Safety of Plant Cosmetic Raw Materials

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ABSTRACT

The paper discusses the market of cosmetic raw materials of natural origin. Various legal and administrative regulations relating to the group of natural products in Europe and North America were shown, which ensure the safety of their use. One discussed the role of international organizations in supporting various continents and countries in unifying operations, whose aim is to maintain the security. Attention is paid to safety issues concerning natural products that are associated with the widespread and independent use of these products by consumers without consulting a doctor. Due to the differences in the legal systems, the same materials are used in some countries as cosmetic products, medicinal, while in others, they have the status of food and are used as dietary supplements. Attention was also paid to the inadequate mechanisms of the quality control and supervision of their use, which results in the appearance of the risks associated with their side effects.

Key words: cosmetics' market, the origin of cosmetic raw materials, certification, standardization, control mechanisms, PCP

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1.0 INTRODUCTION

Cosmetics are substances or mixtures designed primarily to keep the body clean. They also have care and protective properties. Due to the fact that cosmetic products come into direct interaction with the skin and belong to everyday products, their safety becomes particularly important (Wojciechowska *et al.*, 2008; Antignac 2011). According to the Regulation of the European Parliament and the Council of November 30, 2009, cosmetic products should be safe under normal or reasonably rational conditions of use and should not cause a risk to human health (EU Regulation No. 1223/2009). Cosmetic's security is primarily conditioned by its microbiological purity. Microorganisms may cause adverse effects in the cosmetic formulation, which may, among other things, result in a change of its consistency and flavor. Changes in cosmetic products caused by micro-organisms may lead to adverse reactions to human skin. To maintain the purity of the product, preservatives are used - that is compounds having antimicrobial activity (Streinberg, 2006). This is particularly important in the case of cosmetics with high water content; the risk of contamination by microorganisms is then higher. Such an environment favours the development of pathogenic bacteria e.g. *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa* (Foltynowicz *et al.*, 2013). It is believed that cosmetics of natural origin are better tolerated by humans, as they do not cause side effects and, above all, are much cheaper. In modern cosmetology, one is looking out for substances that act favorably on the nervous and immune systems. These are mainly pills, capsules, wet and dry extracts (powders), extracts, ointments, infusions, aerosols, and the like. The forms of these cosmetics depend on a skin type or disease, and the content of the active substance in the cosmetic. Herbal blends and herbal extracts also play an important role on the European market of plant cosmetics. The most commonly used herbal cosmetics include: shampoos, bubble bath, conditioners (Clement *et al.*, 2005, Archer and Boyle 2008, Wojciechowska *et al.*, 2008, Jambor, 2010, Różański, 2012, Rodewald, 2013). Sanderski (2004) considers modern plant cosmetic to be the same as the synthetic one. The use of both synthetic and natural cosmetic inhibits the side effects of the synthetic cosmetic.

In Europe, plant cosmetics account for approx. 30% of all cosmoceutics. The quality and innovation of cosmetics, in addition to the brand and prestige, affect the classification of cosmetic products into the category of luxury. Luxury products, including cosmetics, can be considered Veblen goods, because often the main purpose of the purchase is to meet the needs of conspicuous consumption. Luxury product should be of high quality. The assessment of their quality should include, among others, checking the microbiological purity, as well as the assessment of the package, which is an integral part of the assessment of cosmetics (Foltynowicz *et al.*, 2013, Romanowski, 2016). Providing microbiological stability is particularly important in the case of cosmetics with high water content (e.g. shampoos, bubble bath, conditioners), because then the risk of contamination by microorganisms is higher. In order to ensure microbiological purity of cosmetics, preservatives are used (Streinberg, 2006). However, despite their positive impact, they also exhibit side effects in the form of allergic reactions to consumers. In the case of body care cosmetics, the smell of the cosmetic and low content of preservatives is the most important for consumers (Li et al. 2007, Rodewald 2013, Kuberska-Maciejewska 2015). Due to the fact that cosmetic products come into direct interaction with the skin, and belong to everyday products, their safety becomes particularly important (Streinberg, 2006, Wojciechowska *et al.*, 2008, Foltynowicz *et al.*, 2013, Kuberska-Maciejewska, 2015, Truchliński *et al.*, 2015). The safe use of cosmetics can, however, is provided not only with preservatives.

2.0 NATURAL INGREDIENTS

2.1 Components of Cosmetics

Natural ingredients are an increasingly important component of cosmetics. The main driving force of natural or organic components is a consumer's demand for products that are perceived as healthier, organic and ecological. Consumers more often pay attention to the components of personal hygiene cosmetics (PCP), containing natural extracts, as well as ethical and certified organic ingredients. However, the certification of PCP, both natural and organic, is typically

performed in accordance with the standards of the individual producer. The increase in the number and complexity of the natural and organic components and products, and a lack of a clear process for certification or internationally harmonized standards may result in the appearance of products with a lack of appropriate standards of quality and/or safety. Loose adherence to safety requirements of manufacturers of raw materials for cosmetics and dietary supplements has become a subject of criticism of society (Coppens *et al.*, 2006, Ashar and Rowland-Seymour 2008). Botanical components used in cosmetic for personal hygiene (PCP) include many preparations such as plant extracts, in a form of juices, tinctures, waxes and oils, fats, carbohydrates, vegetable essential oils as well as purified plant components such as vitamins, antioxidants, other substances having biological activity (Allemann and Baumann, 2009, Antignac *et al.*, 2011, Cieszynska, 2015). The diversity of plants supplying these components varies from food plants (grains, fruits, vegetables, roots, bulbs, spices), to herbs and exotic plants and their components. Botanical ingredients of cosmetics can be obtained from both crops and wild plants (Tables 1, 2).

Table 1. Plants and other natural materials used in personal hygiene products

Sources	Specifications
Sources	Wild plants, cultivated plants, food plants, prepared plant foods, tea plants, traditional medicinal plants, spices, algae, fungi, lichens, mosses, microorganisms
Plant raw materials	Whole plants, fruits, berries, seeds, leaves, needles, stems, branches, roots, bulbs, flowers, flower parts, barks, buds, shoots, wood
Plant processing/preparations	Fresh plants, dried plants, fermented plants, expressed juices, aqueous extracts, solvent extracts, supercritical CO_2 extracts, acid/alkaline extracts, dry or steam distillation, crushing, milling, lyophilisation, maceration, fermentation supernatants, column separation fractioning
Ingredient forms	Powders, solutions, enriched concentrates, tinctures, macerates, suspensions, emulsions, starches, carbohydrates, lipids, oils, waxes, hydrocarbons, tars, resins, sterols, proteins, peptides, carotenes, saponins, polyphenols, flavonoids, vitamins, alkaloids, enzymes, thickening agents, colorants, essential oils, terpenes, terpenoides, aldehydes, esters, ketones, aromatic fragrances, organic acids

Source: Chochół 2006, Alleman & Bauman 2009, Bakkali *et al.*, 2008, Antignac *et al.*, 2011, Kiełtyka-Dadasiewicz *et al.*, 2014, and Sawicka *et al.*, 2014.

Table 2. The examples of the use of functional / biological plant components

Ingredient type/function	Exampls
Antioxidants	Lycopene, resveratrol, α-carotene, β-carotene, catechins, vitamin C, vitamin E, green tea, soy isoflavones, curcumin, pomegranate extracts (anthocyanins, delphinidin, cyaniding, pelargonidin), grape seed extracts, polyphenols, essential oils, kojic acid
Anti-ageing/free radical scavenging	Lycopene, genistein, vitamin C, vitamin E, pomegranate extracts, grape seed extract, silymarin, soy proteins, anthocyanins, green tea extracts, *Polypodium leucotomos* extract, polyphenols, resveratrol, curcumin, pomegranate seed oils, soy isoflavones
Anticancerogens	Resveratrol, lycopene, green tea, genistein, pycnogenol, curcumin, lycopene, pomegranate seed oils, polypodium extracts, vitamin E, silymarin
Antiinflammatory/anti-	Vitamin C, pycnogenol, oatmeal, curcumin, avenanthramides,

irritant	salicylic acid, polyphenols
Fragrances	Essential oils, terpenes, terpenoides, aldehydes, alcohols, esters, ketones, phenols, methoxyphenols
Hydration/moisturising	Silymarin, lipids, sterols, omega-3 fatty acids
Natural colourants	Henna, lawsone, indigo, chamomile, lycopene, crocin, carmine, anthocyanidins, carotenoids
Photo-protection	Pomegranate seed oils, genistein, green tea extracts, *Polypodium leucotomos* extract, polyphenols, avenanthramides
Preservatives, antiseptics	Saponins, essential oils, benzoic/salicylic acids and derivatives, organic acids and esters, phenols, usnic acid, thymol, bacteriocins
Skin whitening	Kojic acid, arbutin, soy proteins, aloesin, vitamin C
Surfactants	Saponins, phospholipids
Thickening agents	Carrageenan, starches, carbohydrates

Source: Streinberg, 2006, Alleman & Bauman, 2009, Bakkali *et al.*, 2008, Antignac *et al.*, 2011, Kiełtyka-Dadasiewicz *et al.*, 2014

Regardless of the legal status, PCP safety containing ingredients of plant origin must take into account their intended use (Table 2). The safety of all the ingredients of PCP, whether traditional or botanical, in the main European and US cosmetic regulations refers to 2 principles: (a) cosmetic/PCP may not cause damage to human health; (B) the manufacturer is responsible for the safety of PCP cosmetics marketed in the European Community. For this purpose, safety assessment of finished products is made, taking into account the toxicological profile of the ingredients, their chemical structure and external and systemic exposure (Antignac, 2011).

2.2 Preservatives' requirements in cosmetics

Preservatives used in cosmetics must meet several demands. Above all, they must be safe, non-toxic, well tolerated by the human body. Moreover, they should not be absorbed through the skin and mucous membranes. They should be effective at low concentrations, then it reduces the risk of side effects. Preservatives used in cosmetics should be active against a broad spectrum of microorganisms (gram-positive and gram-negative bacteria, fungi) without jeopardizing the bacterial flora existing saprophyticly on the surface of human skin (Streinberg, 2006, Bojarowicz *et al.*, 2008, Truchliński *et al.*, 2015). It is also important that they are characterized by adequate water solubility, because it is very significant that preservatives are present in the aqueous phase and at the border water phase/oil. Meanwhile, the vast majority of preservatives are the organic compounds having a greater affinity to non-polar phase. Preservatives used in cosmetics should be stable over a wide range of temperatures and pH. It is particularly important to draw attention to the interaction between the preservatives and other ingredients of the preparation. It is also desirable for preservatives not to have fragrance and to be colorless (Streinberg, 2006, Li *et al.*, 2007, Kuberska-Maciejewska *et al.*, 2015). Preservatives are necessary ingredients of cosmetics. They are added to cosmetic preparations in order to extend their longevity. They act against a broad range microorganisms, as they suppress the activity of bacteria; mould of fungus, viruses, which in tum delays the lowering of cosmetics value. Preservatives used in cosmetics meet a great number of requirements, most importantly they must be safe and effective (Streinberg, 2006, Bojarowicz *et al.*, 2008). So far studies on the allergy to cosmetics have proven that the preservatives constitute en important allergic factor (Li *et al.*, 2007). However, the safe use of cosmetics can be provided not only with preservatives.

3.0 REGULATORY REQUIREMENTS IN COSMETIC INDUSTRY

3.1 Legal aspects of preservatives

In Europe, the legal and administrative issues concerning the preservatives used in cosmetics were developed on the basis of legislation of the European Union (EU) and the guidelines of the European Medicines Agency (EMA). One did not raise, in detail, the issues of various European

countries due to the fact that, being members of the EU, they have adopted European legislation and made use of all the guidelines of the European Medicines Agency. European legislation in the field of natural products can be divided into 2 groups: 1) legal acts relating to cosmetic products, medicinal and 2) associated with food. In both areas of law and at their border line, there are products of natural origin. The issues not regulated by law, relating to the border line of these two areas are regulated by the European Court of Justice (ECJ) (Chochół 2008; Bojarowicz *et al.*, 2008, Kuberska-Maciejewska, 2015).

Since July 11, 2013, in all countries of the European Union, the Regulation of the European Parliament and the Council 2009/1223/EC is used, which replaced Directive 76/768/EEC (the so-called. Cosmetic Directive), and thus all the national laws implementing the Directive, for example, Polish law on cosmetics (Dz. U. 2001 Nr. 42, item. 473 as amended).

Regulation 1223/2009/EC regulates in detail the issues concerning the marketing of cosmetic products, including their composition (detailed list of substances prohibited for use in cosmetics, and the list of allowed colorants, preservatives and UV filters), labeling, the contents of the documentation, rules of safety assessment of the product, necessary research, manufacturing conditions, creating marketing declarations, rules of notification, cases of side effects of the product, the identification of products in the supply chain, the requirements for testing, a ban on animal testing. Cosmetic product and its individual components are also subjected to the beyond sector and horizontal regulations. Substances used in cosmetic products (components) are subjected to the rules of the two regulations: REACH − Regulation (EC) No 1907/2006 of the European Parliament and the Council of December 18, 2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Directive 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; CLP − Regulation of the European Parliament and Council Regulation (EC) No 1272/2008 of December 16, 2008 on classification, labeling and packaging of substances and mixtures, repealing Directive 67/548/ EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

In accordance with Article 33 of Regulation (EC) No 1223/2009, the Commission will prepare an update, a glossary of common cosmetic components' names. This inventory is indicative and does not constitute a list of substances authorized for use in cosmetic products. It is divided into 2 parts: Section 1 − ingredients of cosmetic raw materials other than fragrances and aromatic; Section 2 − perfume and aromatic raw materials. The list must include: information on the identity of the substance, especially the INCI (ex CFTA), Ph Eur, pension, IUPAC of chemical names; EINECS/ELINCS, CAS and Colour Index; The common ingredient name, referred to in Article 33 of Regulation (EC) No 1223/2009; Ingredients "functions and any mandatory restrictions, conditions of use and warnings."

The basis of the pharmaceutical legislation is the need to provide citizens with health care, by ensuring the safety, efficacy, therapeutic applications and, above all, the quality of use of cosmetic products and treatments through their application. Three institutions are responsible for European legislation: the European Commission, Council of Europe and the European Parliament. In the European legislation, there are two basic acts: Directive (European Union Directive) and Regulation (European Union Regulation). European directives are laws that at a certain time, Member States are obliged to introduce to their own systems of law. Regulations, however, without any changes, are effective from the moment of their publication in all Member States (Różański, 2012; Rodewald, 2013; Kuberska-Maciejewska, 2015, Matczak *et al.*, 2016).

Cosmetics, both conventional and natural, are subjected to the regulations of the law on cosmetics, which regulates the composition, labeling and safety of cosmetic products. An official document defining the criteria for natural cosmetics is the guidelines of the Committee of Experts on Cosmetic Products at the Public Health Committee of the Council of Europe. On the domestic markets in the EU, there are also a number of certification organizations, which have their own criteria and procedures for auditing companies. According to the guidelines of the Council of

Europe, natural cosmetic is a cosmetic preparation derived from ingredients of natural origin, mainly of plant or animal origin (beeswax INCI Cera Alba; lanolin Lanolin − INCI) and mineral. A method of obtaining plant material include: pressing, extraction, filtration, steam distillation, and the like as well as microbiological or enzymatic methods. In these processes, the plant material is processed at a minimum possible extent. Natural cosmetic should not include synthetic substances in its composition, although some certification organizations, for example, Ecocert allow 5% of synthetic substances in their composition. The production process itself is also important, which should be carried out with respect for the environment (Bubela *et al.*, 2008; Różański 2012, Rodewald, 2013).

According to the Regulation 1223/2009, marketing of cosmetic products must be preceded by the appropriate application of this fact to the European Commission. Such notification is in electronic format and contains the most important information about the cosmetic product. It aims to identify the most important characteristics of cosmetic products: the labeling, purpose and qualitative and quantitative composition, as well as those responsible for the proper conduct of its turnover on the market. Regulation 1223/2009 widely points to a list of the necessary information. For an entrepreneur, this means that he can enter a specific product on the market as soon as a notification to the European Commission is made and does not need to wait for any confirmation from the authority. This is tantamount to the fact that, for cosmetic products there is a lack of any initial control of a public authority. This results in an opposite situation, which occurs in relation to medicinal products. The lack of such initial inspection also means that the risk of trading a cosmetic product on the market mainly burdens the entrepreneur (Kaczynski and Kumala, 2015).

The risk of quality defects in a series of specific cosmetic products and the reported adverse reactions are real, and in this case the regulations of the law oblige the entrepreneur to an appropriate procedure. The basic principles of marketing of cosmetic products result from the provisions of the Regulation of the European Parliament and the Council No. 1223/2009 of November 30, 2009 on cosmetic products (Regulation 1223/2009). In addition, the law provides a range of penalties of an administrative or criminal character, which may be applicable in case of breach of duties relating to the introduction of cosmetic products on the market (Burns & Burns, 2008).

The risk resulting from the lack of initial inspection of a public body is somehow minimized by the rules of the Regulation 1223/2009. For example, the rules introduce the obligation to designate a person responsible for product quality, safety reporting, sampling, and also limit the permitted composition of cosmetic products. This is achieved by the introduction of the following in the Annexes of Directive 1223/2009: prohibited substances in cosmetic products; acceptable substances in cosmetic products solely with certain restrictions (e.g. a prohibition of the use of substances in products for children under 3 years); allowed colorants, preservatives, UV-filters. Appropriate requirements as to their marking, and conducted communication are added to the above mentioned qualitative and quantitative restrictions in the composition of cosmetic products. In practice, however, there are situations where even the limitations of the Decree 1223/2009 may not be sufficient. This may result in placing on the market cosmetic products with a quality defect created at the stage of manufacture, which may involve a risk to consumers (e.g. exceeding the allowable concentration of the substance in the mixture). In this case, there is a risk that a particular cosmetic product ceases to be perceived as safe. As a result, the entrepreneur should have adequate internal procedures for determining the appropriate proceedings (Kaczynski and Kumala, 2015).

Bearing in mind the dangers that are associated with the use of cosmetic products, Regulation 1223/2009 introduces the definition of adverse reaction and serious adverse reaction associated with their use. Side effect is an adverse effect on human health attributable to the normal or reasonably foreseeable use of a cosmetic product. While severe side effect is such an effect of cosmetic product, which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate threat to life and death. In addition, the entrepreneur leading the turnover of cosmetic products should ensure monitoring and reporting of adverse effects (i.e. CosmetoVigilance). Supervision of cosmetic products is performed by Chief

Sanitary Inspectorate (GIS), to whom the responsible person and the distributor must provide all the information about all serious adverse reactions that are known to them, or whose knowledge can reasonably be expected. In terms of these data, there should be information that will enable the identification of the product and determine corrective actions (Kaczynski and Kumala, 2015).

4.0 PLANT MATERIALS SAFETY

4.1 Safety studies of plant materials

Plant materials used in food, for example, dietary supplements are not subjected to any control procedures taking into account the need for research (Law on food safety and nutrition). The raw materials used in medicines are, on the other hand, subjected to the requirements of research results presentation. The documentation of safety use is made by the demonstration of one's own research results, or data from literature, including different types of toxicity, pharmacological and pharmacokinetic data. In the case of herbal medicines, there are not the same procedures as for synthetic drugs, because herbal medicines are available almost exclusively in terms of the WEU (Well Establish Use − Well-established medicinal use) and THMP (Traditional Herbal Medicinal Product − Traditional herbal medicinal product). According to the law, it is sufficient in the case of herbal medicine in the category of WEU, to present documentation regarding safety in the form of published literature test results [Ernst 2001, 2006]. Also for THMP, security can be justified by reference to the available literature; however, the intention of the legislators was to document safety on the basis of reasonably long experience associated with its use in humans. An absolute requirement of the qualification of the drug in the THMP category, is documenting the safety of its use (Babu *et al.*, 2005, Ernst 2000, 2007, Ashar and Rowland-Seymour, 2008).

Toxicological danger, on the part of plant material, is present in the species, which contain aristolochic acid and pyrrolizidine alkaloids. One did not consider typical plant materials classified as toxic, for example, aconite, as they currently have no therapeutic use. Poisonings by them are very rare and are usually associated with the use of drugs or preparations of natural origin (E). Toxic and pharmacological properties of the plant materials are tested in vitro and in vivo. Only in a few cases, clinical trials have been made for the herbal medicines. Currently, one published guidelines related to the necessity of research of plant materials in terms of genotoxicity. Legislation in the field of herbal medicines is based on the principle of not testing, which from the point of view of their long-term presence on the market, is not necessary, eg. acute toxicity studies. The guideline EMA was developed for traditionally used herbal medicines: Guideline on Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorization (Bibliographical and Mixed Applications) and in Applications for Simplified Registration. It includes a fully comprehensive analysis of preclinical documentation, which is required for herbal medicines. In addition, EMA published two detailed guidelines relating to the issue of genotoxicity: Guideline on the assessment of genotoxicity of herbal substances/preparations and the Draft Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products (EMEA/HMPC/67644/2009). WHO also published a guideline Guidelines for Assessing quality of herbal medicines with reference to contaminants and residues/concerning the issues related to the quality of herbal medicines, but especially in regard to safety (i.e. marking residues of dangerous substances present in the environment) (Ashar and Rowland-Seymour, 2008; Malhorta, 2016).

The safety of medicines and plant cosmetics is also related to the content of ethanol in their traditional forms. This is the issue particularly important in the case of the use of drugs or cosmetics in children, because EMA has developed the guideline: Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children (Malhorta, 2016). Their safety assessment of THMP category is mainly based on the results of preclinical studies, not required to prove effectiveness in form of clinical trial results. It should be noted, however, that the EMA has published a guideline for assessing clinical research, dedicated to the needs of created Community monographs. It is: Guideline on the assessment of clinical safety and efficacy in the preparation of community herbal monographs for well-established and of community

herbal monographs/entries to the community list for traditional herbal medicinal products/substances/preparations. It is required for THMP that a cosmetic or corresponding product has been used in medicine for at least 30 years (Cuzzolin *et al.*, 2006).

4.2 Selected plant materials exhibiting toxicity

Some plant products may contain chemicals having toxic effects. Some of them have long been known as raw materials affecting toxically), for example. Monkshood (*Aconitum napellus*). For other raw materials the results of recent tests confirmed the possibility of a risk to health, e.g. for comfrey (*Symphytum officinale*) containing pyrrolizidine alkaloids or celandine (*Chelidonium majus*) containing the isoquinoline alkaloids, which are responsible for hepatotoxicity (Moro *et al*., 2009). The largest group of substances of plant origin that may cause a health hazard, are the alkaloids, such as aconitine present in the aconite tubers, or the above mentioned pyrrolizidine alkaloids. They are usually compounds having strong pharmacological activity and, as isolated compounds were the largest group of active compounds of plant origin, which have been used in therapy. Some of them reveal their toxic effect immediately, and some have a carcinogenic effect, even after many years. Laxative raw materials that have been used in medicine for many years also have toxic effects. Available evidence suggests that their overdose or chronic use may be dangerous to human health. This group mainly includes antranoid compounds, present in many commonly used plant products (fruit and leaf senna, buckthorn bark, the fruit of the Indian mulberry). Antranoid compounds such as Emodin and Emodin alonowa are suspected of genotoxic activity. For plants, there is a lot of data on the acute or chronic toxicity, but there is little available data on genotoxicity, or effects on reproduction or fetal development. The toxic effects of plants can be divided into categories, eg. cardiotoxicity (*Glycyrrhiza glabra, Ephedra sinica, Caulophyllum thalictroides*), pneumotoxicity (*Sauropus androgynus*), nephrotoxicity (*Aristolochia* sp.), hematotoxicity (*Ginkgo biloba, Angelica senensis*) and hepatotoxicity (*Kava kava, Tussilago farfara, Symphytum officinale, Senencio longilobus, Senencio vulgaris, Senencio Jacobea*) (Tovar, 2009). In the United States, commercial preparations of natural origin categorized into CAM category dominate, which is dominated by various types of dietary supplements, particularly vitamins and minerals compositions (Ashar and Rowland-Seymour, 2008). About 15% of the total quantities of those products are the herbal medicines. Therefore, the FDA grasped a series of activities aimed at improving the safety of the raw materials of vegetable origin. FDA developed a database "Poisonous Plant Database"[1] included scientific information on toxic plants. According to the commentary, this database has no overall merit of the administration, except for scientific information exchange. This database is being dynamically changed, the information is being added to it, and existing one can be modified in accordance with the current state of knowledge. Those interested in toxic plants or the related issues, in the US, can contact respective centers dealing with intoxication: Poison Control Center, which is listed on the website of the American Association of Poison Centers (The American Association of Poison Control Centers). This is a very important initiative on the market dominated by dietary supplements, in which security controls do not fully regulate the legality of the products that are commercially available. In addition, because of its demographic specificity in the US, it combines many influences of various kinds of natural therapies, such as TCM, Ayurveda, or traditional medicine practiced by the people of Central America (Ashar and Rowland-Seymour, 2008; Różański, 2012). In Europe, so far we have not established such a uniform database containing updated toxicological information of plant materials. Some initiatives to create lists of plant materials that may/or may not be approved for use as ingredients in drugs, or dietary supplements, have been dropped. This was due to the lack of clear legal basis that could justify the creation of such a list. Similar lists were created in other European countries, but also for legal reasons are not developed (especially the judgments of the ECJ).

[1] http://www.accessdata.fda.gov/scripts/plantox/index.cfm

An activity relating to the creation of a list of plant materials for toxicity has been taken by EMA. However, given that similar measures relating to the creation of a list of poisonous plants have not yet been adopted by the EFSA, currently, they have no legal significance and only scientific value. On October 26, 1992, the EC published a document of the Committee dealing with medicinal products CPMP (Committee for Proprietary Medicinal Product) Fri. "Listing of herbs and herbal derivatives withdrawn for safety Reasons − Herbal drugs with serious risks." This document referred to the plant medicines available in the Community on August 15, 1992. In recent years, EMA has taken some actions related to the document KE 1992 Fri. Herbal drugs with serious risks.[2] In November 2005, the HMPC published a document Fri. "Public Statement on" CPMP List of Herbal Drugs with Serious Risks, dated 1992 which confirmed the importance of the information about the safety of the mentioned plant raw materials, simultaneously withdrawing from the amendment of the document in the form in which it existed before. Safety data are evaluated in the process of creating Community monographs, the first category is the most important, which contains the most dangerous plant materials, with high risk of use, and the absence of any benefit from their use (Bardia *et al.* 2007). These raw materials, in CPMP opinion should not be re-admitted to trading in the extensions of existing permits.

4.3 Certification and standardization of plant materials

European Pharmacopoeia is responsible for quality standards for medicines and natural cosmetics in Europe. Besides specific quality standards of processed or plant raw materials, it contains a number of general standards of quality, including quality of plant cosmetics and microbial contamination of these products (Tobin and Walsh, 2008; Kaczynski and Kumala, 2015). Normalization is a process involving the determination of the quality parameters (norms) for plant cosmetic products (substances and herbal preparations), aimed at ensuring proper quality of cosmetic product. For this purpose, one developed quality specifications of products based on the normative documents in force in the European Union (Pharmacopoeia, 2015).

The standardization process provides quality repeatability of authorized natural cosmetic, including plant, whose origin is very varied due to the variability of soil conditions, climate, variety of growing conditions, harvesting or storage, which, in turn, can cause variability of cosmetic raw material. In the procurement and storage of plant substances (divided by plant organs) there are valid EN-standards or EN-ISO, but they can not form the basis for introducing cosmetic on the market. The requirements contained in them concern the determination of identity, purity, weight loss after drying and the content of active bodies (for some vegetable matter). In the certification and standardization of cosmetic raw materials of vegetable origin EU Regulation No. 1223/2009 relating the safety of cosmetic products is applied. According to the Regulation of the European Parliament and the Council of November 30, 2009 cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk and benefits should not justify a risk to human health (Regulation EU Regulation 1223/2009). Standardization of herbs used in the production of natural cosmetics includes: the identity, determination of additives and contaminants, determination of the content of contaminant, which is the substance that was in the raw material in a way not intended by man, and is present there as a result of processing, handling, packaging, transport, storage or pollution, the designation of active substances, determination of contaminants (heavy metals, pesticides, microbiological contamination) (EU Regulation No. 1223/2009). Types of contamination of herbal raw materials, for the production of cosmetics are: the remains of mineral fertilizers, residues of pesticides, defoliants, desiccants, growth regulators, residues of heavy metals, nitrates, nitrites, aflatoxins, mycotoxins, microbial pathogens and pests (EU Regulation No 1223/2009). Table 3 shows the DDT residue tolerances for food products according to FAO.

[2] http://www.emea.europa.eu/pdfs /human/HPMC/ CPMP List of herbs with serious risks. pdf

Table 3. Tolerance of DDT residues for food products, FAO/WHO

Food product	DDT content (ppm)
Milk and milk products	1.25
Apples	7.0
Strawberries	1.0
Citrus	3.5
Vegetables	7.0
Meat	7.0
Fish	7.0
Eggs	0.5

Source: FAO/WHO.

Disappearance of pesticide residues in plant material used in the production of cosmetics is very slow (Wieteska, 2016). This is illustrated in Table 4 and 5.

Table 4. The disappearance of dichlorophos residues in herbal plants after administration of liquid Winylofos 50. the concentration 0.1%

Raw materials	Date of spraying	Dichlorophos residues in days after the use of ($mg \cdot kg^{-1}$)					
		Control object	2-4	6-8	12-15	20-21	22-28
Coriander (inflorescence and friut)	23.07[b]	11.98	0.11	0.11	0.02	0.04	0.06
Pepper minth (herb)	23.07.1987[b]	12.60	5.61	6.32	2.61	0.59	0.11
Marigola (flowers)	29.07.1987[a]	12.63	0.05	<0.01	<0.01	<0.01	<0.01
Marshmallow (leaves)	23.07.1987[a]	8.74	0.02	<0.01	<0.01	<0.01	<0.01

[a] – dose of preparation 0,8 $dm \cdot ha^{-1}$; [b] – dose of preparation 1,0 $dm \cdot ha^{-1}$; Own study based on

Table 5. Residues of pesticides in herbal raw materials in the years 2000-2002

Compound	N	n	%	NDP Pharm Eur.	P	%	MRL RP	P	%
Aldryne (dieldryne)	10	0	0.0	0.05	0	0	0.02	0	0.0
DDT (sum)	8	42	38.	1.0	0	0	0.20	8	7.4
Edirne	10	0	9	0.05	0	0	0.01	0	0.0
□, β – HCH	8	0	0.0	0.3	0	0	0.2	0	0.0
γ - HCH	10	33	0.0	0.6	0	0	0.1	11	10.
Metoksychlor	8	18	30.	10.0	0	0	2.0	0	2
Diazinon	10	8	6	0.5	0	0	0.3	0	0.0
Dichlorfos	8	2	16.	1.0	0	0	0.1	0	0.0
Dimetoad	10	1	7	1.0	0	0	0.2	0	0.0
Fenitrotion	8	0	7.4	0.5	0	0	0.1	0	0.0
Fozalon	10	0	1.9	0.1	0	0	1.0	0	0.0
Heptenofos	8	0	0.9	0.0	0	0	0.5	0	0.0
Malation	10	0	0.0	1.0	0	0	0.1	0	0.0
Mankozeb	8	0	0.0	2.0	0	0	0.1	0	0.0

N – number of samples analyzed, n – number of samples containing residues p – the number of samples containing pesticide residues exceeding the MRLs – maximum residue levels – Farm Euro

– for herbal medicines by the provisions of the European Frarmakopea, RP – for food of plant origin

The heavy metals in plant material due to the high concentrations of these metals in the soil are listed in Table 6.

Table 6. Total content of heavy metals in dry mass of soil ($mg \cdot kg^{-1}$)

Element	Content	Soil contaminated	The concentration tolerated
Cadmium (Cd)	0.1-1.0	< 200	3
Chrome (Cr)	2.0-50.0	<2000	100
Copper (Cu)	1.0-20.0	< 2200	100
Merkury (Hg)	0.1-1.0	<500	2
Nickel (Ni)	2.0-50.0	<10000	50
Lead (Pb)	0.1-20.0	<4000	100
Zinc (Zn)	3.0-50.0	<20000	300

Source: Bielicka-Giełdoń *et al.*, 2011.

The most common causes of contamination of herbal raw materials with heavy metals are: soil loaded (with increased levels of Cd as a result of phosphorus fertilization, with increased metal content as a result of fertilization slime tailings, slag from blast furnace, industrial waste, etc.), Contamination of communication (Table 6), a natural metal content heavy soil, permanently or periodically new load due to the proximity of industrial plants, steel mills, processing plants of heavy metals, heating plants, highways road and air transport, as a result of flooding of rivers and rainfall, as a result of the composting loaded parts of plants, rain-laden dust metals; interaction between the various soil factors (Bielicka-Giełdoń *et al.,* 2011) (Table 7, 8).

Table 7. Effect of traffic contamination on growthing of *Digitalis purpurea* L. and content of heavy metal in the raw material

Distance from the traffic road (m)	Mean plants height (cm)	Mean number of leaves on the plant	Fresh mass of the oveground part of one part	Content of heavy metals ($mg \cdot kg^{-1}$)			
				Cu	Zn	Pb	Cd
Control	34.8	10	17.1	7.80	173.32	26.35	3.47
1.5	32.95	10	20.2	16.50	183.31	45.45	1.83
1.5	33.35	8	11.4	14.52	339.72	40.65	5.81
46.5	20.60	15	17.4	N	N	N	N
91.5	37.30	10	23.4	12.69	150.81	15.23	0.71
122.0	31.80	6	16.2	7.80	173.32	26.35	1.77

N – not tested; Own study based on: Bielicka-Giełdoń et al. 2011, Różański 2012.

Table 8. Contents of Cu, Pb and Zn in $mg \cdot kg^{-1}$ dry weight in the herb of selected species of herbal plants

Raw materials	Cu	Pb	Zn
Rosmarini fol.	0.00190	Ślad	0.00740
Coriandri fruc.	0.00136	0.0047	0.01049
Foeniculi fruc.	0.00104	-	0.00621
Menthe herb.	0.00123	0.0020	0.00791
Hyperici herb.	0.00122	0.00043	0.01957

Agropyri rhiz.	0.00038	0.00008	0.00292
Pimpanellae rad.	0.00074	0.00047	0.00619

Own study based on: Bielecka-Giełdoń, 2011, Rodewald, 2012, Różański, 2012.

Table 9. Contamination of herbal raw materials molds

Kind of moulds	Contamination of herbal raw materials molds	
	Amount	%
Aspergillus	75	36.0
Penicilium	28	13.5
Fusarium	7	3.4
Trichothecium	4	1.9
Alternaria	3	1.4
The other	91	13.8
Total	208	100.0

Source: Rodewald 2012, Różański 2012, Foltynowicz *et al.*, 2013.

Sources of contamination of herbal medicines by microorganisms are medicinal substances, herbal raw materials, auxiliary substances, water, indoor air of production unit, equipment, staff (personal hygiene), packaging (Rodewald 2012, 2013). The main fungi attacking the herbal raw materials are: *Aspergillus* spp., *Penicillium* spp., *Fusarium* spp., *Alternaria* spp., (Table 9-11).

Table 10. Cosmetic raw materials of molds from the genera producing mycotoxin

Kind of moulds	Contamination of herbs by moulds[3]	
	Amount	Percent
Aspergillus	75	3.0
Penicillium	28	13.5
Fusarium	7	3.4
Trichothecium	4	1.9
Alternaria	3	1.4
Other	91	43.8
Total	208	100.0

Examination included 50 herbal plants. Source: Rodewald, 2012, Foltynowicz *et al.*, 2013, Sikora, 2015.

Table 11. Presence of moulds producing mycotoxins in plant material

Name of raw materials	Kind of the isolated mould	Produced mycotoxin
Fol. Salviae	*Aspergillus*	Aflatoxin B_1
Sem. lini	*Aspergillus*	Ochratoxin
Rh. Tormentillae	*Aspergillus*	Aflatoxin B_1

Examination included 65 moulds from *Aspergillus* and *Penicillum genera;* Source: Rodewald 2012, Foltynowicz *et al.*, 2013

In turn, the bacteria contaminating herbal materials are mainly aerobic bacteria: *Bacillus*, and anaerobic: *Clostridium* + *Escherichia coli*, *Salmonella*, *Enterobacteriae*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* (Table 12).

Table 12. Contamination of herbs by bacilli from the *Enterobacteriaceae* family and *Escherichia coli* ones (7)

Microorganisms	Amount of samples	Microorganisms contamination of herbal plants	
		Amount	%
Bacilli from the *Enterobacteriaceae*	420	265	63.1
Family	104	20	19.2
Esherichia coli bacilli			

Source: Rodewald 2012, Foltynowicz *et al.*, 2013

Microbicidal activity of herbal raw materials and some of their components include both Gram (-) and Gram (+) and yeasts and molds (Sikora, 2015). The main source of contamination of herbal raw materials microorganisms include: epiphytic microflora, microflora of the soil, air and water, micro-organisms which result from diseases of herbal plants, improper drying and storage of raw materials (Rodewald, 2013; Sikora, 2015). The prevention of microbial contamination, according to many authors consists of: cultivation of herbs on microbiologically clean areas; careful preparation space and seeds for sowing; organic fertilization, preferable for forecrop (free of faeces); location of plantations away from livestock; proper spacing of plants in the field; adequate soil moisture during the growing season; irrigation of plantation with clean water; proper care of plants (disease prevention); cleaning of harvesting machinery at least once a day; conducting a one-step set of herb in dry weather, avoid leaving the plants in the field; appropriate storage, lack of contact with the ground; rapid transport of the raw material after harvest and drying; appropriate drying (dried in its entirety and accurately); avoid moisturizing plants after drying, appropriate packaging and storage conditions (Foltynowicz *et al.*, 2013).

There are quality requirements for herbal raw materials for industry. The herbal industry is based on three quality systems GMP, GHP and GAP. These principles relate to: the production of cosmetic raw materials, quality control, production requirements of herbal raw materials. GMP plant products require the determination of: sampling and control of the starting materials, storage of starting materials, documentation of the origin of raw materials, research durability. GMP: Purpose: to prevent the formation of mistakes and errors during the manufacturing process, and in the event − the immediate withdrawal of the part from the market and any indication of critical manufacturing steps (to show error, the introduction of new solutions). In the cosmetic and pharmaceutical plants the following are used: specifications for raw materials used in production and packaging materials; operating instructions on the materials used in the manufacturing process, their quantities, equipment used, describing the subsequent manufacturing operations; packing instructions; reports of operations carried out, studies, tests; standard operating procedures for all activities affecting the quality of the pharmaceutical agent. The law does not require cosmetic labeling to have FDA approval before cosmetic products go on the market, and FDA does not have a list of approved or accepted claims for cosmetics. However, there are limits that apply to cosmetic labeling claims. Under the law, information on cosmetic labeling, including claims, must be truthful and not misleading. In addition, if a product is marketed with claims for purposes such as treating or preventing disease, or affecting the structure or function of the body − including the skin − it's a drug according to the law, and it must meet the requirements for drugs, even if it affects the appearance (Malhotra, 2016).

GMP requires the implementation and introduction of: training of personnel, proper organization of hygiene magazines; record-keeping, labeling GHP − actions that must be taken and hygienic conditions which must be met and controlled at all stages of production and marketing to ensure food safety. GMP/GHP forces, that each stage of production was defined, and specific measures were provided in an appropriate: place, time, quantity, and the use was as ended. GHP requires the creation and implementation of specific instructions to the production process and the

requirements for such elements as: the purchase and receipt of raw materials, buildings and production facilities, machinery and equipment, cleaning and disinfection, storage, distribution, water and waste, by-products and waste, training, GAP - means the basic standards of management, taking into account environmental protection, to be followed by reasonable farmer (Matczak *et al.*, 2016). These standards include: rational fertilizers, protection of water and soil, preservation of active habitats and species of plants and animals, protection of agricultural landscape.

5.0 CONCLUSION

The market of cosmetic products of natural origin in Europe and the US is developing very dynamically. The legal and administrative solutions connected with a group of natural products in Europe and North America ensure the safety of their use, and international organizations to the same extent support the European countries and North America, in realigning operations, whose aim is to maintain the safety.

The use of cosmetic products of natural origin is considered generally safe. This means that issues related to the safety of this product group are not as well documented as in the group of synthetic cosmetics. Safety issues concerning natural products are not limited to matters related to toxicity. It should be noted that toxicological data are, for this group of products, very limited, and the issues related to the widespread and independent use of these new preparations by consumers without consulting a doctor are a problem. Natural products present in the markets of Europe, North America, and Asia are part of many cosmetics, medicines and even dietary supplements (Babu *et al.*, 2005, Ashar and Rowland-Seymour, 2008). Due to differences in legal systems, the same materials are used in some countries as cosmetic products, medicinal, whereas in other countries, they have a status of food and are used as dietary supplements. Raw materials of natural origin have the status of cosmetics or drugs mainly in Europe, and (dietary supplements) are used as food on the North American continent. Widespread market presence and insufficient mechanisms of control and supervision of their use results in the emergence of risks associated with the occurrence of interaction with synthetic cosmetics and their side effects. The harmonization of cosmetics market and herbal medicines is a basic requirement for the European industry and health professionals and will also be useful for consumers. E.g. herbal remedies, herbal medicines are generally sold as dietary supplements, but a common legal status in various European countries does not exist. Consequently, information about the clinical indications on the use, effectiveness and safety are influenced by a variety of opinions in accordance with clinical experience, or folk traditions of different drugs available in every European country (Babu *et al.*, 2005, Ashar and Rowland-Seymour, 2008). The European Directive 2004/24/EC, published in 2004 by the European Parliament and the Council of Europe is the basis for the use of herbal medicines in Europe in the future. The directive states that herbal medicines released on the market require a permit issued by the national regulatory authorities in each European country, and that the products should have the recognized level of safety and efficacy. Safety of herbal cosmetic products and medicines will be assessed on the basis of the existing scientific literature (clinical trial data, case studies, preclinical studies). When safety data are not sufficient, it is passed to the consumer. According to the criteria of safety and efficacy, there will be two types of herbal medicinal products in the future: (a) “established use of herbal products” (medicinal herbs with a recognized level of safety and efficacy); and (b) “traditional herbal products you use”. This category will include medicinal plants do not have recognized level of efficacy but are acceptably safe. Although the primary objective of the new legislation is to harmonize the market of herbal cosmetics and herbal medicines, important regulations were introduced, which contribute to safer use of the herbal substances, adopted by the whole community.

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