017-CFMR	Spanish
Colombia	INVIMA [61]	Decree 219/1998	Spanish
Malaysia	NPRA [65]	Drugs and Cosmetics Control Regulations, 1984—Sale of Drugs Act, 1952	Malay/English
The Philippines	FDA of the Philippines [72]	Republic Act n. 9711/2009 and Republic Act n. 3720/2009	Filipino/English
Indonesia	NADFC [76]	NADFC acts—Law n. 33/2014 of Halal Products	Indonesian
The EAU	ESMA [85]	GSO 1943:2021	Arabic/English
India	Indian Ministry of Health and Family Welfare CDSCO [91]	Drugs and Cosmetics Act, 1940 Cosmetic Rules, 2020	Hindi/English
Jordan	JFDA [96]	Foundations and Legislations of Cosmetics and Pharmaceutical Cosmetics, 2016	Arabic
Egypt	EDA [99]	Resolution 106/1996	Arabic

Table 2. *Cont.*

	Regulatory Body	Reference Law	Language
Cameroon	DPML [104]	Cameroonian Standards for Cosmetics, 2018	French/English
Nigeria	FMOH—NAFDAC [107]	Cap F33 LFN 2004	English
Montenegro	Montenegrin Ministry of Health [116]	Legislation on Cosmetic Products, OG n. 24/2019	Montenegrin
Serbia	Ministry of Health [119]	Law on Cosmetic Products, n. 60/2019	Serbian
Albania	Ministry of Health and Social Protection [120]	Law of Cosmetic Products, n. 26/2017	Albanian

Table 3. Regulatory aspects: ingredients list, animal testing, and approval procedures.

	Classification	Presence of Positive/Negative Ingredient List	Animal Testing	Market Access
The EU	Cosmetic	Yes	Banned	Notification to European portal—CPNP
Mexico	Cosmetic	Only prohibited/restricted	Banned	Notification to COFEPRIS
Brazil	Cosmetic Grade 1 Cosmetic Grade 2	Yes	Allowed (depending on the state)	Grade 1, electronic notification to ANVISA Grade 2, registration on ANVISA
Argentina	Cosmetic Grade 1 Cosmetic Grade 2	Yes	Allowed	Grade 1, electronic notification to ANMAT Grade 2, registration on ANMAT
Ecuador	Cosmetic	Yes	Allowed	Mandatory sanitary notification to ARCSA
Colombia	Cosmetic	Yes	Banned	Mandatory sanitary notification to INVIMA
Malaysia	Cosmetic	Yes	Allowed	Electronic notification to NPRA
The Philippines	Cosmetic	Yes	Allowed	Electronic notification by e-portal of FDA
Indonesia	Cosmetic	Yes	Allowed	Electronic notification via NADFC
The EAU	Cosmetic	Yes	Allowed	ECAS notification via ESMA website
India	Cosmetic	Yes, except for dyes	Banned	Authorization online from CDSCO
Jordan	Cosmetic Cosmetic Pharmaceutical	Only negative	Allowed	Cosmetic notification to JFDA Cosmetic pharmaceutical authorization from JFDA
Egypt	Cosmetic	No	Allowed	Authorization from PACA and EDA
Cameroon	Cosmetic	No	Allowed	Authorization from DPML
Nigeria	Cosmetic— Dermatological Product	No	Allowed	Authorization from NAFDAC

Table 3. Cont.

	Classification	Presence of Positive/Negative Ingredient List	Animal Testing	Market Access
Montenegro	Cosmetic	Only negative	Allowed	Notification to Montenegrin Ministry of Health/EU Commission
Serbia	Cosmetic	Yes	Banned	Notification to Serbian Ministry of Health
Albania	Cosmetic	Yes	Allowed	Notification to National Business Centre/Ministry of Health

3. Conclusions

The global cosmetic industry is highly competitive and continuously evolving. To ensure safety and effectiveness, cosmetic products are regulated and monitored on a global scale. However, regulatory frameworks currently vary significantly among countries, creating challenges for trade and marketing cosmetics worldwide. Consequently, selling the same product in every market is virtually impossible, creating challenges for trade between EU countries and the rest of the world. One of the primary challenges is the language used in regulatory frameworks, which, in some countries, is only available in the national language without an English version. While the cosmetic regulations of the countries mentioned in this review are accessible on the websites of different competent organisations, language remains a significant issue in many cases.

Secondly, the classification of cosmetics varies between countries, creating an additional obstacle against the export of these kinds of products from the EU to other parts of the world. For instance, the EU places all cosmetics in one category and analyses borderline products on a case-by-case basis. Meanwhile, other regions, such as the MERCOSUR, divide cosmetics into two categories, each with different notification procedures. This requires businesses to have extensive knowledge on the various regulations, making it challenging to market their products globally.

Another significant issue for the free market is animal testing. While the EU completely bans animal testing under Regulation 1223/2009, it is still authorised in other regions. While some countries outside the EU are aware of the ethical concerns associated with animal experiments, many have yet to take a clear stance on banning animal testing.

A further regulatory barrier that represents a considerable obstacle for the cosmetic market is the existence of different restrictions on ingredients that vary from country to country. Indeed, while many countries, such as the EU countries, have established positive and negative lists of cosmetic ingredients, others, such as Nigeria, only have a list of banned whitening substances and lack comprehensive legislation on this issue.

Overall, the need for a greater harmonisation of the regulatory frameworks in the cosmetic market is present, as it would promote market expansion, making products safer and more accessible for consumers worldwide. Nonetheless, while the global harmonization of cosmetic laws may promote consistent safety and efficacy standards, it is important to consider the potential drawbacks, such as limiting innovation and hindering market competition. Moreover, different countries and geoeconomic areas may have unique cultural preferences and attitudes towards cosmetics, and a standardized approach may not consider these differences.

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