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Composition, labelling, and safety of food supplements based on bee products in the legislative framework of the European Union – Croatian experiences

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The European Union market is overflown by food supplements and an increasing number of consumers prefer those where bee products play an important part in their composition. This paper deals with complex European Union legislation concerning food supplements based on bee products, placing a special emphasis on their composition, labelling, and safety. Correct labelling of food supplements also represents a great challenge since, in spite of legal regulations in force, there are still open issues regarding the statements on the amount of propolis, which is not clearly defined by the legal framework. One of the key issues are the labels containing health claims from the EU positive list approved by the European Food Safety Authority. Emphasis will also be placed on informing consumers about food, as statements which imply the healing properties of food supplements and their capacity to cure diseases are forbidden. One of the key elements of product safety is HACCP based on the EU Regulations EC 178/02 and 852/2004. Health safety analyses of food supplements with bee products used as raw materials, which are standardised by legal regulations will also be discussed. In the future, attention should also be paid to establishing the European Union "nutrivigilance" system. Croatian experiences in addressing challenges faced by producers, supervisory entities, and regulatory and inspection bodies may serve as an example to countries aspiring to become part of the large European family.

KEY WORDS: *approved health claims; HACCP; labelling; legislation; nutrivigilance; propolis; royal jelly*

The European Union market is overflown by a variety of food supplements and an increasing number of consumers prefer those of natural origin where bee products, especially propolis and royal jelly, play an important part in their composition.

Food supplements are concentrated sources of vitamins, minerals, and other substances (e.g. amino acids, essential fatty acids, fibres, organs, herbal extracts, microorganisms, fungi, algae, bee products) with a physiological or nutritional effect.

Food supplement forms include: dosage forms such as capsules, pastilles, tablets, as well as powders, granules, liquids, and other forms which are ready for consumption in measured quantities or with specific mode of administration (1, 2). Their purpose is to enrich normal diet and maintain healthy lifestyle.

Food supplements – overview of the European and Croatian legislation

In the context of legal framework for food supplements, it is extremely important to underscore that Croatia had established a national one before becoming the EU Member State in July 2013. When it officially entered the European Union, it became mandatory to transpose current EU legislation into the existing national framework as part of the undertaken international commitments.

From the very beginning, food supplements have been under the jurisdiction and supervision of the Ministry of Health of the Republic of Croatia. This is in conformity with the Croatian Food Act. However, food supplements are also subject to special regulations on labelling, advertising and presenting food to consumers, which is the jurisdiction of the Ministry of Agriculture.

The European Commission has established legal frameworks for food, fortified food, novel food, and food supplements.

The Directive 2002/46/EC concerns food supplements, vitamins, and minerals. It prescribes that chemical substances used, as sources of vitamins and minerals in the manufacture of food supplements, should be safe and available to be used by the body (1). All chemical forms of vitamins and minerals, which may be added to food supplements, are regulated by the Regulation (EC) No 1170/2009 (3). Annex XIII of the Regulation (EU) No 1169/2011 regulates daily reference intake of vitamins and minerals and their nutrient reference values (4).

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Labelling of food supplements is specific. Besides general labelling requirements listed in the Regulation (EU) No 1169/2011, the Directive 2002/46/EC adds some specific particulars for food supplements (1). Labelling, presentation, and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties. Food supplements are meant to benefit health. Their label can bear approved health and/or nutritional claims. In order to harmonise these claims, the European Union published Regulation 1924/2006 on nutrition and health claims made on foods (5).

Health claims imply that there is a relationship between a product and a health condition whereas nutritional claims state, suggest or imply that a food has particular nutritional properties. The latter state that the content of a nutrient (e.g. vitamin, mineral or other substance) is "source" or "high" or "low" in it (e.g. sugar, fat, salt).

The European Food Safety Authority (EFSA) evaluates scientific data on claims provided by the Applicant. Afterwards, it puts these forward to the European Commission for approval and authorisation. More than 60 % of the Regulation (EU) No 432/2012 refers to the approved claims related to vitamins and minerals. Some other nutrients and foods are also on the positive list of that Regulation. Still, if one is looking for a specific nutrient, which is not on that list, then its status has to be checked in the EU Register. The status can be either Authorised or Non-authorised, and for botanicals in the EFSA Register of Questions – "on hold" ("Under Consideration") (6).

There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to vitamins, minerals, amino acids, essential fatty acids, fibres, and various plants and herbal extracts. Propolis and royal jelly belong to this group.

Propolis and health claims

Propolis is a complex mixture of compounds which has no approved health claims provided in the Regulation (EU) No 432/2012 (7).

In the EU Register of Nutrition and Health Claims (8), there are eight health claims for propolis, all non-authorised. For each of these, a non-compliance with the Regulation has been pronounced as on the basis of scientific evidence assessed such food has been deemed not sufficiently characterised to be claiming an effect on a health condition and the claim could not therefore be substantiated. Only nutritional claims such as "containing propolis" can be displayed on the product label but the quantity of propolis contained in the product is obligatory.

The non-authorised claims are the following:

Antioxidants can protect from free radicals and help in case of food intake deficiency or increased amount of nutrients (ID 3797)

Helps increase the antioxidative capacity of the body (ID 1243)

Helps natural defences (ID 1248)

Helps physiological blood fluidity (ID 3526)

Helps to maintain healthy liver function, supporting digestion and body purification (ID 3527)

Increases the physiological resistance of the organism in case of severe ambiance conditions (ID 3798)

Promotes upper respiratory tract health (ID 1242)

Supports the immune system and the body's defence (ID 3799).

Before Croatia joined the EU, the Croatian Ministry of Health had been in charge of rendering decisions on the approved purpose for food supplements containing propolis. The validity of such decision was five years from the date of issue and it covered the product as a whole rather than just its specific ingredient. At that time, the manufacturer had an obligation to submit each food supplement to the Ministry of Health for registration. Having received complete documentation, the Scientific Committee for Food Supplements assessed the conformity of a food supplement with legal requirements and issued a decision on the approval to put it on the Croatian market accordingly.

The situation changed after the 1st of July 2013 and the EU brought about more responsibility for manufacturers. The greatest challenge for them was the adjustment of their products to new European rules, which meant no more health claims for propolis on the product label. They also needed to decide on the following: the revision of the existing products (i.e. reformulation by adding vitamins and/or minerals for which there are approved health claims); analysis of compliance with new regulations; definition of the claims that were planned to be submitted for the EU approval in accordance with Commission Regulation (EC) No 353/2008 (9); preparation of the claim admissibility dossier in collaboration with the Ministry of Health; regulation of stocks of finished products and packaging materials; classification and registration of food supplements in another category (e.g. medical device, medicine, etc.).

Stating the amount of propolis on the label

One of the key issues in the Republic of Croatia, as well as in all other EU countries, is how to state the amount of propolis (%) in food supplements correctly, as there is no legal requirement prescribed. In Croatia, until mid-December 2014, a non-mandatory Guidance for Labelling, Advertising, and Presentation on Food, 8th Edition, published by the Ministry of Agriculture Republic of Croatia in January 2013 was in force.

This was distributed to manufacturers so that they could gain an insight into several possibilities of stating the amount of propolis in alcoholic/ alcohol-free extracts, depending on the product name, as follows (10):

"The alcoholic extract of propolis" Contains at least _____ % propolis extract (or dry residue)

"Alcoholic solution of propolis" Produced of ___% of propolis

"The alcoholic extract of propolis" Contains at least ___% of dry residue equivalent to ___% of propolis.

Authorised laboratories also used these possibilities of stating the amount of propolis when they performed conformity checks of food supplement label information. These guidelines are no longer in use but the manufacturer is entitled to put them on the label to inform consumer better on the product.

In order to solve this problem, there are now new trends in standardising statements on the amount of propolis in terms of some of its active components. These are done at national levels and are to be considered at the EU level. The final solution is still underway as propolis with different geographical origin contain different biologically active components.

Royal jelly and health claims

Royal jelly (Gelée Royal) is a complex mixture of compounds which has no approved health claims provided in the Regulation (EU) No 432/2012 (7).

In the EU Register of Nutrition and Health Claims (8), there are 12 health claims for royal jelly, which are also non-authorised. The same as for propolis, on the basis of scientific evidence assessed, such food is said not to be sufficiently characterised to be claiming a health effect and the claims could not therefore be substantiated. Claims are as follows:

Helps to maintain calm and comfortable menopause/ helps women coping with the tell-tale signs associated with menopause, such as hot flushes, sweating, restlessness and irritability/Royal jelly is an effective dietary supplement for the improvement of quality of life in menopausal women (ID 1328)

Royal jelly helps strengthen your body / strengthens the body (ID 1225)

Regulates the function of endocrine glands; Royal jelly helps promote milk secretion in breastfeeding mothers (ID 1228)

Royal jelly contains vitamins, fatty acids, and hormone substances that promote its beneficial effect on skin; Vitamins and other biologically active substances contained in royal jelly benefict the skin (ID 1230)

Royal jelly normalises metabolism (ID 1226)

Helps to support body's vitality (ID 1231)

Promotes a good heart functioning and a balanced level of the blood lipids (ID 4696)

Reconstituent and tonic (ID 1703)

Stimulates blood circulation (ID 1227)

Royal jelly could promote the protection of cells against certain harmful effects provoked by free radicals (ID 1229)

As stimulant - nourishes the human body and supplies energy. It supplies vitamins and minerals from natural sources. It has positive effects during menopause and for overall rejuvenation of the skin and human body (ID 3190)

As immune function/immune system - nourishes the human body and supplies energy. It supplies vitamins and minerals from natural sources. It has positive effects during menopause and on the overall rejuvenation of the skin and human body (ID 3191).

The situation with food supplements containing royal jelly prior to Croatia's accession to the EU was the same as with supplements containing propolis. After the 1st of July 2013, it is only allowed to provide nutritional claims and the quantities in the table of ingredients.

Safe production of food supplements containing propolis and royal jelly

Food safety criteria depend on the type of food and ingredients, risks for the environment, use of agro-technical measures, storage, production technology, and storage before and after delivery to the customer.

There are numerous factors that play a key role in food supplement safety: developed national and European legal framework, Hazard Analysis & Critical Control Points scheme (HACCP), Good Beekeepers Practice, food safety analyses, legal authorities (Ministry of Health, Ministry of Agriculture, Croatian Food Safety Agency, laboratories, inspection service), and good cooperation between Croatian institutions and their peers in other EU Member States.

The Croatian Food Act is the legal framework established in order to transpose European food law. It clearly stipulates that all food marketed in the EU must be safe and deals with requirements regarding complete transparency in the food chain (11). It is extremely important for all food business operators to produce and ensure safe and high-quality food supplements for consumers applying the HACCP-based procedures (12).

Good Beekeepers Practice (GBP) is a set of rules and guidelines that must be observed during the production process and represent a higher degree of diligence and beekeepers responsibility.

Although HACCP and GBP are well covered by the European and national legislations, there is a lack of systematic control of their implementation. Furthermore, the awareness of all stakeholders in the process dealing with food supplements on the fact that only their strong mutual cooperation can result in safe food supplements fit for human consumption has not been sufficiently raised yet. In particular, beekeepers need to be strongly aware that their safe bee products are vital for high quality and safety of the final products.

Inspection services are responsible, among other things, for the official controls of food supplements. The priorities of official controls are to determine the following: unauthorised substances and ingredients, unauthorised advertising and labelling of food supplement properties like medicines, applying health claims from the negative list, and other nonconformities.

Food supplement safety analyses

Food safety control of food supplements covers basic analyses (microbiological analysis, heavy metals, organoleptic), specific analyses (pesticides, GMOs, mycotoxins, colours, preservatives, allergens), targeted analyses for the basic nutritional value (carbohydrates, fats, protein, energy value) and specific nutritional value (vitamins, minerals, other bioactive substances) (13). All these analyses are defined by the relevant national regulations and legislative acts of the European Union (14-17).

Honey has also been recognised as an important bee product whose safety is meticulously observed. Different ingredients can be added to honey as to enhance its effects on the body: other bee products, vitamins, herbal extracts. Consistent with this, honey with additives needs to be analysed as a food supplement and be in compliance with relevant food supplement legislation.

In Croatia, there is a relevant national ordinance relative to substances that may be added to foodstuffs and used in food production, and the substances whose use in foodstuffs is prohibited or restricted (18). Propolis and royal jelly are both regulated with the above mentioned ordinance and both may be added to food supplements.

One of the critical parameters for food supplement safety is label, which must be in compliance with the valid Croatian and European legal frameworks. Significant parts of labels are health claims referring to the amount of active ingredients in the recommended daily intake. Authorised laboratories have the task of confirming label compliance with the requirements.

Analyses of propolis at the Croatian Institute of Public Health

Flavonoids represent a large group of secondary metabolites present in all plants. They are responsible for the colouring of flowers and leaves, normal growth, and development and defence of plants. Galangin is one of the flavonoids present in propolis in temperate regions and numerous extracts were standardised based on its total content.

A number of spectrophotometric procedures used to quantify total phenols or total flavonoids in propolis have been published (19). These methods are easy to perform but have a big disadvantage of not determining the concentration of individual substances.

The Croatian Institute of Public Health is one of the leading control bodies in Croatia which analyses various types of food including propolis-based food supplements. Microbiological and contaminant analyses are the general analyses carried out by the Institute and these are covered by all relevant EU regulations. Besides that, the Institute has also developed an in-house method for determination of galangin content in the samples containing propolis. The results are expressed quantitatively.

From 2009 to 2012, the Ministry of Health and the Croatian Institute of Public Health conducted monitoring of these products. The results were as follows: of the total number of 83 samples, 5 were incompliant, 18 showed a lower amount and some 20 a higher amount of galangin than indicated and other samples were in conformity with declared values (20). All samples/products were alcoholic extracts taken from the market. Despite the fact that the above mentioned data is publicly available, this is more of an exception than the rule; since these analyses are performed for private clients, as well as for the needs of inspection services, control bodies are obliged to keep the results as a business secret. It is only the competent authorities that can make some data available to the public. For instance, the public report of the Croatian Food Safety Inspection is available on the website of the Ministry of Health.

Analyses of royal jelly at the Croatian Institute of Public Health

The substance which is always present in royal jelly is unsaturated fatty acid 10-hydroxy-2-decenoic acid (10-HDA). A number of biological properties have been attributed to this substance which is usually present in the amount from 1.5 to 2 %. It was described in detail as early as in 1959 (21). Since 10-HDA has so far not been found anywhere else in nature and cannot be produced synthetically, its presence and quantity are considered an indicator of authenticity and quality of royal jelly. It is therefore the most effective analytical parameter for proving these (22). The detection of 10-HDA in royal jelly and products containing royal jelly using high performance liquid chromatography (HPLC) technique has become a standard procedure for the assessment of their quality. The results of the analysis show that the quantity of 10-HDA decreases in proportion to the degree of adulteration and, from that point of view, royal jelly in which the presence of 10-HDA has not been confirmed is not authentic, meaning that 10-HDA has been entirely replaced by another, less expensive and ineffective substance (23-25) (e.g. corn syrup, egg white, starch, yogurt, milk powder, water).

Royal jelly-based products are analysed at the Croatian Institute of Public Health using a confirmative method. The HPLC method has been used since 2009 as a standard procedure for the evaluation of royal jelly quality (20). The analytical reports confirm only the presence but provide no quantitative value of 10-HDA. The limits of 10-HDA substance for the sample to be considered acceptable are the detection limit values and the sensitivity of the instrument on which the analysis is carried out. Neither the results of these analyses nor the limits of 10-HDA for the sample to be considered acceptable are publicly available; only in the reports of the Ministry of Health.

Besides safety analyses, which are mandatory, quality analyses must also be paid attention to. For royal jelly food

supplements, this also refers to the presence of 10-HDA and its comparison with what is indicated on the label. Such results are in accordance with the EU Regulation No 1169/2011.

Monitoring system for food supplements in the Republic of Croatia

All food supplements and food with health claims must be part of the Monitoring System implemented by the Ministry of Health (26). There are two ways of applying to be included in the system:

Information procedure

This procedure is applicable to the products in which the quantities of vitamins and minerals do not exceed the upper permitted levels and which have chemical forms in line with the Regulation (EC) No 1179/2009; which contain nutrients from the positive list of botanicals and other nutrients; or which bear health claims according to the Regulation (EU) No 432/2012.

In this case only the label and some company information have to be sent via e-mail and the products can then be freely marketed.

Notification procedure

This procedure is applicable to the products in which the quantities of vitamins and minerals exceed the upper permitted limit; or nutrients and botanicals not present on the positive lists; or with "on-hold" health claims. In this case, additional documentation is required (certificate of origin, Certificate of Analysis, evidence of main chemical components, quantities of active nutrients, statements of interactions, non-toxicology data, and human safety data) and this is sent together with the label, EFSA ID and some company information to the Scientific Committee of the Ministry of Health.

"Nutrivigilance" system in Croatia and the European Union

While pharmacovigilance is mandatory to monitor the safety of medicinal products, the term "nutrivigilance" is not used in food legislation framework. Consistent with this, such system is not established either in Croatia or in the European Union. Embedding this into relevant legislation would be the first step towards forming a mechanism and a tool for monitoring consumer and food supplement safety. Food supplements, including those with bee products, can cause allergies and other contraindications and these have to be carefully observed. France is a very good example of a successful "nutrivigilance" system. The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has been working since 2010 on nutrivigilance seeking to identify the adverse effects of consuming food supplements and certain special food items. The results have shown that since the beginning of the ANSES's nutrivigilance scheme, it has received over 1500 reports of adverse effects. Among these, 76 % were due to the consumption of food supplements and 24 % to fortified foods or foods for special dietary uses (27). Led by the French example of good practice, the rest of the European Union is now investing a lot of efforts into establishing a nutrivigilance network, which will be the first step towards sharing information and transferring knowledge on the side effects of products covered with the mentioned network (28, 29).

CONCLUSION

Bee products, which contain propolis and/or royal jelly belong to the food supplement category and it is therefore not allowed to attribute them the property of preventing, treating or curing a human disease, or refer to such properties. Their labels can bear authorised health and/or nutritional claims. However, there are still no authorised health claims provided by the EFSA Register of Questions and the EU Register of Nutritional and Health Claims. The analyses of these products are based on the presence of biologically active substances, galangin, and 10-HDA, which are naturally occurring in such products. The safety of bee products is very important for consumers and factors that ensure food supplement safety are: national and European legal framework, HACCP, Good Beekeepers Practice, food safety analyses, legal authorities and cooperation between EU Member States.

By joining the European Union, Croatia experienced numerous positive changes: it adopted and transposed most of European legislation into national legislation establishing thus a sound legal basis; it gained access to open markets and the free flow of goods and services; authorities are now compelled to bring order to the market of food supplements; and food supplement analyses are more available and cheaper for producers.

Nevertheless, some issues such as delays in adopting legislative acts, brief periods for adjustment, insufficient information for producers and consumers, and the inexistence of approved health claims for bee products were and still continue to be a challenge for Croatia.

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Sastav, označavanje i zdravstvena ispravnost dodataka prehrani koji se temelje na pčelinjim proizvodima u pravnom okviru Europske unije – hrvatska iskustva

Tržište Europske unije preplavljeno je dodacima prehrani i sve se više potrošača okreće upravo onim dodacima prehrani u čijem sastavu pčelinji proizvodi igraju bitnu ulogu. Ovaj se rad bavi složenim zakonodavstvom Europske unije o dodacima prehrani koji se temelje na pčelinjim proizvodima, s naglaskom na njihovom sastavu, deklaraciji i zdravstvenoj ispravnosti. Ispravno označavanje dodataka prehrani također je velik izazov s obzirom na to da unatoč pozitivnim propisima još uvijek postoje otvorena pitanja vezana za izjave o količini propolisa, što nije jasno utvrđeno pravnim okvirom. Jedno od ključnih pitanja su deklaracije koje sadržavaju zdravstvene izjave s EU-ova popisa koji je odobrila Europska agencija za sigurnost hrane. Naglasak će isto tako biti na informiranju potrošača o hrani s obzirom na to da izjave koje upućuju na ljekovita svojstva dodataka prehrani i njihovu sposobnost liječenja bolesti nisu dopuštene. Jedan od ključnih elemenata zdravstvene ispravnosti hrane je HACCP, koji se temelji na Uredbama EU-a 178/2002 i 852/2004. Analize zdravstvene ispravnosti dodataka prehrani koji sadržavaju pčelinje proizvode kao sirovine, standardizirane pravnim propisima, također su predmet ovog rada. U budućnosti bi pažnju valjalo posvetiti uspostavi sustava „nutrivigilancije“ na razini EU-a. Hrvatska iskustva u rješavanju izazova s kojima se suočavaju proizvođači, mjerodavna tijela te regulatorna tijela i inspekcije mogu poslužiti kao primjer onim zemljama koje žele postati dijelom velike europske obitelji.

KLJUČNE RIJEČI: *HACCP; nutrivigilancija; matična mliječ; odobrene zdravstvene tvrdnje; označavanje; propolis; zakonodavstvo*