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Review of National Regulatory Requirements for Propolis Quality for Compliance with International Standards

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Abstract. Given the growing demand among consumers of the international market for propolis, it is important to review the compliance of national documentation with international, particularly the leading countries in the production and processing of this product. Integration and adaptation of national legislation to the norms of the world community legislation also requires revision of approaches to the quality and safety of propolis. Therefore, the purpose of the study was to analyse the current international and national regulatory legal acts of the leading countries of the world, which play a key role in the international market for the production and sale of propolis in terms of safety and quality of propolis. Authors used the Torraco method to analyse and synthesise scientific and regulatory data; the Springer scientific and metric database and the Google Scholar search. The materials included regulatory documents of Ukraine, EU, Brazil, Argentina, Poland, Mexico, East African region. It was established that the criteria for assessing the quality of propolis in international regulatory and technical documentation are organoleptic (appearance, consistency, colour, smell, taste), physicochemical (dry matter, total ash content, wax, resin) microbiological (yeast, moulds, *Escherichia coli, Staphylococcus, Candida albicans, Paenibacillus, Salmonella*) indicators of biological activity (flavonoids, oxidation, phenols, antioxidant activity, ethanol-soluble resins) and contamination (heavy metals, pesticide and antibiotic residues, radionuclides). The study revealed the non-compliance of the current regulatory document in Ukraine with the requirements of international regulations, namely in terms of: phenol content, ethanol and water-soluble resins, dry matter; total ash content; antioxidant activity; colony-forming units. It was determined that in Ukraine propolis is not divided into categories depending on wax impurities; the ambient temperature is not accounted for when determining the consistency index; botanical origin and methods of its selection are also not considered when assessing organoleptic properties. The approach for regulating the propolis market in Ukraine is substantiated as such that will contribute to the formation of added value for raw propolis when grouped by purpose and method of production and processing. The materials of the article are of practical value for the formation of new and harmonization of existing normative and technical regulations on the quality of propolis and can be applied by the working party on beekeeping development under the Ministry of Agrarian Policy of Ukraine

Keywords: statutory regulation, bee products, propolis specification, propolis identification, types of propolis

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Introduction

Ukraine is not among the leaders in the world market of propolis production. At the same time, the demand for propolis in the world is growing, as evidenced by the results of market research and forecasts based on them. The overall propolis market is expected to grow at an average rate of approximately 6.23% from 2022 to 2030 in monetary terms [1]. Over the past 14 years, the regulatory legal acts regulating the quality and safety of propolis have not been updated. Instead, the international standardisation organisation, which includes 167 member countries, focuses its attention on propolis. Thus, the standard ISO/CD 24381 Bee propolis – Specifications [2] is under development. This standard will contribute to achieving sustainable development goals such as good health, reducing inequality, and responsible consumption.

Raw propolis is used in food [3], pharmaceutical [4] and other industries [5; 6]. The use of propolis in the food industry necessitates its standardisation, which guarantees safety, quality and excludes the use of counterfeit raw materials [7]. Propolis has a very complex and variable set of compounds. Only in propolis collected by honeybees in different geographical regions with *Populus* spp. a total of 344 substances were identified [8; 9]. A total of 8 species of *Populus* spp. serve as sources of propolis in different geographical regions. In the world, 16 plant sources, except *Populus* spp. are known and proven as sources of propolis [10]. Propolis usually contains 40 to 70% balms (flavonoids and phenolic acids), 1-3% essential oils, 20-35% waxes, and 5% other substances [11].

The composition of propolis may include pollen grains from plants that were the sources of propolis and others in the flight zone of bees that produce pollen. Palynological analysis of propolis can serve as one of the methods for determining and confirming its geographical origin [10; 12; 13]. Since propolis is of proven botanical origin and contains fragments of the source plant (trichomes, leaves, buds), their comparison can be used as one of the possible tools to prove the authenticity of the product [14]. While the plants that serve as the source of propolis are not subject to treatment with agrochemicals and pesticides, contamination of propolis with plant protection products does occur and affects the quality of propolis. According to the results of a study of various products made from propolis in Spain, Portugal, Belgium, England, the USA, and Chile, seven acaricides, fungicides and herbicides were found, with triadimefon present in 65% of the samples [15]. Samples of propolis obtained from the Czech Republic, Bulgaria, Slovenia, Serbia, Italy, Greece, and Canada were examined for the content of residues of agrochemicals and pesticides. The presence of acetamiprid, imidacloprid and thiacloprid was detected in seven samples out of thirty samples [16].

One of the equally important factors that affect the quality of propolis is the collection methods and proper observance of sanitary and hygienic requirements for keeping bees. Such methods of propolis collection are distinguished [17]: the use of means that are placed inside the hive (nets, grids, cloth) and do not require modification of hives; collectors that are traditionally used in Latin America and provide for the creation of external holes in the walls of the hive; traditional and much more common way of obtaining propolis through cleaning the elements of the hive. Studies [18] of Argentine propolis for lead content were conducted. Thus, propolis collected using nets contained 2 mg/kg of lead and collected by the traditional method of cleaning the elements of the hive – 8 mg/kg. The authors [19] note that the use of collectors and collection methods “Propolizador Inteligente”, “De Propóleo Pirassununga”, “Cuadros Colectores de Propóleo”, “Marco Colector de Propóleo”, “Método Propolizador Campechano” have a number of disadvantages that affect the quality of propolis. Among the main ones, the authors distinguish: the openness of the collectors and dust ingress into the propolis; propolis accumulated in the collectors is not protected from sunlight and can melt under high temperatures; loss of volatile substances. According to the results of studies [20], propolis stored in an open container at room temperature of 24°C for seven hours lost weight of 0.9 ± 0.3%, which is associated with the evaporation of volatile substances. Cleaning the hive elements as a way to obtain propolis, in addition to its mechanical contamination, is accompanied by an increase in the wax content in the product. Besides, the wax can be contaminated with pesticides and agrochemicals, which additionally contaminate the obtained propolis [21; 22].

Preferably, no more than 0.05 mg/kg of pesticide residues are allowed in food [22]. At the same time, for prohibited organochlorine substances, this indicator is no more than 0.01 mg/kg. And for most agricultural organophosphates, carbamates and pyrethroids, the permissible residues are in the range of 0.01-0.05 mg/kg (kumafos, chlorphenvinfos, boscalide) [23].

In the absence of natural plant sources, honeybees can use substitutes (bitumen, household paints, petroleum products, etc.), which significantly compromises the quality of propolis [24; 25]. In countries with arid climates, and also to obtain monofloral types of propolis, it is practised to roam to plant sources [26; 27]. This approach can be applied in Ukraine to improve the quality of propolis by moving apiaries away from technogenically unfavourable zones to collect product of improved quality.

The quality of propolis in Ukraine is regulated by DSTU 4662:2006 Propolis (bee glue). Technical specifications [28]. This standard applies to propolis, a resinous substance with bactericidal properties that bees collect from tree buds, process, and use as a construction and disinfectant material. In Ukraine, propolis is used for industrial processing in the food and cosmetics industries and the manufacture of pharmaceuticals. However, with the improvement of propolis production technologies, the development of new equipment, loading and contamination of the environment as a source of plant resins, there is a need to review the current regulations and requirements for the safety and quality of this product.

The purpose of the study was to analyse the current international and national regulatory legal acts of the leading countries of the world, which play a key role in the international market for the production and sale of propolis in terms of safety and quality of propolis. To achieve this goal, the following *tasks* were identified: 1) to establish the concept of “propolis” and its variations in international legislation; 2) to identify the leading countries producing propolis in the context of the analysis of the world market;

3) to analyse international and national regulatory legal acts regulating the safety and quality of propolis; 4) compare international, national (other countries) regulatory documents and regulations with Ukrainian regulatory documents regulating the safety and quality of propolis; 5) to formulate proposals for improving the legal regulation of propolis quality and safety in Ukraine, based on the latest scientific research.

Materials and Methods

For the theoretical study of the issue, scientific and regulatory and technical information was analysed, which allowed a systematised and generalised approach to the logical processing of the obtained data to obtain a new interpretation of them. Analysis and synthesis of scientific information was performed by the Torraco method [29] using the Springer scientific metric database and the Google Scholar search tool.

The materials for the study were the requirements of Article 1308 of the Argentine Food Code "Propolis and the Inclusion of Technical Specifications", Annex VII "On Regulation of Identification and Quality of Propolis Extract" of the regulatory instruction No. 11 of 10/20/2000 [30]. Ministry of Agriculture of Brazil [31], standards "Propolis – kit pszczeli PN-R-78891" [32], NOM-003-SAG/GAN-2017 "Propolis, Production and Specifications for its Processing" [33], DEAS 990: 2019 "Bee Propolis – Specification" [34], DSTU 4662: 2006 "Propolis (bee glue). Technical conditions" [28].

Results and Discussion

According to Regulation (EU) No 1308/2013, propolis is included in the general term "bee products" along with honey, beeswax, royal jelly, and pollen [35].

According to the Commission Regulation [36], honey, beeswax, royal jelly, propolis or nectar not intended for human consumption belongs to the category of by-products of beekeeping. Commission Regulation (EU) No. 142/2011 defines import and transit requirements for propolis in particular [36]. Propolis must be exposed to -12 °C or lower temperatures for at least 24 hours and not originate from countries that are subject to a ban related to recorded cases of infection with *Paenibacillus larvae*, *Acarapis woodi* (Rennie), *Aethina tumida, Tropilaelaps* spp. At the same time, the Commission Implementing Regulation [37] in Section 5 defines that propolis is classified as edible products of animal origin that are used in the production of pharmaceutical products and food additives and are subject to control at import points into the territory of the EU.

There are no official data on the global production of raw propolis. However, the main producers are China and Brazil. Annual production in China increased from 35 tons in 1984 to 300 tons in 2008 [38]. In 2004, production in Brazil was 250 tons and was estimated to be between 10% and 15% of global production. Most of the propolis produced in Brazil is exported to Japan, and this market is constantly growing [39]. Other major producers of raw propolis in the world include the United States, Spain, Romania, Argentina, and Chile. According to this study, total industrial production ranges from 1,800 to 2,400 tons/year [1].

When raw propolis is converted to processed propolis, its recovery rate in the bee nest is approximately 37-47% at the beginning of the season. During the season, the recovery rate ranges from 15% to 25%, as nectar enters the nest and bees add more wax to the propolis. It is known that one scraping from the hive produces from 30% to 40% pure propolis [40]. But not all commercially produced propolis is processed into pure propolis, some is consumed as raw propolis. The main enterprises operating in the global propolis market are shown in Table 1.

Table 1. *Main enterprises in the global propolis market*

Company name	Countries
Apis Flora	Brazil
Wax Green	Brazil
Comvita	New Zealand
Apiario Polenectar	Brazil
King's Gel Propolis	Brazil
MN Propolis	Brazil
Ponlee Propolis	Brazil
Manuka Health New Zealand	New Zealand
Zhifengtang	China
Beijing Baihua Apiculture Technology Development Corp	China

Source: *[1]*

The prevalence of Brazilian companies among the two companies of China and New Zealand deserves consideration. According to Comvita, in 2017 its annual sales turnover amounted to NZD 156 million and its profit to NZD 9.4 million. In the same year, another company, Manuka Health New Zealand had an annual sales turnover of NZD 80 million and a profit of NZD 3.5 million [1].

According to Annex VII "On the Regulation of the Identification and Quality of Propolis Extract" of the Normative Instruction No. 11 of 10/20/2000 [31] of the Ministry of Agriculture of Brazil, the main purpose is to establish minimum requirements for the quality of propolis extract. Propolis extract is understood as the product of extracting propolis components in neutral alcohol (food grade) according to the technological process. Quality indicators are determined using sensory and physicochemical properties.

They are characterised by aroma, colour, taste, and appearance, as well as the content of dry substances, wax, phenolic and flavonoid compounds, alcohol, methanol, etc. There is a requirement for the absence of additives and polluting, foreign substances. Also, the product must not contain microscopic foreign substances of any nature. Special attention is paid to the presence of larval spores *Paenibacillus*.

East African Standard (Republic of Uganda) DEAS 990: 2019 "Bee Propolis – Specification" defines general requirements, sampling, and test methods for bee propolis [34]. Bee propolis is a bee glue or resinous mixture that bees produce by mixing bee secretions and beeswax with collected exudate from tree buds, sap flows or other botanical sources. Among the sensory indicators, the appearance, colour, taste, smell, consistency, and presence of foreign inclusions are determined. This standard also provides for specific requirements, including humidity, total ash content, wax and resin content. The content of heavy metals, pesticide residues and veterinary drugs is strictly controlled. Microbiological requirements are also established. Test methods are carried out in accordance with international ISO standards [2], and the limits of indicators correspond to the established indicators of the Codex Alimentarius Commission [41]. The standard provides for labelling requirements and sets out mandatory items that must be indicated on the package. In addition to the above, this standard is constantly aimed at implementation with international standardisation organizations, interested states during use and implementation, the World Trade Organisation, and the Codex Alimentarius Commission [41].

The official Mexican standard NOM-003-SAG/GAN-2017 "Propolis, production and specifications for its processing" [33], in addition to the generally accepted sections (such as scope, literature, definitions, sensory, physicochemical, and antimicrobial requirements, test methods, conformity assessment), additionally contains sections on penalties and compliance with international standards and recommendations. The standard provides for physical (colour, smell, taste, consistency), chemical (flavonoids, common phenols, oxidation index) characteristics and antimicrobial activity. Regarding antimicrobial activity, all samples must be analysed for such microorganisms as *Staphylococcus aureus* (ATCC), *Escherichia coli* (ATCC) and *Candida albicans* (ATCC). Confirmation of compliance with all requirements must be provided by an official, approved or authorised laboratory indicating the number of the reference strain used in the analysis. In addition, the standard in the section of test methods details the methods of research and all procedures.

Article 1308 bis of the Argentine Food Code refers to the product called "Propolis and the inclusion of technical specifications" [30]. This regulation evaluates the characteristics, properties, and safety limits of propolis. The labelling also indicates allergenic characteristics. Sensory characteristics include aroma, colour, taste, consistency, and appearance. Raw propolis must meet physical and chemical requirements, namely, set limits for the content of ash, phenolic compounds, flavonoids, lead, arsenic, pesticide and antibiotic residues, oxidation rate, etc. It is forbidden to use additives and foreign impurities. In addition to the requirements for raw propolis, this article also establishes requirements for soft propolis extract and indicates where the use of propolis as an ingredient will be allowed. Mild propolis extract semi-finished product, which is obtained by processing propolis raw materials with ethyl alcohol, to extract biologically active components, impurities and wax. The alcohol must be evaporated under a controlled temperature, so as not to affect the bioactive compounds, to produce a purified substance with a paste-like consistency. Raw propolis and mild propolis extract are designed to meet the special nutritional and nutritional needs of certain population groups: food to meet the specific dietary needs of certain groups of healthy people; food to meet the nutritional needs of people with a certain physiological condition; fortified foods; biological supplements; food with propolis.

Polish standard "Propolis – kit pszczeli PN-R-78891" applies to the production and trade of propolis. Following the example of other standards, sensory and physicochemicall parameters are monitored. Special requirements apply to batch packaging and individual propolis packaging. A characteristic feature is that in this standard, propolis is divided into two classes I and II [32].

The analysis of the above-mentioned international and national regulatory documents regulating the safety and quality of propolis revealed discrepancies between most indicators. Regulatory documents of countries determine the consistency and appearance of propolis differently (Table 2).

Table 2. *Description of the appearance and consistency of propolis in different countries of the world*

Countries	Indicators	
	Appearance	**Consistency**
Argentina	Homogeneous or heterogeneous, preferably in uncompressed pieces	At room temperature: forged or hard, depending on botanical and/or geographical origin
Brazil	Hard, hard or soft substance of uniform colour, depending on the botanical origin	At room temperature: from plastic to solid, depending on the botanical origin
Poland	-[1]	Solid at temperatures up to 20 °C, sticky and plastic at temperatures above 20 °C.
Mexico	Resinous substance, hard, brittle	At room temperature, it is pliable or hard, depending on its botanical origin
East African region	Characteristic, depending on the origin	Lipophilic in nature, with decreasing temperature it becomes brittle, hard, as the temperature rises – soft, pasty, sticky
Ukraine	Lumps, crumbs, or briquettes	Dense, hard, heterogeneous at fracture

Note: [1]the standard "Propolis – kit pszczeli PN-R-78891" does not regulate the indicator [32]
Source: *grouped by authors based on sources [28; 30; 31-34; 42]*

The normative document of Ukraine [28] does not account for the ambient temperature when determining the consistency of the tested samples. Given the physicochemical characteristics of propolis and their dependence on temperature, it should be noted that failure to take this into account may lead to erroneous assumptions about these parameters. When assessing the appearance, the origin of propolis (plant sources) and methods of its selection are not included.

In the regulatory documents of the countries, there is a tendency of similarity of the established requirements for colour, odour, and taste, but there are also characteristic differences (Table 3).

Table 3. *Sensory characteristics of propolis in different countries of the world*

Countries	Indicators		
	Colour	Smell	Taste
Argentina	Yellow, brown, greenish, reddish, brown and their shades, depending on botanical and/or geographical origin and concentration	Resinous or balsamic, depending on its botanical and/or geographical origin	Varied, from mild to strong, bitter, and spicy
Brazil	It is diverse, depending on the origin and concentration (amber tones, reddish and greenish)	Characteristic, depending on the botanical origin (balsamic and resinous)	characteristic, mild to strong, bitter, and spicy
Poland	Yellow to dark brown, often with a green or red tinge	Balsamic, pleasant	-[1]
Mexico	Red, red-yellow, dark yellow, brown-green, brown, or black, depending on the botanical origin	Resinous (woody smell) or balsamic (waxy smell), depending on its botanical origin	From mild balsamic to strong and spicy, depending on its botanical origin
East African region	Characteristic, depending on the origin	Characteristic, depending on the origin	Characteristic, depending on the origin
Ukraine	Dark green, brown, greenish-brown, brown, grey with greenish, yellow or brown tint	Resinous (a mixture of smells of honey, pine needles, and poplar)	Bitter, slightly burning

Note: [1]the standard "Propolis – kit pszczeli PN-R-78891" does not regulate this indicator [32]
Source: *grouped by authors based on sources [28; 30; 31-34]*

The main sensory characteristics of propolis in different regions are primarily determined by different botanical sources of origin. The aetiology of bees during the accumulation of propolis contributes to the polyfloricity of its composition and colour heterogeneity. In addition, the method of collection and cleaning can affect the main sensory parameters of raw propolis.

Requirements for the content of biologically active substances are contained in most regulatory documents. The indicators almost do not differ among themselves (Table 4).

Table 4. *Biologically active substances of propolis*

Countries	Indicators				
	Flavonoids	Oxidation	Phenols	AOA (CA50)[4]	Ethanol-soluble resins
Argentina	min 0.5%	max 22 c	min 5%[2]	-[5]	min 30%
Brazil	min 0.25%	max 22 c	min 0.5%	-[6]	methanol max 0.4 mg/l
Mexico	min 0.5%[1]	max 22 c	min 5%[3]	min 100 mcg/ml	-[7]
Ukraine	min 25%	0.6 per 1 mg cm[3]		-[8]	

Notes: [1]expressed as quercetin equivalents; [2]expressed as gallic acid; [3]expressed as the equivalent of gallic acid; [4]ability of the substance to absorb free radicals, antioxidant activity; [5] the Article 1308 bis "propolis and inclusion of technical specifications" does not regulate this indicator; [6]in Annex VII "On Regulation of Identification and Quality of Propolis Extract" the indicator is not regulated; [7]in NOM-003-SAG/GAN-2017 "Propolis, Production and Specifications for its Processing" the indicator is not regulated; [8]in DSTU 4662: 2006 "Propolis (bee glue). Technical conditions" does not regulate the indicator
Source: *grouped by authors based on sources [28; 30; 31; 33]*

The regulatory documents of Ukraine should include the definition of the total amount of phenols, AOA (antioxidant activity), the content of ethanol and water-soluble resins, and the methods for determining all indicators should be brought to international standards. Requirements should be divided according to the purpose of further use (for example, for the food or pharmaceutical industry). The analysed regulatory documents of Poland and the East African region (Uganda) do not regulate the content of biologically active substances of propolis [34].

Regarding physicochemical characteristics, only the standard of the East African region (Uganda) DEAS 990: 2019 "Bee propolis – specification" [34] requires compliance with all the following indicators. Other countries specify in their regulations certain indicators that, as they believe, have the greatest impact on the quality of propolis (Table 5).

Table 5. *Physical and chemical characteristics of propolis*

Countries	Indicators			
	Dry substances, %	Total ash content, %, max[1]	Wax, %, max[1]	Resin, %, max[1]
Argentina	10	5	-[2]	
Brazil	11	-[3]	1	-[3]
East African region	6	10	30	50
Ukraine	-[4]		15.0	-[4]

Notes: [1]maximum allowed value; [2]Article 1308 bis "Propolis and Inclusion of Technical Specifications" does not regulate indicators; [3]Annex VII "On the Regulation of Identification and Quality of Propolis Extract" does not regulate indicators; [4]DSTU 4662: 2006 "Propolis (Bee Glue). Technical Conditions" does not regulate the indicators

Source: *grouped by authors based on sources [28; 30; 31; 34]*

It is necessary to introduce the parameters of dry matter content and total ash content into the normative documentation of Ukraine. Depending on the collection method, the wax content will vary. It would be necessary to divide propolis into categories depending on the wax content. Propolis of category 1 with a wax content of up to 5%, category 2 up to 10% and category 3 up to 15%. The less wax, the higher the content of plant resins in propolis, and accordingly, the value and cost of propolis should be higher. This approach would encourage the industry to improve the technology for greater benefits, and the market would receive a better product.

The analysed regulatory documents of Poland [32] and Mexico [33] do not regulate the physical and chemical characteristics of propolis.

Contamination is important in developing the quality and safety of both raw materials and finished products. It is important that the most common heavy metals, pesticides, antibiotics, and radionuclides must be controlled by regulatory documents during production. Some countries try to control most of the indicators, and some countries do not regulate these indicators in the analysed regulatory documents (Table 6).

Table 6. *The normalisation of propolis pollutants, mg/kg*

Countries	Indicators				
	Arsene (As)	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Pesticide and antibiotic residues
Argentina	1.0	2.0	-[1]		Not allowed
East African region	0.5	1.0	0.05	0.2	-[2]
Ukraine	0.5	1.0	-[3]	0.05	0.005

Notes: [1]Article 1308 bis "Propolis and Inclusion of Technical Specifications" does not regulate this indicator; [2]in DEAS 990: 2019 "Bee Propolis – Specification", the indicator is not regulated; [3]DSTU 4662: 2006 "Propolis (Bee Glue). Technical Conditions" does not regulate the indicator

Source: *grouped by authors based on sources [28; 30; 34]*

In the analysed regulatory documents of Brazil [31], Poland [32] and Mexico [33] heavy metals, pesticide and antibiotic residues in propolis are not regulated. The content of radionuclides in the analysed regulatory documents is not regulated. According to DSTU 4662:2006 "Propolis (Bee Glue). Technical Conditions" the content of radionuclides is determined by the state hygiene standards GN 6.6.1.1-130-2006. The permissible levels of Cs-137 and Sr-90 radionuclides in food and drinking water approved by the Ministry of Health of Ukraine on 05/03/2006, in particular, should not exceed the permissible levels of 137Cs any more than 600 Bq/kg, ^{90}Sr no more than 200 Bq/kg. [28]

The standard "Propolis – kit pszczeli PN-R-78891" [32] does not regulate microbiological indicators. In addition, most of the reviewed regulatory documents do not pay special attention to microbiology, which may adversely affect the safety properties of propolis (Table 7).

Table 7. *Regulation of microbiological indicators*

Countries	Indicators					
	Yeast/mould CFU/g	***Escherichia coli***	***Staphylococcus***	***Candida albicans***	***Paenibacillus***	***Salmonella***
Argentina	n = 5 c = 2 m = 10 M = 100[1]	-[2]	-[2]	-[2]	-[2]	n = 10 c = 0 m = 0[1]
Brazil	-[3]	-[3]	-[3]	-[3]	Prohibited	-[3]
Mexico	-[4]	Prohibited	Prohibited	Prohibited	-[4]	-[4]
East African region	10 CFU/g	Prohibited	Prohibited	-[5]	-[5]	-[5]
Ukraine	under 100	Prohibited	-[6]	-[6]	-[6]	Prohibited

Notes: [1]n = number of units that make up the sample, C = number of samples that have values between m and M; [2]Article 1308 bis "Propolis and Inclusion of Technical Specifications" does not regulate indicators; [3]in Annex VII "On Regulation of Identification and Quality of Propolis Extract", indicators are not regulated; [4]the Standard NOM-003-SAG/GAN-2017 "Propolis, Production and Specifications for its Processing" does not regulate the indicators; [5]in DEAS 990: 2019 "Bee Propolis – Specification" indicators are not regulated; [6]DSTU 4662: 2006 "Propolis (Bee Qlue). Technical Conditions" does not regulate the indicators

Source: *grouped by authors based on sources [28; 30; 31; 33; 34]*

It is proved that propolis contains wax of animal and vegetable origin [43; 44]. Bees can transfer old wax during nest rebuilding [44]. Contaminated old wax, together with the remains of veterinary drugs and pesticides, can penetrate into propolis. Thus, cleaning the nest elements from old honeycombs (wax) and propolis improves the quality of the latter.

As a result, the national regulatory legal acts regulating the quality of propolis should be updated in accordance with international market requirements. Adapting regulatory documents to international ones should contain the principles of good beekeeping practice in propolis production, which is currently absent in Ukraine.

The authors also consider it expedient to harmonise the main quality indicators of raw propolis with the requirements of regulations of the leading countries of propolis producers (Brazil). In regulatory documents, it is necessary to divide the methods of determining quality into basic (general) and special, depending on the further use of the batch under study.

There are no requirements in the national regulatory framework on the quality of propolis regarding the quality of imported valuable types of propolis imported to the domestic market. The requirements should also be updated. Particular attention should be paid to the prevention of counterfeit and low-quality propolis in large batches for export. As a result of the analysis and systematisation of scientific information, international and national regulatory documents, it is proposed to elaborate:

1) a normative document regulating the process of obtaining propolis with the use of advanced technology as a preventive approach to obtaining safe and high-quality propolis that will meet the requirements specified in the regulations;

2) regulations for identifying propolis types (the type of propolis is labelled according to the dominant source of plant resin);

3) classification and relevant requirements depending on the further purpose and method of production/processing:

– Group I Raw Propolis is intended for use and processing in food, pharmaceutical, medical, and veterinary industries in Ukraine and/or for export.

– Group II Raw Propolis is intended for use and processing as technical raw materials in Ukraine and/or for export.

– Group III Raw Propolis obtained in an organic apiary.

– Group IV propolis, which is imported to Ukraine.

4) list of the most common agrochemicals and veterinary drugs that need to be identified in organic propolis, and the procedure for its mandatory review every 10 years;

5) methodology for determining the main substances of markers to identify the regional and botanical origin of propolis (plant fibres, palynology).

The proposed approach will regulate the propolis market in Ukraine and will contribute to the formation of added value for raw propolis in the case of its grouping by purpose and method of production and processing; will allow exporting propolis as raw materials or finished products.

Conclusions

The main producer in the world market of propolis is Brazil, the second place is shared by New Zealand and China. The norms of the national standard were analysed for compliance with some foreign regulatory documents that contain the most criteria for assessing the quality of propolis, namely: Brazil, Argentina, Poland, Mexico, East African region. European requirements for regulating the international propolis market are also given.

The regulatory document of Ukraine does not account for: ambient temperature when determining the consistency of propolis origin (plant sources) and the methods of its selection when assessing the appearance; total phenols, antioxidant activity, the content of ethanol and water-soluble resins; dry matter content; total ash content; categorisation depending on the impurity of wax; microbiological indicators. Regulations on the content of residues of veterinary drugs and pesticides should be expanded to reflect the modern drugs used.

Significant differences in national and international standards make it impossible to realise the export potential

of Ukraine. It is recommended to develop new regulatory documentation for regulating the production, processing, and quality assessment of propolis.

Prospects for further research are to develop technologies for obtaining and identifying various types of propolis.

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Перегляд національних нормативних вимог до якості прополісу на відповідність міжнародним стандартам

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Анотація. Зважаючи на зростання попиту серед споживачів міжнародного ринку на прополіс, є актуальним переглянути відповідність національної документації до міжнародної, зокрема країн які є лідерами з виробництва й переробляння цього продукту. Інтеграція та адаптація національного законодавства до норм законодавства світової спільноти вимагає також перегляду підходів до якості та безпечності прополісу. Тому, метою дослідження було проведення аналізу чинних міжнародних та національних нормативно-правових актів провідних країн світу, котрі відіграють ключову роль на міжнародному ринку виробництва та реалізації прополісу за показниками безпечності та якості прополісу. Використовували метод Торрако для аналізу та синтезу наукової й нормативно-технічної інформації; користувалися науково-метричною базою Springer та пошуковим інструментом Google Scholar. Матеріалами слугували нормативні документи України, ЄС, Бразилії, Аргентини, Польщі, Мексики, Східно-Африканського регіону. З'ясували, що критеріями для оцінювання якості прополісу у міжнародній нормативно-технічній документації слугують органолептичні (зовнішній вигляд, консистенція, колір, запах, смак), фізико-хімічні (сухі речовини, загальна зольність, віск, смоли) мікробіологічних (дріжджі, плісняви, *Escherichia coli, Staphylococcus, Candida albicans, Paenibacillus, Salmonella*) показники біологічної активності (флавоноїди, окислення, феноли, антиоксидантна активність, етанол-розчинні смоли) та контамінації (важкі метали, залишки пестицидів і антибіотиків, радіонукліди). Встановлено невідповідність діючого в Україні нормативного документа до вимог міжнародних регламентів, а саме за показниками: вмісту фенолів, етанольно- та водорозчинних смол, сухих речовин; загальної зольності; антиоксидантної активності; колонієутворюючі одиниці. Визначено, що в Україні прополіс не розділено за категоріями залежно від домішок воску; не враховано температуру зовнішнього середовища під час визначення показника консистенції; не береться до уваги ботанічне походження та способи його відбору під час оцінювання органолептичних властивостей. Обґрунтовано підхід для урегулювання ринку прополісу в Україні, що сприятиме формуванню доданої вартості на прополіс-сирець у разі його групування за призначенням та способу виробництва і переробляння. Матеріали статті становлять практичну цінність для формування нових та гармонізації існуючих нормативно-технічних регламентів щодо якості прополісу, та можуть бути використані у робочій групі з розвитку бджільництва при Мінагрополітики України

Ключові слова: нормативне регулювання, продукти бджільництва, специфікація прополісу, ідентифікація прополісу, типи прополісу