

Intellectual property and regulation of functional foods *

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Summary: Today, there exist scientific evidences that functional foods have favorable physiological and psychological effects as well as additional functions in relation to health, apart from the basic nutritional effects, thus offering the potential of enhance health or reduced the risk of diseases. Since interest in this category of foods has increased, new products have appeared as well as the need to introduce and set up standards and guidelines for the development and promotion of such foods. Technological development in this area and involvement of great multinationals in research investment and development of new products have reinforced the importance of the intellectual property rights, especially of patent protections and trademarks.

Keywords: functional foods, intellectual property, regulation

Rezime: Danas postoje naučni dokazi da funkcionalna hrana ima povoljne fiziološke i psihološke efekte, kao i to da ima dodatnu funkciju u odnosu na zdravlje, odvojeno od osnovnih nutritivnih efekata, i na taj način nudi mogućnost za poboljšanje zdravlja ili smanjenje rizika od bolesti. Kako je interes za ovu kategoriju hrane rastao, pojavili su se novi proizvodi, takođe se javila potreba za uvođenjem i razvojem standarda i vodiča za razvoj i promociju takve hrane. Tehnološki razvoj u ovoj oblasti i angažovanje velikih multinacionalnih kompanija na investiranju u istraživanje i razvoj novih proizvoda pojačali su značaj prava intelektualne svojine, napročito patentne zaštite i žigova.

Ključne reči: funkcionalna hrana, intelektualna svojina, regulative

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1. INTRODUCTION

Nowadays, the consumers expect that the food not only satisfy hunger and supply the caloric necessities of the individuals but to have functions associated to the health, such as: to reduce cholesterol, to be adjusted the diabetes carrying people, not to fatten, to prevent illnesses caused by vitamins and minerals deficiencies, to supply energy and for possessing integrant components to the cellular structures. The food sector is evaluated as being extremely strategic for the economy of many countries. The market globalization leads to the necessity of constant development and implantation of new technologies, aiming at obtaining the products with better quality and minor price and at productivity increase. The creation of the World Trade Organization (WTO) and, in cooperation with the World Intellectual Property Organization (WIPO), the appropriation of the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS) made that the signatory countries have to harmonize its legislation of intellectual property [10]. Some countries (Brazil, India, China and others) were obligated by TRIPS to grant patent rights in areas where the previous legislations didn't grant them, especially for pharmaceutical, chemical and food products.[4] This modification of legislation is very important for technological development and for involvement of great multinationals in research investment and development of new products.

2. DEFINITION OF FUNTIONAL FOODS AND REGULATION

The term "functional foods" has no unitary accepted definition and in most countries there is no legislative definition of the term, thus drawing the border line between conventional and functional foods is challenging even for nutrition and food experts (Mark-Herbert 2004)[6]. A number of national authorities, academic bodies and industry experts have proposed definitions for functional foods, ranges from the very simple to the more complex: "Foods that may provide health benefits beyond basic nutrition" or "Food similar in appearance to conventional food that is intended to be consumed as part of a normal diet, but has been modified to subserve physiological roles beyond the provision of simple nutrient requirements"[8]. Although the first fortified products resulted from public health endeavors, vitamin B enriched flour, was introduced in the 1940s to combat pellagra, later were introduced iodine-fortified salt substantially decreased incidences of goiter and vitamin D enriched milk virtually eliminated rickets, the term "functional food" came in sight in the 1990s, when Japan systematized its "Food for Specified Healthy Use (FOSHU)" and "self-medication" programs that instruct people to manage their own health through dietary practice [20]. Japanese consumers were maintained to adopt a healthy

lifestyle which involved choosing foods that reduced sugars, fats and carbohydrates and increased fibre, vitamins and minerals and other ingredients to decrease their risk of diabetes, manage allergy symptoms and to improve intestinal regulation. In 2005 Japan's government appropriated regulations on food for specified health use and companies had to go through an application of new products. Two categories of functional food are defined in Japan: unregulated and regulated. Fig.1 shows classification of health foods in Japan [20].

FOSHU (Foods for Specified Health Use)	FNFC (Foods with Nutrient Functional Claims)	All other Foods	Medical Drugs
Require prior approval. Foods that can expect some specified health purpose and may label the claim	Approval not required but restricted to approved vitamins & minerals	Including nutritional supplements (General foods category)	Require prior approval

Source: [20]

Figure 1- Classification of Health Foods in Japan

The regulated category FOSHU allows labels and means that a product has certain health benefits.

It is very important that Japanese government was (and still is) very supportive of the functional foods market. Nowadays, research and development in Japan is focused on blood pressure, teeth health related, blood sugar level and cholesterol.

In the USA, production and market of functional foods are very important thus regulation and labeling have been arranged. Fig. 2 shows comparison of the regulation between the functional foods, medicinal foods and prescription drugs [13].

In the USA functional foods are used, distributed and regulated differently from medicinal foods and drugs. "Reduction of risk of disease" claims have been permitted since 1993 for certain foods. Health claims are authorized by the Food and Drug Administration (FDA) on the basis of "the totality of publicly available scientific evidence and where there is significant scientific agreement amongst qualified experts that the claims are supported by the evidence" [6].

Difference	Functional foods	Medical foods	Prescription drugs
Uses	Energy enhancement; weight management; bolster gut, bone or heart health; disease risk reduction; memory improvement	Dietary management of a disease or condition with distinctive nutritional requirements (e.g. difficulty swallowing, loss of appetite, nutrition repletion post-surgery)	Treatment of disease, symptom, or condition
Method of obtainment	No prescription or supervision needed; consumer selects	Used with medical supervision	Prescribed by health provider
Distribution channels	Supermarkets, drugstores, online, major retailers	Hospitals, pharmacies, drugstores, online	Pharmacies, hospitals
Regulatory body	No specific body, but is considered food and is therefore subject to FDA regulation' (FDA regulates any specific health claims that might be made)	No additional FDA review/approval needed, but must abide by regulations concerning foods, e.g., labeling (FDA regulates any specific health claims that might be made)	FDA approval needed, a multiyear, multistage review process
Amount consumed	As desired	As needed	As prescribed

Sources: Company reports, Nutraceutical World, The New York Times, FDA, Institute of Food Technologies, [13]

Figure 2-Comparing functional foods with medical foods and drugs in USA

European legislation has not yet considered functional foods as specific food categories. Generally, functional foods are considered as the foods intended to be consumed as part of the normal diet containing biologically active components which offer the potential of enhanced health or reduced risk of disease. Due to increasing interest in the concept of “functional foods” and Health Claims”, the EU set up a European Commission Concerted Action on Functional Food Science in Europe (FUFOSE), which defined functional food as follows:” A food product can only be considered functional if together with the basic nutritional impact it has beneficial effects on one or more functions of the human organism thus either improving the general and physical conditions or/and decreasing the risk of the evolution of diseases. The amount of intake and form of the functional food should be as it is normally expected for dietary purposes. Therefore, it could not be the form of pill or capsule just as normal food form”. (Since 2001 FOSHU products in Japan can take the form of capsules and tablets, although a great majority of products are still in more conventional forms.) The FUFOSE project considered six areas of science and health, growth, development and differentiation: substrate metabolism; prevention against reactive oxidative species; functional foods and cardiovascular system; gastrointestinal physiology and function; and the effects

of foods or behavior and psychological performance [14]. According to the EC regulation on nutrition and health claims made on foods (EC No. 1924/2006), a list of authorized claims has to be published for all member states, and nutritive profiles also have to be established for foods containing health claims. Health claims can be “functional claims” and reduction of disease risk claims” [7]. In the absence of a Directive on health claims, EU Member States have applied different interpretations of the existing labeling legislation. But, there is a broad consensus that health claims must be properly substantiated to protect the consumer, to promote fair trade and to encourage academic research and innovation in the food industry.

3. THE MARKET OF FUNCTIONAL FOODS

A number of factors are responsible for changing consumer attitudes toward foods and reshaping food supply trends. The consumer trends in the world food and beverage market have been influenced by a number of changes in society, especially that an aging population is fueling demand for health and wellness as well as functional and organic food products. Ethnic foods, beauty foods, and “free of” foods [e.g. lactose and gluten-free products] are further trends. These include an aging population, increased health care costs, consumers desire to enhance personal health, change in consumer awareness and expectations, advancing scientific evidence that diet can alter disease prevalence and progression, advances in food science and technology, and changes in food regulations. Following the trends observed in consumer demand, the food industry introduced a new category of products named functional foods.

It is difficult to estimate the global market of functional foods due to various definitions of the term “functional foods”. According to the French Technology Press Office (2008), the market was currently estimated at over US\$ 129 billion; the market in Europe was estimated to be the largest (US\$ 34 billion), the market in USA amounted to US\$ 26 billion and in Japan US\$ 22 billion. The industry growth is expected to rise 16 percent annually, according to Scott Wolfe Management (2002) [19].

According to the other source, the USA functional foods market is estimated to be the largest in the world, representing between 35 and 50 % of global sales and the top 20 functional foods companies account for about 70% of the market [13]. Some of the key functional food players on the 2006 USA market are given in Fig. 3.

Player* (rank)	Key functional brands
1. PepsiCo (1)	Quaker, Gatorade
2. Coca Cola (2)	Vitamin Water, Odwalla
3. General Mills (3)	Cheerious, Yoplait
4. Kellogg (4)	Special K, Kashi
5. Nestle (9)	Nesquik, Powerbar
6. Danone (11)	Activia, Essensis

* ranking according to USA functional food sales in 2006.

Source: PwC analysis, Nutrition Business Journal, The Wall Street Journal, AC Nielson, Scientia Advisors, Leatherlead Food international,[13]

Figure 3- Key functional food players in USA

In Japan, the important role of food in curing illness has long been recognized and has led to the development of functional foods market. Japan could be ranked as the second largest functional foods and drinks market in the world. It amounted to US\$ 16,4 billion dollars in 2007 and, according to Datamonitor projections, that market will grow 5,9% to US\$ 21,8 billion over the 5 year period from 2007-2012.[5] In 2007, 755 FOSHU products were approved for sale, with retail sales totaling US\$ 6,5 billion. The digestive health category is the largest accounting for 51% of sales; the next largest category, accounting for 24% of sales was weight management, followed by teeth health accounting for 14% and metabolic syndrome risk factor for 10% of sales [17].

3.1 Some examples of functional food products

The functional food products have been mainly launched in the dairy-, confectionary-, soft-drinks-, bakery-, and baby-food market [8]. The potential benefits of food components by categories are given in Fig. 4.

Products	Categories
Non-altered products nutrients or components	Foods naturally containing increased content of
Fortified products	Increase the content of existing nutrients
Enriched products	Adding new nutrients or components not normally found in a particular
Altered products	Replace existing components with beneficial components
Enhanced commodities	Change raw commodities to alter nutrient composition

Source: [8]

Figure 4- Categories of the products and Potential Benefits of Food Components

In Japan, USA and Europe, the functional foods market is dominated by gut health products, in particular, probiotics, which can be defined as “ live microorganisms, as they are consumed in adequate numbers confer a health benefit on the host”. Probiotic products represent a strong growth area within the functional foods group and intense research efforts are under way to develop dairy products into which probiotic organisms such as *Lactobasillus* and *Bifidobacterium* species are incorporated. Some commercial examples of probiotic products are given in Fig. 5.

Trade name	Description	Producer
Actimel	Probiotic drinking yogurt with <i>L. Casei</i> ImunitassR cultures	Danone, France
Gefilus	A wide range of LGG products	Valion, Finland Jovita
Probiotisch	Blend of cereals, fruit and probiotic yogurt	H&J Bruggen
GermanyProViva	Refreshing natural fruit drink and yogurt in many different flavours containing <i>Lactobacillus plantarum</i>	Skane mejerier, Sweden
Revital Active	Yogurt and drink yogurt with probiotics	Olma, Chez Republic
Snack Fibra,	Snacks and bars with natural fibers and extra minerals and vitamins.	Caligueta, Spain,
Soytreat	Kefir type product with six probiotics	Lifeway, USA
Yakult	Milk-drink containing <i>Lactobacillus casei</i> Shirota	Yakult, Japan

Sources: [8]

Figure 5- Some commercial probiotic products

Prebiotics are non-digestible food ingredients that beneficially affect the host by stimulating the growth and/or activity of one or a limited number of bacteria in the colon, thus improving host health. Prebiotic products contain some ingredients as the main components: fructo-oligosaccharide (FOS), inulin, isomalto-oligosaccharides (IMO), polydextrose, lactulose and resistant starch.

Functional drinks are non-alcoholic beverage fortified with vitamins A, C, and E or other functional ingredients.

Functional cereals, in particular oat and barley, are very convenient for functional foods production. Cereals can be used as fermentable substrates for the growth of probiotic microorganisms and can be applied as sources of non-digestible carbohydrates and act as prebiotics.

Bakery products contain the nutritional elements normally available in conventional food and functional ingredients.

Spreads, like cheese, cream, margarine, butter, as functional foods have launched on the market as cholesterol-lowering products, for example: BecelR

margarine containing phytosterol esters; BenecolR product containing camelina oil as a source of omega-3 fatty acids, and BaladeTM low-cholesterol butter, produced in that way that 90% of the cholesterol in milk fat has been removed by the addition of crystalline beta-cyclodextrin to the molten butter.

Functional meat and functional eggs contain numerous ingredients to be functional and they are of particular interest from a functionality of view.

3.2 Innovations in the food products

R&D investment in food and drink manufacturing has traditionally been low compared to other industries. Food and drink companies, both within and outside the EU, in spite of the economical crisis, have continued to invest. The food and drink industry's R&D expenditure (R&D investment as a percentage of output) in EU has been the lowest when compared to the majority of developed countries. The R&D expenditure levels are higher and continue to increase in Japan, USA, Australia and South Korea, while the EU has experienced relative stagnation at 0, 37% in 2006, close to 2005 levels (0, 38%) [10]. Biotechnology is one of the most promising activity of innovation and growth in the food and drink sector and for agricultural application [2]. Table 1 shows the European 10 most innovative food sectors [15.]

Table 1- Europe's 10 Most Innovative Food Sectors 2009*

Sector of the products	Food innovations per sector (%)
1. Dairy products	7,6
2. Frozen products	7,1
3. Soft drinks	6,4
4. Ready-made meals	6,3
5. Biscuits	6,1
6. Meat, fine foods, poultry	5,2
7. Chocolate products	4,3
8. Cheeses	3,9
9. Groceries for aperitifs	3,6
10. Condiments and sauces	2,7

*Percentage of total European food innovation

Source: Food Drink Europe and Trends of the European Food and Drink Industry 2011, [15]

In Europe, the German food industry and public and private institutes continuously conduct R&D activities to develop new products. Total R&D spending in the German food and beverage industry for 2010 reached EUR 347 million, in 2011 the R&D budget will increase by 3 % to 358 million EUR. Table 2

shows ongoing German R&D projects in the field of food science and technology [15].

Table 2 -Overview of R&D Germany Projects in Food Technology

Sector	Institutes	Ongoing projects	Finished projects	All projects
Food chemistry	75	31	125	156
Food processing	129	99	214	313
Food microbiology	31	17	24	41

Overview of R&D Projects of Nutritional Science

Nutrition physiology	88	28	135	163
Home economics	9	2	9	11
Nutritional behavior	32	18	23	41
Toxicology	31	15	22	37

Source: Bundesanstalt für Landwirtschaft und Ernährung 2011, [15]

As of the April 2008. Japan launched health guidance for "Metabolic syndrome", the name for a group of risk factors linked to overweight and obesity that increase the chance for heart disease and other health problems such as diabetes and stroke. Researchers have been focused to research and development of new products on blood pressure, blood sugar level, cholesterol and intestinal regulation. Food market in Japan needs projects focused on "searching for ingredients that have excellent functions" and "evaluation standards that will confirm the effects" [17].

Advanced technology	New health category	New food category
Technologies that enable creation of more stable functional food formulations. Technologies that improve taste/smell. Technologies that remove grainy texture of fibers added to beverages.	Researching the immune system benefit category; adding probiotics, prebiotics and synbiotics to not only yogurt and dairy beverages but also to juices, baked goods, soups and coffee to improve the body's defenses against disease and infection.	Probiotics in beverage and baked goods. Fibers in beverages and dairy products. Healthy oils in dairy products.

Sources: New Nutrition Business, Food Institute Report, Scientia Advisors [13]

Figure 6- Research areas of the USA companies in the functional foods

In USA the functional foods companies and institutes are currently researching. Fig. 6 shows research areas, new health categories and new functional foods categories of the research and development projects of USA's companies.

4. INTELLECTUAL PROPERTY PROTECTION

Intellectual property rights are very important in the field of the functional foods technologies and products, especially patents and trade-marks [3]. A search of the patent collections from the USA, Europe, Japan and the PCT (Patent Cooperation Treaty) offices showed approximately 3.900 patents and patent applications in 2009, which pertaining to health foods, functional foods or "foods for wellness". These patents and patent applications consist: approximately 1.000 Japanese patents since 2003, fewer than 500 US patents since 2001, EPO 200 since 2003 an PCT/WIPO more than 500 since 2000 and 1.700 others [19].

According to any national patent law, patent conventions (the Agreement on Trade Related Aspects of Intellectual Property Rights ,TRIPS, and European Patent Convention, EPC) or PCT, inventions fall into three categories: an invention of product, an invention of a process and an invention of a use product. The patentability for any invention, whether products or processes is allowed in all fields of technology, if it is new, involve an inventive step and are capable of industrial application. Under EPC, the European Patent Office (EPO) has retained the following exceptions of patentability[11]: "Methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; plant and animal varieties and essentially biological processes for the production of plants and animals" (USA patent law doesn't fall in such type of exception [24]). Additionally, EPC incorporated the essence of Directive 98/44/EC for considering the patentability of biotechnology applications. [12] The EPO recognizes two types of "use patent": medicinal and non-medicinal and each with different patentability requirements. The first medicinal indication, "first medicinal use", has been dealt with as a product claim, whereas the second (or further) medical indication, "second medical use" as a process claim. A claim to a known substance or composition for the first use in therapeutic, surgical and/or diagnostic methods should be in a form such as: "substance or composition X for use as medicament", or as an "antibacterial agent" or "for treatment of malignant tumors"..., whereas a second medical use claim was in the form: " Use of a substance or composition X for the manufacture of a medicament for therapeutic application Y". According to the EPO decision G2/08, the medical use claim " Use of substance X in the preparation of a medicament for treatment Y" will no longer be allowed in applications filed on or after January 29, 2011.[9]. The claims filed to further medical uses must thus be drafted in the new form : "Substance X for use in a method of treating disease Y". Actually, the USA have

adopted a more restrictive approach to the protection of new uses, "method –of-use" claims, because these patents do not encompass protection of the product as such [18]. Functional foods innovations can fall between two types of use claims: medicinal and non-medicinal. An additional problem can emerge due to the order of the patentability meaning that a product can be patented if it is new and some functional foods are known natural products. But, it is important to know that Biotechnology Directive allows patentability of natural products [12]. European patent practice shows that a typical approach to patenting the functional food would be to write a claim to a medical use, for example: "A nutritive product containing a compound of Formula I for use in treating high blood pressure".

Under Japanese Patent Law, inventions fall into three categories: an invention of a product, an invention of a process and use product. According to the Japanese Patent Office (JPO) Examination Guide, a use invention is defined as follows: "Generally, a use invention is construed as an invention based on discovering an unknown attribute suitable for a new use due to the presence of such attribute" and a use invention is a process claim [18]. Under Japanese patent practice, foods have a common feature with medicine and cosmetics in that these are all applied to a human body and a use invention of a food is not generally protected by a product claim, nor by a process claim. Further, according to the JPO Examination Guide a discovery of a new attribute of a publicly known food does not provide a new use. An example is the following claim: "Yogurt containing Ingredient A, for use in strengthening bones". In this case the summary of the judgment was: Even though "yogurt containing Ingredient A, for use in strengthening bones" is an invention based on an unknown attribute that it promotes calcium absorption in bones, both "yogurt containing Ingredient A" and "yogurt containing Ingredient A, for use in strengthening bones" are used for foods. Therefore, "yogurt containing Ingredient A, for use in strengthening bones" can not be regarded as providing a new use as a food; and "yogurt containing Ingredient A, for use in strengthening bones" is regarded as lacking novelty in light of "yogurt containing Ingredient A"[18].

In the last ten years, in the USA many producers of nutraceuticals were positioning their products in the medicinal foods category. This foods category include foods that are formulated to be consumed or administered entirely under the supervision of a physician. These products are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements have been established on the basis of recognized scientific principles. Because of that, they are very convenient for patent protections.

Functional foods patents with a medicinal attribute have the international class code A61K ("preparations for medical, dental, or toilet purposes"), the others are coded with A23L ("foods..not covered by other subclasses: their preparation or treatment) or/and by chemistry classes [16].

According to Mintel's Global New products Database (GNPD), the number of patent filings per country does not correspond with the number of products on

the market which claim "functional food" status. Nearly 8.000 products categorized as functional foods were marketed in Europe started in 2002, compared to about 5.000 in the Asia Pacific, 3.500 in North America, 1.000 in Latin America and 3.500 in 500 in Africa/Middle East. Such a big number of products in Europe may be due to the fact that there are more countries in Europe that are producing functional foods. Germany, France, Spain, the UK and Netherlands have large functional food markets as compared to Hungary, Poland and Russia. In Asia, Japan alone has more than 1.700 functional products [19].

In the field of functional foods, trademarks are very important intellectual property rights for protection, identification and affirmation of the products. A trademark is " a distinctive sign or indicator used by an individual, business organization, or other legal entity to identify that the products or services to consumers with which the trademark appears originate from a unique source, and to distinguish its products or services from those of other entities"[23]. It is clear that the position of the functional foods product on the market depends on the celebrity of the trademark.

In the world, increased attention has been given in the past few years to organic foods production, based on traditional knowledge, which can be covered by intellectual property rights (IPRs). While typical IPRs (such as patents) protect new and inventive products and processes, geographical indications (Gis) don't protect novelty but the traditional knowledge and skills associated with certain products, which are typically passed down through generations, and which have a strong link with the underlying geographical territory [1, 3].

5. FUNCTIONAL FOODS IN SERBIA

On the Serbian market there are the functional foods products, mainly launched as the dairy-, confectionary-, soft-drinks-, bakery-, and baby-food products. But this market is dominated by gut products, in particular, probiotics, produced by both the multinational and domestic companies, Fig. 7. Serbian company "Imlek" has a few products, especially yogurts, which are of high quality.

Dietary supplements, which are concentrated sources of nutrients or other substances with nutritional or physiological effects and they are considered as food, can be present on the market as pharmaceutical dosage forms too. Thus, Probiotic forte capsules, producer "Ivančić and sons" and Probiotics Rosell Institute, which contain probiotic yeast *Saccharomyces boulardii* and three probiotic microorganisms (*Lactobacillus* Rosell-52; *Lactobacillus* Rosell-11; *Bifidobacterium* Rosell-175) is on the market as a dietary supplement. Probiogal forte capsules is the probiotic product of the pharmaceutical company "Galenika", protected by the Serbian patent application RS-20100436 [25],

based on two probiotic microorganisms: *Lactobacillus plantarum* and *Lactobacillus casei*.

Trade name	Description	Producer
Activia	Probiotic drinking yogurt with <i>Bifidobacterium lactis</i> R culture, DN-173010	Danone
Balans plus	Probiotic yogurt and cheese with <i>Bifidobacterium lactis</i> culture, LA5 and BB-12	Imlek
Fitt	Probiotic yogurt with coenzyme Q10 and L-carnitine	Imlek
Probiotic	Probiotic capsules with yeast <i>Saccharomyces boulardii</i> and <i>Lactobacillus Rosell-52</i> ; <i>Lactobacillus Rosell-11</i> ; <i>Bifidobacterium Rosell-175</i>	Ivancic and sons
Brobiogal	Probiotic capsules with <i>Lactobacillus plantarum</i> and <i>Lactobacillus casei</i> cultures	Galenika

Source: own investigation

Figure 7- Some commercial probiotic products on the Serbian market

There are products on the Serbian market, which include weight control, vitamin or mineral fortification, diabetes control and digestive aid. For examples: "Bambi" company's products ("Plazma" biscuit, with vitamins and minerals supplements; Wellness products); Nutrilans products with omega-3 fatty acids; "Aleva" company's natural products.

Organic products increased production and sales value, as these products became more accessible to a broad consumer group. These products involve traditional knowledge and they are convenient for protection as designation of origins or geographical indication (meat, sausages, hams, cheeses, wines, mineral waters and others).

Serbia harmonized Patent law and Medicinal Products and Medical Devices law with the EU regulation.

The Patent Law (2011) is in line with EPC, and the TRIPS Agreement, and has the exceptions of patentability related to the "methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body; plant and animal varieties and essentially biological processes for the production of plants and animals" and implements Biotechnology Directive 98/44/EC [22]. Serbian patent practice is, also, in accordance with EPO practice.

Medicinal Products and Medical Devices Law (2010) regulates the production, authorization and launching of the medicinal products to the market. [21] But, until now, there were no regulations for the categorization, production and trade of functional foods products in general and particularly of dietary supplements. Quality standards necessary to be implemented into these products legislation are: ISO 22000, Codex Alimentarius (HACCP) and Good Manufacturing

Practice (GMP). However, there are cases that the products are placed on the market without any controls.

6. CONCLUSION

Functional foods are defined as foods and food components that provide a health benefit beyond basic nutrition for the intended population. Examples may include conventional foods (fortified, enriched or enhanced foods), dietary supplements and medical foods. They can be present on the market as the dairy-, confectionary-, soft-drinks-, bakery-, baby-food products and dietary supplements. An official law-regulation for these products depends of their medicinal grade; these products belong to the food sector rather than to the pharmaceutical one. Intellectual property protection in the functional foods area is very important. Patents protection of the inventions depend (as in all fields of technology) on whether products or processes provide that they are new, involve an inventive step and are capable of industrial application. Patent Office can grant the product patent, or can protect an invention of a process and an invention of a use product. Innovations in the functional foods often have a medicinal aspect and then they are protected as medicinal use claims. Trademarks are very important in functional food products. Celebration of the trademarks is reflected on the market position of these products. Organic food products can be protected by traditional knowledge protection and designation of origins or geographical indication.

Serbia has the functional foods products on the market, produced by both multinational and domestic companies. Also, organic products increased market and sales value. Legislation is adjusted to EU regulation.

REFERENCES

1. Ammann, K., Reconciling Traditional Knowledge with Modern Agriculture, A Guide for Building Bridges, Handbook of Best Practices, Chapter 16.7, MIHR: Oxford, U.K.,2007, www.google.com
2. Jovanović, S., Reljić, M., Sikora, S., Zaštita intelektualne svojine u biotehnologiji, *Industrija*, 39(4), 2011, 209-223
3. Jovanović, S., Matović, D., Petrović, S.D., Vrednovanje intelektualne svojine, *Industrija*, 39(2),2011, 93-117
4. Jovanović, S., Patents in the pharmaceutical industry, *Chem. Ind.*,57 (3), 2003,133-137
5. King, H., Denison, Ch. (2011), Functional food patents: beware potential pitfalls, *Chemistry & Industry*, August 08. 2011, p. 15

6. Loyd, S.L., Leber, M.J., Functional Food Patents-Manufacturers Starting to Rely on Patented Technologies for Protection, 2010, www.google.com
7. Menrad, K., Market and marketing of functional food in Europe, *Journal of Food Engineering*, 56, 2003,181-188, www.elsevier.com/locate/fooding
8. Siro, I., Kapolna, E., Kapolna, B, Lugasi, A., *Appetite*, 51, 2008, 456-467, www.elsevier.com/locate/appet
9. Zeman, S.M., Zimmer, F.J., Swiss-type medical use claims: The search for harrmony, *European Biotechnology News*, EPO, 2011, www.eurobiotechnews.eu
10. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),1994,WIPO, Geneva
11. Convention on the grant of European patents, *Intellectual Property Laws and Treaties (EPC)*, 2000, EPO
12. Directive 98/44/EC
13. Functional Foods, Beyond nutrition: initiatives in functional foods, www.google.com
14. Functional foods , 2006, www.eufic.org
15. Industry Overview, *The Food&Beverage Industry in Germany*, 2011, www.gtai.com
16. International Patent Classification ,2010, WIPO, www.wipo.com
17. Invest Japan Department, Japan External Trade Organisation, *Japan's growing health-food market, market Highlights*, 2008, www.google.com
18. Managing Intellectual Property, Tap into Japan's demand for functional foods, www.managingip.com
19. Nerac Insights ,*Functional Foods, Patents and Health Claims*, 2009, www.nerac.com
20. New Zealand Trade&Enterprise, *Market Profile for Functional Foods in Japan*, 2008, www.google.com
21. Zakon o lekovima i medicinskim sredstvima, "Sl. glasnik RS", 30, 2010
22. Zakon o patentima, "Sl.glasnik RS", 99, 2011
23. Zakon o žigovima, "Sl. glasnik RS",104, 2009
24. US Patent law, 1990, www.uspto.com
25. www.zis.gov.rs

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