There is a certain dissonance between the rate of increase in demand, for an expanded range of perfumery and cosmetic goods, and the slow development of regulatory and legal regulation of their production and safety.

During the research, it was established that the inertia of state bodies regarding the approval of laws has a significant impact on the economic development of industry enterprises. Problems in methods for determining substances have been identified; ambiguity of the legislative framework regarding the legal liability of producers for falsification, use of non-regulated components, labeling requirements.

To solve the problem, a critical analysis of the regulatory impact of the regulatory framework, in time, on the economic condition and competitiveness of industry products was carried out. The legislative requirements put forward in Ukraine, EU countries, Canada, America, China on control of production and testing of cosmetics on animals have been analyzed. As a result of the research, four stages of reforming regulatory regulation by the state and bringing the legislative framework of the industry in line with European requirements have been identified and substantiated. New categories introduced into the regulatory framework have been identified and the prospects for exporting goods produced within the framework of the new regulatory framework are shown.

Based on the results of the research, identical and different requirements of the Ukrainian and European regulations for cosmetic products, for packaging, labeling, methods for studying stability, physical and chemical indicators, sampling procedure for expert evaluation were established.

It is shown that the introduced changes meet the requirements of European standards and could increase the competitiveness and investment potential of domestic enterprises of the cosmetic industry. Keywords: enterprises, cosmetic industry, regulatory framework, competitiveness, economic development, market, Technical Regulations, investment potential.

1. Introduction

In the global cosmetic market, every year, there is an increase in investment in the development of new products of the industry, in order to affect the quality of life of consumers, and, accordingly, the expansion of sales and export operations [1].

Cosmetics is defined as a complex chemical composition that can comprehensively affect the body and perform sev-
eral inherent functions. Particular attention should be paid to quantitative evaluation of preservatives [2], adjustment of formulation, chemical composition, product quality control, research into microbiological purity and toxic safety [3, 4].

However, the establishment of the quality and safety of products according to a sample consisting of several prototypes, from the batch, when produced, cannot guarantee the final quality for the consumer [4, 5]. This is due to the possible change of various factors at all stages of the life cycle of cosmetic products. Therefore, the responsibility for the goods should be borne not only by producers but also by intermediaries specializing in the sale and distribution of goods among the population. This obligation should be implemented in regulatory documents at the legislative level. After all, guaranteed safe cosmetic products are competitive in the domestic market of the country and have a strong export potential, besides it does not pose an environmental hazard.

At the same time, there is a certain issue regarding the imperfection of regulatory documentation, in the industry, namely the need to finalize regulatory documents in accordance with the current state of scientific and technological progress and the requirements of European norms [6, 7].

Now the production of cosmetic products based on artificial compounds occupies a significant part of the market in almost all countries, since it is in a more affordable price segment for the consumer. Although the norms for chemical compounds is regulated in state sanitary norms and rules, the chemical composition of cosmetics is difficult to investigate and analyze due to a number of components, the complexity of chemical processes, the outdated methods and testing devices [8]. It should be noted that this direction requires gradual improvement.

Scientists in different countries of the world are working on this issue. Specialists are engaged in improving the technology, introducing new formulation components, bioactive substances from natural raw materials of plant and animal origin [9–11], which improve the effectiveness of cosmetics and penetration of skin epidermis everywhere. However, in many cases, manufacturers introduce new components without proper legislative argumentation at the state level [12, 13]. At the same time, the development of new technological solutions is not reflected in the regulatory framework. That is, the issue of regulatory regulation of the industry remains relevant.

Additionally, one of the urgent problems includes complications arising from the lack of a scientifically reasoned regulatory framework for regulating the size of individual components and the use of nanoparticles in the cosmetic industry [14, 15]. At the same time, the development of means using micromedones, substances stabilized by nanoparticles, is gradually increasing [16]. The number of registered innovations in the field of nanocosmetics is growing rapidly, and there is no study of the production of such cosmetics in the domestic industry to ensure an adequate level of consumer protection [17].

In addition, it should be noted that the imperfection of the regulatory framework is investigated not only in the production sector and the field of cosmetics sales. Additionally, this concerns the regulation of the activities of cosmetology rooms and beauty salons, which, in addition to cosmetic services, will receive a percentage of profits during the resale of cosmetic goods of various directions [18, 19]. These issues should be identified, discussed, and addressed.

Thus, the cosmetic market is growing and has significant potential for economic development. However, the direction of imperfection of the regulatory framework regarding technological support, humanization of production, and safety of cosmetic products is an urgent issue of our times that needs to be addressed.

2. Literature review and problem statement

The rapid development of the cosmetic industry, the growing demand for cosmetic products and cosmetic services lead to the need to improve the regulatory and legal regulation of activities in the cosmetic industry, in accordance with the legislative requirements of the leading countries of the world. As the country goes the way of joining the EU, the priority is to gradually eliminate the existing problems of regulatory regulation of the process of production and sale of finished cosmetic goods. The purpose of this process is to produce safe and competitive, in the world market, goods.

The issues of development and improvement of regulatory and technical principles for ensuring the testing and quality of cosmetic goods, the legal regulation of cosmetic services and the need to strengthen them by the state are highlighted in work [19]. However, the issues of the legal framework of good production practice, cosmetics, are not paid enough attention.

Ways to strengthen the control of production and circulation of cosmetic products are proposed, as well as the issue of harmonization of standards in the field of production of cosmetic goods with international ones has been raised [20]. Attention is paid to the problems of the implementation of European requirements in the production of cosmetic products; practical instructions for the application of the rules of Good Manufacturing Practice and risk assessment have been developed. At the same time, there is no target direction regarding the impact of the proposed ideas on the competitive state of the cosmetic industry and goods.

Paper [21] addresses the problems of regulating the market of cosmetic goods in China. The authors focused on the new category, regarding “cosmetics with a new declared effect”, technical lists of cosmetic ingredients, product safety, etc. At the same time, there are no studies on further prospects for the development of organic products and their further humane testing. Study [8] draws attention to the legal status of providing cosmetic services. It is also noted that the development and introduction to the international market of new products is complicated by the lack of technical regulations on cosmetic products, their proper labeling and advertising. However, not enough attention is paid to the positive and negative aspects of the development of the domestic regulatory framework.

The analysis in [8] also makes it possible to establish that in the domestic market imported cosmetic products are about 70%, which is primarily due to the lack of competitive production facilities and proper legislative regulation. Although the situation is gradually changing. A constant trend of the global cosmetic market is the growth of the share of premium products, which is now account for more than 27%. At the same time, in the markets of developing countries, consumers are becoming more knowledgeable, with special preference given to the latest cosmetic drugs of multifunctional action (for example, VV creams, products for all skin types, etc.). However, the update of the regu-
The reduction of domestic production of perfumery and cosmetic goods has led to a sharp increase in the number of foreign products. Along with this, the importance of cosmetics is growing in accordance with the increase in intellectual awareness and cultural development of consumers who are becoming more demanding.

At the same time, consumers in Europe, America, Japan, and other countries demand the development of a trend to improve the safety and consumer characteristics of cosmetic products. Thus, the authors of [22] focused on the potential opportunities and current use of compounds and extracts derived from plant agronomic disposable waste in the field of cosmetics. Attention is emphasized that when using such substances, special tests should be used to study possible microbial contamination and the presence of pesticide residues. However, the issues of economic efficiency and the regulatory framework that should regulate these analyses are not paid attention.

Paper [23] proposes to solve the problem of increasing the consumption properties of cosmetic goods by introducing natural, e-modified peptides with predicted intelligence. At the same time, attention is paid to tests conducted in vitro, but there are no data on the analysis of the conformity of production of such goods, good manufacturing practice, and the impact on the development of the industry.

The study of biologically active components, with the possibility of providing potentially new properties to cosmetic products, ensuring their natural composition, is paid a lot of attention [24]. However, the authors prefer new ingredients, their potentially new impact on the skin condition, and almost do not touch on the issue of legislative quality assurance of the proposed product. Therefore, certain actions are required to modernize the regulatory and technical support of the industry, to ensure the safety of consumers.

Additionally, one of the most relevant issues is the direction of research on ensuring the environmental friendliness of the goods and the introduction into the legislative framework, on cosmetic products, amendments, on the prohibition or restriction of animal tests.

The first steps to address the problem were taken in Europe, where a single European certification system for organic and natural cosmetics was introduced, which is indicated on the packaging by the NaTrue sign. This marking technique is a clear sign of the informing quality, even to uninformed consumers, with information about the contents of the components indicated on the labeling.

Since the beginning of the XXI century, the problems of improving the regulatory framework and regulatory methods for studying the quality and safety of cosmetic goods have been gaining maximum attention among scientists and industry specialists. The authors of [25] focused on narrowing the gap between regulatory chemical tests and modern safety science. Their research shows the intensification of the activities of organizations that opposed the conduct of regulatory research and research on the safety of animals. Until now, the activities of these organizations have been quite successful since modern methods have been developed where skin sensitization testing is carried out without the use of animals and these methods were recognized by states, members of the OECD (Organization for Economic Cooperation and Development). It is noted that the actions taken regarding the official validation and adoption of guidance on new ways of testing. However, attention is emphasized that this is a long process that requires an assessment of the risks and rules for handling chemicals for humans. At the same time, in the cited work, less attention is paid to the standards and standardized guidance for research and their impact on the competitiveness of the product and the development of the industry.

The wide resonance and demands of certain actions, from the authorities of different countries, led to progressive steps in the prohibition of the study of cosmetics on animals. After the introduction of legislation of Israel, Norway, and EU countries, in 2013, a ban on the sale of ingredients and products tested on animals, this example began to be followed by other countries. Additionally, in 2014, at the initiative of the Brazilian federal regulatory authority for animal experiments, the law was voted for in Brazil [26], and, later, in a number of other countries. At the same time, the improvement of other aspects, from the state of development of the regulatory framework, was paid little attention.

In the United States, a bill to ban the use of animals in testing was introduced in 2014. However, a ban on cosmetic testing on animals was introduced only in certain states [27]. South Korea is also potentially on track to stop testing cosmetics on animals. That is, the issues of the perfection of the legislative framework are unresolved and need to be finalized. In China, in 2017, a number of national organizations engaged in the use of testing methods without the use of animals forced the government to revise the legislative requirements governing the use of animal tests for cosmetic companies. This contributed to the abolition of mandatory testing, most types of cosmetics of Chinese production, from May 2021 [28]. The authors focused on the dominant role of the Chinese cosmetic industry and ways to adopt ethical standards. However, the problem of regulatory regulation of the industry and approval of research methods remains open.

At the same time, in a number of countries, the regulatory framework for cosmetic products is not perfect, other countries do not provide permission to familiarize themselves with and data on possible animal research. As a result, there is no opportunity to learn about reliable data on the safety of cosmetic products sold in countries and exported.

The above suggests that it is expedient to conduct research on the control procedure by state bodies, the system of regulation, and modernization of regulatory and technical support of the industry. This is necessary for the preservation of consumer health, economic development of the industry, and further harmonization with the EU Regulation.

### 3. The aim and objectives of the study

The purpose of this study is to determine the peculiarities of the market and economic development of cosmetics enterprises in the context of reforming the regulatory framework and harmonization to the requirements of the EU regulations. This will make it possible to expand the market of cosmetic products that meet international standards and will contribute to the economic development and increase the investment attractiveness of the industry.

To accomplish the aim, the following tasks have been set:
- to conduct research on the regulatory framework of the cosmetic industry in the “post-Soviet” economic space;
- to conduct research of the second stage of formation of the regulatory framework in the cosmetic industry;
– to conduct a study of the impact of world trends on the formation of the domestic regulatory framework in the cosmetic industry;
– to conduct a study of the process of harmonization of national legislation with the European one as an economic necessity for the development of investment attractiveness;
– to investigate the dynamics of indicators of foreign trade in cosmetics before and after the improvement of regulatory and legal support of the cosmetic industry of Ukraine.

4. The study materials and methods

To obtain the most objective, accurate, systematic information, the principles were used: objectivity, consistency, essential analysis of the regulatory and technical framework, current legislative and regulatory acts (domestic and European), scientific publications. These documents regulate the production, circulation, safety, and sale of cosmetic goods.

In the methodology of research of this problem, philosophical (systemic, theoretical, and methodological, system-structural), general scientific (analysis, synthesis, analogy, classification), special-legal (comparative-legal), methods and tools were used. To study the past trends in the technical and economic development of the cosmetic industry, elements of the retrospective (dialectical) method of analysis were applied; for the study of the structure of relations between the elements of the regulatory framework, a structural and functional method was applied [29].

5. Research of the economic and regulatory state of the cosmetic industry at the stages of harmonization with European standards

5. 1. Analysis of the problems of the regulatory framework of the cosmetic industry at the first stage of the "post-Soviet" development of the economy

As the analysis showed, a number of problems that exist in the cosmetic industry and characterize low investment activity are determined by the need to implement certain actions in the field of state regulation. This applies to the entire life cycle of the cosmetic product, ranging from its development, control of raw materials, formulation, production cycle, control of the technological process and quality of the final product, the packaging procedure, and the type of packaging. And ending with the transportation and sale to consumers in retail or in the provision of appropriate cosmetic services. Unstable quality of cosmetic products is a consequence of uncertainty of the rules of control in production (supervision) and control over the circulation of cosmetic products in the domestic market. Additionally, quality guarantees are limited by the absence of clearly defined requirements for the formation of a safety system for cosmetic products [30].

Analyzing the legislative and regulatory and technical regulation of the process of manufacturing and selling cosmetic and perfumery products, three main stages were identified. The first of them began after the formation of Ukraine as an independent state. Then, imported goods almost completely mastered the market, and the domestic cosmetic industry, inherited, was quite inert and gradually lost its competitive position. The regulatory and technical base of those times was characterized by the presence of GOST and industry regulations (GOST 28303-89 Perfumery and cosmetic products. Packaging, labeling, transportation and storage; GOST 17237-93 Liquid perfume products. General specifications; GOST 29189-91 Cosmetic creams. General specifications; GOST 26878-86 Shampoos for hair care and baths. Method for determining chloride content, etc.), the requirements of which were to regulate the quality of goods in good-faith production, but there were no legislative requirements for proper technological production, and taxation required reconstruction. During that period, imported cosmetics and perfumes are gaining considerable popularity, the market share of which reaches more than 85 %. At the same time, the share of counterfeiting increases. The conditions for the development of such a situation were laid not only by imperfect legislation but also by the internal psychological state of consumers who sought to "be satisfied with imports".

Foreign investors are beginning to step up, who see a potentially huge market, where consumers are educated on a deficit and are convinced that "Import means high-quality", which causes the flow of non-certified cosmetics. That period is characterized by the beginning of investment in establishing a distribution trading network.

5. 2. Prospects of the second stage of formation of the regulatory framework and development of entrepreneurial and investment activity in the perfume and cosmetic industry

The next stage began after the entry into force of the law on the simplified system of taxation of small businesses and the establishment of a single tax for entrepreneurs and small businesses, based on the Decree of the President of Ukraine [31]. That was an incentive not only to reduce the informal activities of trading enterprises for the sale of cosmetic goods and informal employment but also for the development of entrepreneurial activity in the production sector.

Every year there is a trend of growth in sales of cosmetic and perfumery products. The first Ukrainian cosmetic companies and the first Ukrainian brands began to appear because since then, legal entities on the simplified system have paid 6% and 10% of profits.

To control the safety of cosmetic products, in 1999 the State Sanitary Rules and Safety Standards of the Perfumery and Cosmetic Industry were developed and implemented [32], which are now a valid document. The document sets certain requirements for the quality and safety of cosmetic and perfumery products of Ukrainian production. That led to the need to introduce stricter control over production conditions, compliance with technology and a professional approach to the development of the range and the introduction of new formulation components.

The late 1990s and early 2000s are typical for starting new production companies, both Ukrainian founders and foreign investments. These are companies such as Bulgarian-Ukrainian LLC "Piranha", LLC "Scientific and Production Company "Vilarus" (German manufacturer in Ukraine), Company "Vigor-cosmetics natural", and others. Active registration of domestic brands has begun: "My whin", "Delicious secrets", "Viva oliva", "For men" (pharmaceutical research center "Alliance of Beauty"); "Green Pharmacy", Lady Caramel, Dr. Sante, BIO, O’Herbal, Salon (cosmetics and pharmaceutical group "Elf"), "Color me", Kaetana, etc. Less active but increased was the investment potential in the production of perfumes. Among the enterprises with the infusion of foreign investments are the Kyiv
company with PE “Wexhold” (perfumes were made on the basis of French recipes and packaged in imported cardboard containers), LLC “Euro perfume” (Lviv region). One of the most successful, at that time, was the Crimean LLC “Avalon”, which occupied up to 20% of the market, as well as the perfumery and cosmetics factory LLC “Aroma”, reorganized enterprise PJSC “Effect”, and others.

A deterrent to business development, in this direction, was the need to obtain a license and pay excise duty on alcohol. In 2004 in Ukraine there were 14 licenses for the production of perfumery, in 2006 – 8, and by the beginning of 2010 there were 6 [33].

From 1999 to 2009, the number of enterprises of manufacturers and distribution companies, and, accordingly, single-tax payers, increased rapidly, and, in some years, reached up to a thousand units. The rapid development of the cosmetics business was accompanied by the import of smuggling and “gray imports”, as well as the emergence of enterprises for the production of counterfeit goods for well-known brands. The dynamics of business activation on counterfeit goods were growing. Thus, the International Chamber of Commerce found that in terms of the volume of supplies of counterfeit perfumery to the European market (19%), Ukraine was second only to China (37%), which definitely undermined the authority of Ukrainian products and manufacturers [8].

5. 3. Influence of world trends on the formation of the regulatory framework in the cosmetic industry

One of the directions for solving the issue could be the improvement of the regulatory and technical base and the introduction of strict control over the production and sale process. At this, the third stage, the work of scientists and industry specialists on the development and registration of new Ukrainian DSTU began. That was supposed to provide clarity of control over cosmetic and perfume products both in laboratories and at enterprises and during independent expert research.


However, in some countries, the concept of safety has remained a certain problem in cosmetology. Substances referred to as antibiotics were not regulated in cosmetics and are used by a number of manufacturers to extend the implementation period, in anti-dandruff shampoos, although such drugs for use in cosmetic drugs are prohibited.

A characteristic difference of that period was the lack of a systematic classification and a clear definition of terms in the cosmetic industry. Existing methods of forming a trade range do not take into consideration a set of factors that characterize the quality, determine the storage conditions and the procedure for the sale of goods. That led to the introduction of regulatory documentation for each assortment group of goods.

A significant impact on the economy of Ukraine, and accordingly on business in the cosmetic industry, was exerted by a global crisis, the aggravation of which the country experienced in 2008–2009. The rapid growth of the dollar exchange rate caused the bankruptcy of many enterprises, the growth of unemployment, and the fall in the purchasing power of the population. Competition, in the market of cosmetic and perfumery products, is determined by the possibility of varying the price of goods, the amount of capital, and production capacity. These factors negatively affect small enterprises without large investments in production, some of which are forced to gradually leave the market. The share of production and sale of goods for export decreases. Perfume production volumes are reduced by the following dynamics: 1.5% in 2009, to 41% in 2010, and in 2012 to almost 3.5 times. Accordingly, the export of cosmetic and perfumery products decreased in 2010 by almost 25%, compared to 2008 [33].

In addition, the position of Ukrainian exporters, at that time, was negatively affected by the adoption of a number of legislative changes in the cosmetic industry, which were carried out in the EU, Canada, and other countries. In accordance with those changes, the term “cosmetic products”, safety requirements, labeling and requirements for good manufacturing practice were clearly defined.

Thus, since November 2009, the EU countries, on the issues of terminology, requirements for the production and safety of cosmetics in circulation in all EU countries, began to be guided by the requirements of Regulation No. 1223/2009 of the European Parliament and of the Council on cosmetic products (Brussels, 30 November 2009). The main distinguishing feature of the EU Regulation was the statement defined in article 8 “Good practice of production organization”. Namely, that cosmetic products presented on the market, to ensure their safety, must be manufactured in accordance with the good practice of the organization of production, which must be observed by each manufacturer [34].

The Regulation contained a list of substances that were prohibited or restricted for use in the cosmetic industry, and had items that established a ban on testing cosmetics on animals. That document had a significant impact on manufacturers and the reorganization of the process of manufacturing and selling cosmetic goods.

Almost simultaneously, in Canada, the “Reference Document: Classification of Goods On the Border Between Cosmetics and Medicines” was put into effect [35]. That document was the managing, and was an interpretation of the Food and Drug Act, the Food and Drug Regulations, the Cosmetic Regulations, and the Natural Health Products Regulations. In addition, the document contained clear definitions on a reasonable approach to the classification of products and cosmetic products, the definition of which is complicated, because of the thin boundary between cosmetics and medicines. For enterprises, it is forbidden to carry out any actions with cosmetic goods under “unsanitary” conditions. To comply with that rule, the Ministry of Health in Canada recommended that all manufacturers adopt good manufacturing practices of the International Organization for Standardization (ISO) 22716: Cosmetics.
Good Manufacturing Practice (GMP) and Good Manufacturing Practice Guide. The documents were supplemented by the Federal Food, Medicines and Cosmetics Act existing in Canada. According to the Law, a cosmetic product can be recognized as falsified, since it can be harmful to users under normal use. That can happen if the product or its packaging contains potentially harmful substances, dirt, unauthorized paint additives. Additionally, the goods may be considered unfavorable for use if the goods are manufactured or stored under unsanitary conditions, and as a result this may harm consumers [35].

Additionally, the Federal Law on Food, Medicines and Cosmetics of Canada provides data (section 602), which provide reasons for recognizing the cosmetic product as substandard. Signs of this may be: misleading labeling; absence, at a certain place, of information regulated by law; the presentation or filling of the container is misleading.

At that time, the bill on the abolition of mandatory certification, which united the hands of non-conscientious manufacturers, had a significant negative impact on the process of quality control of goods in Ukraine. Probably, at that time, that was not a timely step that preceded the process of establishing a quality control system in Ukraine. However, that was the first step in transforming the legislation into meeting the cooperation with the European Union and encouraging foreign investment in the perfume and cosmetic industry. At that time, the quality of industry goods had to comply with state regulatory documentation.

Returning to the changes in the Legislation that influenced the development of cosmetic industry enterprises, in addition to ISO standards and the European Regulations, it should be noted the tax amendments to the Tax Code of Ukraine introduced in 2011. After the entry into force of legislative changes, the division of taxpayers – individuals into categories, was carried out according to the criteria of income, the presence of employees, and the type of activity. That greatly affected the economic condition of production since most enterprises did not fall under the category with a fixed tax rate. Accordingly, the amount of tax deductions for enterprises has increased, and profitability has decreased. Those who did not adapt to the new changes expected bankruptcy or mergers with larger enterprises, which became the basis for the growth of corporations. Such enterprises began to expand the range, introduce new brands of cosmetic products: LLC MNVO “Biocon”, pharmaceutical research center “Alliance Beauty” (brands “My whim” “Eco control”, “Viva oliva”, “For men”, “Family doctor”, etc.), cosmetics and pharmaceutical group “Elfa” (brands “Green Pharmacy”, Lady Caramel, Dr. Sante, BIO, O’Herbal, Salon, etc.), and others.

Ensuring the stability of work of enterprises producing cosmetic and perfumery products, supporting the export of products, and providing consumers with safe and high-quality world-class goods was under threat. That is, there was an urgent need to harmonize regulatory and technical regulation in Ukraine with the legislation of the European Union (EU), namely with the EU Regulation in the field of cosmetics No. 1223/2009. In this direction, the Ministry of Health of Ukraine is developing a Draft Resolution of the Cabinet of Ministers of Ukraine “On Approval of the Technical Regulations on Cosmetic Products”. The draft resolution was published and considered in 2013. However, further legislative changes in the industry have become inert, almost until 2019. The main document that was supposed to ensure the safety of cosmetics was DerzhSanPiN 2.2.9.027-99 [32].

Despite the inertia of the legislation, the work of scientists continued, innovative developments replenished the range of manufacturers of industry enterprises. Exports of industry goods slowed down but investment in the industry did not stop, so the pace of development remained gradual.

5.4. The stage of harmonization of national legislation with the European one as an economic necessity for the development of investment attractiveness

From 2019, we can talk about the beginning of the next stage of the “European development” of the perfumery and cosmetic industry in Ukraine. A number of legislative acts were introduced that abolished the effect of DSTU on a certain assortment group of cosmetics, perfumes, and skin and hair cleansing products. Additionally, at the end of 2019, amendments were made to the Technical Regulations developed in 13 and the Draft Resolution of the Cabinet of Ministers of Ukraine “On Approval of the Technical Regulations on Cosmetic Products” was published. After that, the Project was at the stage of discussion for more than a year. As before, the main document regulating the safety of cosmetics and perfumes was DerzhSanPiN 2.2.9.027-99.

The need for reformation in the industry was exacerbated, since the lack of professional and modern regulatory and technical regulation made it impossible to ensure an adequate level of safety of goods and the process of consumer protection, and, accordingly, the further development of enterprises. Detention with the resolution of these issues threatened the legislative collapse of the production sector in the cosmetic industry and the loss of domestic producers, export positions in the international market. This reduces the economic attractiveness of the industry, and, accordingly, investment proposals.

Finally, the main reformation in the industry took place. This step was made in early 2021, January 20, by the decision of the Cabinet of Ministers of Ukraine, a new Technical Regulation on cosmetic products [36]. This stage of legislative reform was made in order to harmonize national legislation with European requirements. The document gave a clear definition of the terms characteristic of the cosmetic industry. From then on, there is no uncertainty in the concept of “cosmetic products” and the name of the industry that produces it. The Regulation provides for a clear classification of cosmetic products by direction of application and method of application. Additionally presented is an abbreviation for ingredients (UV filters, CAS number, CMR substances, INCI, INN). It refers to the Laws of Ukraine “On general safety of non-food products”, “On technical regulations and conformity assessment” and “On state market surveillance and control of non-food products”. These laws state the procedure for using a number of terms, such as “withdrawal from circulation”, “withdrawal”, etc.

With the entry into force of the Regulation, the production of cosmetic products must comply with proper production practice, and cosmetic goods produced in Ukraine must have a clear description and identification drawn up for each cosmetic product. Each cosmetic product must have a description of production methods and a data on compliance with GMP standards; product safety report and its confirmation of the declared effectiveness. Responsibility for proper production rests entirely with the manufacturer, to ensure this provision, a regulatory document harmonized with the international standard – DSTU EN ISO 22716:2015 (EN ISO 22716:2007) “Cos-
metics. Good Manufacturing Practice (GMP). Guidelines for Good Manufacturing Practice."

Consider some of the features that were introduced into the Technical Regulations compared to previous practice. This is the definition of a “responsible person” who must ensure compliance with the relevant obligations for cosmetic products presented on the market specified in the Technical Regulations [36]. In addition, at the request of the state market surveillance authority, the responsible persons provide information about the distributors who were provided with cosmetic products for sale, which aims to ensure identification in the supply chain.

The technical regulations contain an expanded list of substances that are prohibited in the cosmetic industry. Responsibility for the proper production and safety of cosmetic products rests entirely with the manufacturer and the enterprises implementing it.

A ban on any animal testing has been established and an increased list of substances that are not allowed for use has been introduced, or their number is strictly limited.

Further research analyzed the regulatory framework for packaging and labeling of cosmetic products. To regulate the requirements for packaging and labeling, two DSTU were issued: DSTU 5010:2008, which was valid until 2019 and DSTU ISO 22715: 2019 Cosmetic products. Packaging and labeling, which is identical and accepted by ISO 22715:2006 Cosmetics – Packaging and labelling, with minor editorial changes. It should be noted that DSTU ISO 22715:2019 almost duplicates the item of the Technical Regulations “Marking”. After all, the document requirements for packaging and marking information fully and clearly define the procedure for labeling cosmetic products, which are packed at the place of sale at the request of the buyer. The same requirements apply to products that are pre-packaged for direct sale.

The Technical Regulations on packaging labeling provide for the use of symbols designated in Annex 7. Let’s look at such symbols, for example: “The period after opening the packaging” can be depicted as an open jar. A symbol reminiscent of sand clock characterizes “minimum shelf life” and “See information in accompanying materials.” The symbol in the form of an opened book, where the index finger of the hand indicates a certain period, characterizes the “Period after the opening of the packaging”.

Next, the filling of the informative composition of both DSTU was investigated, which clearly regulates the conditions for labeling cosmetic goods, types of packaging for cosmetics of different consistency and components for them. It was indicated that the packaging may be leaflets-tabs indicating marking information that does not fit on the package, or impossible due to the specificity of the goods, while DSTU 5010:2008 noted the expediency of artistically designed markings and postcards. On each unit of consumer packaging there should be a mark on the name and purpose of the product, the name of the manufacturer and its legal address, trademark (if any), the code (number) of the batch for identification, the nominal content of the cosmetic product. Also indicated are the data on the proportion of ethyl alcohol (in the case of its content), shelf life, storage conditions, and the list of components, purpose, method of use and precautions when using cosmetic products (if any).

In addition, a normative document is indicated, according to which the goods are produced, information on certification, barcode, and special precautions, in the case of the content of substances that are limited by ND. For decorative cosmetics one should indicate the color, tone number, group. However, in the new DSTU ISO 22715:2019, the concept of “manufacturer’s name and legal address” has been changed to “name and address of the responsible person for providing products on the market”. There are no data on the designation of the regulatory document and barcode.

Both DSTU, as well as the Technical Regulations, provide for certain requirements for the implementation of labeling of cosmetic products intended for sale on the Ukrainian market and instructions for its use. Their labeling should be carried out in accordance with the requirements of the Law of Ukraine “On ensuring the functioning of the Ukrainian language as the state language”.

 Expedient and necessary, in DSTU 5010:2008, was a paragraph relating to the norm of the list of components in perfumery and cosmetics (denoted by the terms “ingredients” or “composition”). This standard, for the first time, clearly defined what is indicated in the list of components in accordance with the recipes in order to reduce their mass fraction. At the same time, a mixture of fragrant substances should be indicated as one component using certain words “flavoring” (in the new DSTU, “aroma”), “perfume”, “aromatic composition”, etc., without revealing the composition).

In the case of ingredient content that, according to ND, should be limited in the composition of the perfume and cosmetic product, it must be provided with information on the reservation during the use of the product. Ingredients whose mass fraction is less than 1 % should be listed in any order but only after the components included in the amount of more than 1 %. Dyes may contain a CI color index or an acceptable designation and are listed after other components. Dyes of the same name, but different tones are allowed to be listed in an exhaustive list.

Similar requirements are put forward in the Technical Regulations and DSTU ISO 22715:2019 but they added data on the need, indicating in parentheses, the ingredients present in the form of nanomaterials. They are denoted by the word “nano” or by the designation INCI.

Special remarks introduced in DSTU ISO 22715:2019 on the quality of information tools (inks for printing, etc.), clarity of letters and ease of reading them, take place in DSTU 5010:2008.

At the same time, certain objections were raised by the presence, in DSTU 5010:2008, of a clause regarding the possibility of applying advertising information. After all, it is for such information that manufacturers make a calculation if they want to more profitably present their goods to consumers. In addition, this information is applied, as a rule, in capital letters. Since it immediately catches the eye of consumers and, accordingly, affects the subconscious, and controls the emotions of the choice of goods. The new standard does not mention these data. In addition, the technical Regulations prohibit the provision of cosmetic products on the market, which “... look different than they really are, and have signs that consumers and, in particular, children, can take such products for food products, and, as a result, put them in their mouths...” [36]. This makes it impossible to safe cosmetic products and can harm consumers. (It is impossible to break – direct speech).

Additional information specified in DSTU ISO 22715:2019 is the requirements for labeling mono-dose pack-
aging and free samples, determining primary and secondary packaging, as well as marking information about the absence of animal testing.

5. 5. Research of dynamics of indicators of foreign trade before and after improvement of regulatory and legal support of cosmetic industry of Ukraine

Trends in the perfumery and cosmetics market indicate its positive dynamics and stability of development. According to the results of 2021, the volume of the global cosmetics market was determined at the level of USD 287.94 billion, which is more than in 2020, when the market volume amounted to USD 277.67 billion. During 2021–2028, the global cosmetics market is projected to grow by an average of 5.0 % annually to achieve, in 2028, USD 415.29 billion [37]. Most of the global cosmetics market is in the European market. Its volume in 2019 amounted to USD 121.54 billion, in 2020 – USD 102.55 billion [37]. Significant volumes and positive dynamics of sales of cosmetic products prove the attractiveness of the European market in terms of development in this segment of international trade in cosmetics.

Scientists and practitioners identify the main factors that complicate the development of the perfumery and cosmetic industry of Ukraine and the entry of Ukrainian producers into the European cosmetics market. This is a non-compliance of the regulatory framework regarding the production and quality control of products, European standards, as well as other rules and standards, regarding the safety of products, the conditions for its storage, sale, and use. Also among the complications noted is the lack of a comprehensive system for diagnosing crisis conditions of Ukrainian enterprises. One of the factors in reducing the level of influence of economic risk, for most enterprises, and overcoming the crisis of the perfumery and cosmetic industry as a whole, is the development and comprehensive implementation of effective anti-crisis measures using the results of constant diagnosis [38].

At the same time, there are reasons to believe that the improvement of regulatory and technical documentation on cosmetic products should contribute to increasing the export potential of industry enterprises. To test this hypothesis, the indicators of foreign trade in cosmetics were investigated, namely: foreign trade turnover, foreign trade balance, import export coverage ratio. The formulas for calculating are as follows [39]:

\[ FTT = E + I, \]
\[ B = E - I, \]
\[ C_e = \frac{E}{I} \]

where \( FTT \) is the foreign trade turnover, USD million; \( B \) is the balance of foreign trade, USD million; \( C_e \) is the import export coverage, coefficient; \( E \) is the export of products, USD million; \( I \) is the import of products, USD million.

Taking into consideration the information support [40], a study was conducted using data for 2017–2021. Economic indicators were determined taking into consideration the stages of improving the regulatory and legal support of the activities of industry enterprises. Since it was during those years that amendments to the Technical Regulations were made and the Draft Resolution of the Cabinet of Ministers of Ukraine “On Approval of the Technical Regulations on Cosmetic Products” (2019) was published. This is noted as a stage of harmonization of national legislation with the European one. The study of indicators of foreign trade in cosmetics was carried out in the context of two periods, namely 2017–2018 and 2019–2021.

The studies show that during the study period, with the exception of 2020, Ukraine’s foreign trade turnover by cosmetics as a whole and with EU countries increased. The largest increase was observed in 2021. Compared to 2020, the volume of foreign trade in cosmetic goods of Ukraine as a whole increased by 27.1 %, including with the EU countries – by 18.8 % (Fig. 1).

A comparison of the dynamics of exports of cosmetic goods, before and after the amendments to the Technical Regulations that took place in 2019, showed positive changes. That has made it possible to conclude that the rate of exports of cosmetic goods in general and with the EU countries is growing.

![Fig. 1. Dynamics of foreign trade turnover by cosmetics of Ukraine for 2017–2021 (compiled independently according to data from [40])](image-url)
This is a positive trend in the development of the perfumery and cosmetic industry of Ukraine. During 2019–2021, the exports of cosmetic goods grew by an average of 13.8% annually, which is higher than before the amendments to the Technical Regulations. The volume of exports of cosmetic products to the EU countries in the period 2019–2021 increased by 1.8 times, namely from USD 15.3 million in 2019 to USD 27.8 billion in 2021 (Table 1).

Despite the growth in the volume of foreign trade in cosmetics, from year to year, the balance in this area of foreign economic activity, throughout the study period (2017–2021) was negative. After the publication of the Draft Resolution of the Cabinet of Ministers of Ukraine “On Approval of the Technical Regulations on Cosmetic Products” (2019–2021), the situation has not changed for the better. According to the data of 2021, the balance of foreign trade in cosmetic goods of Ukraine is negative and amounts to (−208.1) million US dollars in general and (−126.2) million US dollars and with the EU countries. In 2019, those same figures amounted to (−185.8) and (−135.1) million US dollars, respectively (Fig. 2).

The negative balance indicates an excess of imports over the export of goods. However, the analysis of this indicator is insufficient to determine the nature of foreign economic activity. To understand the peculiarities of foreign trade in cosmetic goods, the coefficients of coverage of export operations, import operations in Ukraine were calculated (Fig. 3).

### Table 1

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Period prior to amendments to the Technical Regulations</th>
<th>Period after amendments to the Technical Regulations</th>
<th>growth rate on average per year 2019–2021, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exports of cosmetics, total, million US dollars</td>
<td>40.5</td>
<td>45.3</td>
<td>111.6</td>
</tr>
<tr>
<td>including to EU, million US dollars</td>
<td>12.9</td>
<td>13.3</td>
<td>102.8</td>
</tr>
</tbody>
</table>

Note: compiled on the basis of data from [40].
As a result of our calculations, it was established that the absolute values of the coverage coefficients for import exports during 2017–2021 are less than 1.0. They are 0.18…0.22, in general, by foreign trade in cosmetics, and 0.10…0.18 – for foreign trade in cosmetics with EU countries. The low values of these coefficients indicate negative trends in the sale of cosmetics, namely, a significant excess of import volume compared to the export of goods of this group. In 2021, the total volume of imports of cosmetics exceeded their exports by 4.8 times, the volume of imports of cosmetics from European countries exceeded their exports to the EU by 5.5 times. Against the background of a significant excess of imports of cosmetics over their exports, in general, we note an increase in the coverage ratio for exports of cosmetic goods to the EU from 2019 to the present. The increase in this coefficient is a sign of a narrowing of the gap between the volume of exports and imports of goods with European countries. During 2019–2021, this gap almost halved. In 2019, the volume of imports of cosmetic goods from the EU exceeded the export of these goods to the European market by 9.8 times, and in 2021 – 5.5 times.

6. Discussion of results of the further improvement of regulatory and technical documentation for the growth of the economic potential of the cosmetic industry

The positive impact of reorganization and updating of the regulatory and legislative framework on the introduction into production and manufacture of new safe types of cosmetic products, as well as on the economic development of the cosmetic industry, was noted. In order to confirm the safety of cosmetic products, under normal or reasonably foreseeable conditions, the responsible person, before placing products on the market, must ensure the passage of a safety assessment. Proper assessment of the safety of cosmetic products is ensured by the high qualification of an expert. It also provides for a report on the safety of cosmetic products, indicating additional information from 10 points, regarding the level of requirements:

1. Quantitative and qualitative composition of the cosmetic product indicating the identification of chemicals (chemical name, INC1, CAS, EINECS/ELINCS, where possible) and indicating aromatic and perfume compositions.
2. The physical and chemical characteristics and indicators of product stability.
3. Microbiological quality.
4. Impurities, traces, information about the packaging material.
5. Intended conditions of application.
6, 7. Effect of cosmetic product and substances; toxicological profile.
8. Toxicological profile of substances.
9. Undesirable effects.
10. Other important information.
Let's take a closer look at some of them.

Paragraph 3 "microbiological quality": regarding the control of microbiological quality, concerns a number of regulatory and technical documentation, which determines the procedure for conducting, methods of conducting, and conformity indicators. That is, all parameters for full-fledged research on product safety that meets the requirements of the EU Regulation have been determined.

The positiveness of the improvement of the Technical Regulations on the prosecution of both responsible persons from the manufacturer and distributors of cosmetic goods was noted. During their stay of cosmetic products, there should be no risk to human health, compliance with established requirements, and storage conditions, or transportation of such. At the same time, in order to ensure confidence in the effectiveness of the measures taken, it is advisable to introduce an addition indicating the qualifications, level and direction of education of such responsible persons.

The above obliges distributors to be responsible for the distribution and provision of services, to take appropriate measures to bring cosmetic goods in line with the requirements of the Technical Regulations, in beauty salons and beauty salons. This is important because the regulatory and legislative framework regulating their activities at the state level remains in the state of the 1990s and must be reformed.

It is noted that from now on in the Technical Regulations, in accordance with the requirements of the EU Regulation, there is a clause regarding the prohibition of tests conducted in vitro. This takes into consideration the opinions of zookeepers and has a positive impact on the development of enterprises and increased exports of cosmetics products.

The studies have revealed the moments of the “Technical Regulations on cosmetic products”, which remained unattended and need to be explained. This applies to the lack of data or a reference to a document that clearly regulates the procedure for sampling and samples and the norms of their selection. The State Sanitary Regulations and Safety Standards of perfumery and cosmetic industry products [32] provide a reference to the requirements of GOST 291880, which is not valid in Ukraine. DSTU for the range of goods of this group is also canceled. In the approved Technical Regulations on cosmetic products, on the procedure for sampling, it is said in general phrases. For example, sampling should be carried out by reliable and reproducible methods defined by national standards that are identical to the relevant harmonized international or European standards [34]. Thus, sampling should take place at the discretion of the expert conducting the research.

There is a lack of clear explanations to the list of "physticochemical characteristics". However, the manufacturer, when conducting research on the goods, must use certain regulatory and technical documents that are in the status of “Canceled”.

As the most convenient and complete, it is noted, is the current DSTU ISO/TR 17276:2019 “Analytical approach to the choice of methods for quantitative determining of heavy metals in cosmetics”. The document contains methods for preparing samples (there is no procedure for their selection), methods and techniques of detection using various methods (colorimetric reaction, X-ray fluorescence, atomic adsorption spectrometry, etc.). The application presents a detailed procedure for conducting research by each of the methods and the procedure for calculating the results of the study, which is quite convenient.

Comments on DSTU ISO/TR 18811:2019 Guidelines for determining the stability of cosmetic products have been identified. Exploring its content component, it is possible to note the difference, its construction and structure, from traditional regulatory and technical documents, which were used by researchers in Ukraine for many years from the time
of the USSR. The main differences are as follows. Stability in the new DSTU is considered as a complex indicator, which is influenced by a number of factors (temperature and its fluctuations, humidity of the external environment, level and availability of lighting, vibration level). Research methods are allowed to be chosen depending on the type of emulsions and dispersed systems but preference should be given to simple methods that do not require dilution and other sample preparation. After all, when determining the shelf life, cyclic and accelerated test methods are allowed for use, subject to the recommended conditions and duration. The possibility of interaction with packaging and recommendations for research of microbiological stability and evaluation of test results, stability, and passing the test protocol were also noted. These stability factors, in previous NTD, were considered as separate physicochemical indicators with recommended research methods, which contributed to their unification and erased the understanding of the global concept of the basic principles of emulsion stability of various types.

The procedure for conducting stability studies, indicating the recommended methods, is advisable to carry out on the example of DSTU ISO/TR 17276: 2019, where the content of toxic components is determined. However, as noted above, state documents approving the norms for physicochemical quality parameters, for almost all types of cosmetic products, have been canceled. The exception is DSTU 4544:2006 Soap, household, solid. Technical specifications and DSTU 4545:2006 Soap shavings. Technical specifications. This indicates the absence of generally established norms and encourages manufacturers to manufacture products according to personally approved technical conditions. This complicates the expert assessment of the physical and chemical characteristics (previously quality indicators) of cosmetic products and makes it impossible to clear the actions for the state market surveillance authorities. However, such inspections are provided for in accordance with the Law of Ukraine “On State Market Surveillance and Control of Non-Food Products”. At the same time, according to the Technical Regulations, it is provided for the definition of the responsible person who ensures compliance with the relevant obligations specified for cosmetic products [36]. What characterizes the presence of additional control over the production of products.

The data on the expediency of testing the effectiveness and change of rheological properties of foam-washing cosmetic products with different water hardness was obtained. This is justified by the fact that the pH of tap water in Ukraine, under normal conditions, is very different in regions and compared to the EU countries. This leads to an increase in the cost of foam detergent when used by the Ukrainian consumer, compared to consumers in the EU countries. However, in order to eliminate this problem, it is necessary to include the appropriate rheological characteristics of detergents in the regulatory and technical documentation. Until now, these problems have not been realized, and no requirements have been registered at the legislative level, which take into consideration the properties of water, as a solvent, when using such means to preserve the quality of products. In addition, we noted the expediency of developing standards for the composition of products, taking into consideration the hardness of water in the regions of Ukraine, which in some way will contribute to the regulation and safety of the quality of detergents [19].

The study revealed the need to take into consideration physical and chemical indicators, for the range of cream scrubs for the skin, the quality of which was determined by DSTU 4765: 2007. The technology of their manufacture involves the introduction of abrasive particles that perform the function of cleansing the skin of dead cells of the surface epidermis. However, to the shape, size, and quantitative content of the abrasive, which is characterized by a wide range of dispersion (from 20 microns to 100 microns), the regulatory documentation does not provide any explanation. Additionally, innovations have been defined in the types of abrasive particles, the variety of their geometric characteristics, and at the same time the lack of norms, regarding the quantitative content of abrasive, which can reach a dangerous 25–30%. These indicators are not normalized according to the State Service of Ukraine on 2.2.9.027-99 where only the list of allowed raw materials is given, which can harm the health of consumers. This requires the application of measures to introduce a clear regulation of the direction of use of cream scrubs depending on the quantitative content, dispersion, and form of abrasive, indicating the information on the labeling. This will provide an increase in awareness of the product, and, accordingly, competitiveness among a certain, intellectually aware, segment of consumers.

It is advisable to review the information on the range of limits for the pH indicator, which are expanded from 5.0–9.0 (for ordinary fat and emulsion creams) to 3.0–9.0. This can have undesirable consequences for human health because all cosmetic products have direct contact with human skin.

Among the main factors that will contribute to the development of the economy and export potential of cosmetic enterprises, improvement of regulatory and technical documentation was noted. This is confirmed by the indicators of foreign trade in cosmetics over 2017–2021: foreign trade turnover of the balance of foreign trade, the ratio of coverage by import exports: presented in Table 1 and in Fig. 2, 3.

The factors – complicators of the development of perfumery and cosmetic enterprises of Ukraine and entering the European market, indicate the lack of a comprehensive system for diagnosing the crisis conditions of Ukrainian enterprises.

It is planned, in further work, to conduct research on the products of enterprises that have switched to working conditions in accordance with the Technical Regulations on cosmetic products. As well as the study of their problems and economic advantages among competitors, the prospects for exporting products produced in accordance with European standards in the European Union and other countries.

7. Conclusions

1. The study of gradual progressive development of production of perfumery and cosmetic goods in the “post-Soviet” space was carried out. This made it possible to identify and conditionally divide the process of regulatory and legal reform of the legislative framework of the cosmetic industry into four stages, which gradually brought it in line with the requirements of the European Regulation.

2. It was established that the second stage of development of the cosmetic industry was characterized by the emergence of new production companies and the beginning of entrepreneurial and investment activities, which is due to
an increase in demand for goods of this group. In parallel, this contributed to an increase in smuggling and gray imports.

3. The situation was noted and substantiated when, in order to develop investment attractiveness and export opportunities of the cosmetic industry of Ukraine, a clear economic need for the final stage of harmonization of national legislation with European requirements arose. This stage dates back to the cancellation of the DSTU on most assortment groups of cosmetic products and the beginning of focused work on the introduction of the Technical Regulations harmonized with the EU Regulations.

4. The studies proved the identity of the requirements put forward in the Ukrainian Technical Regulations, the Regulations of European countries, and the legislation of Canada, as well as in the current regulatory documentation on labeling and other safety parameters of cosmetic goods. It is shown that the goal of the reform has almost been achieved – ensuring good manufacturing practice in accordance with the adopted Technical Regulations, which will enable Ukrainians to use cosmetic goods that meet modern European requirements. The introduced changes are aimed at harmonizing Ukrainian regulatory and technical documentation in accordance with European and world standards. The result of the reorganization of the regulatory and technical base was investigated and noted, namely, an increase in the investment attractiveness of the industry, the establishment of new ties in trade relations and the growth of exports of cosmetic products to Europe and other countries.

Thus, it was noted that the introduction in 2021 of the “Technical Regulations” on cosmetic products was an important step to ensure the export opportunities of Ukrainian cosmetic enterprises. At the same time, a number of moments that were ignored were investigated. These points can complicate the expert assessment of the physicochemical characteristics of cosmetic products and make it impossible to clear the actions for the state market surveillance authorities. These include the following:

1) the absence of a valid document that clearly regulates the procedure for sampling and samples and selection norms;
2) the absence of requirements for the hardness of water, as a solvent, during the production of cosmetic products, which affects the functionality of the product;
3) uncertainty in the item of the list of “physical and chemical characteristics”;
4) the lack of documentation, which approved the norms for physicochemical parameters of all types of cosmetic goods, especially pH requirements;
5) the uncertainty of methods for studying stability in accordance with the range of cosmetic products.

5. The positive dynamics regarding the volume of exports of cosmetic goods from Ukraine to the EU countries were noted, which have been observed since the beginning of harmonization of Ukrainian legislation with the European one. It is proved to reduce, by 1.8 times, the gap between the volume of exports and imports of these goods, with European countries, during 2019–2021.

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