Zeszyty Problemowe Postępów Nauk Rolniczych
nr 595, 2018, 51–67
DOI 10.22630/ZPPNR.2018.595.35

MARKET OF FUNCTIONAL FOOD – LEGAL REGULATIONS AND DEVELOPMENT PERSPECTIVES

Józef Grochowicz[1], Anna Fabisiak[2], Dorota Nowak[3] ✉

[1] Warsaw School of Tourism and Hospitality Management, Faculty of Tourism and Hospitality Management

[2] College of Rehabilitation, Faculty of Physiotherapy, Nutrition and Emergency Medicine

[3] WULS-SGGW, Faculty of Food Sciences

Summary. The concept of functional foods was first developed in Japan in the 1980s. It is defined as the food which reduces the risk of against specified health hazards. In the European Union, the definition of functional foods was established within the framework of the European research project "Functional Food Science in Europe" (FUFOSE). In this paper, the authors presented the current legislation in the European Union and the United States. The aim of this article was to present up-to-date knowledge about functional food markers and components of functional foods, which are an important part of a healthful lifestyle and have a positive influence on human health. The following components were characterized: vitamins, minerals and trace elements; fats, fatty acids and fatty acid composition; carbohydrates; dietary fibre; prebiotics. Functional food market in the European Union was described. At the end of this paper, a new perspective of functional food studies was presented, especially the interaction of nutrients and their association with genetics.

Key words: functional foods, legislation, functional foods market, functional components

INTRODUCTION

In the course of the development of civilization and technology, the knowledge of food has evolved and is now (in the developed world) more than just a necessary factor in the maintenance of life – satisfying thirst and hunger. The demand for safe, easily acces-

Józef Grochowicz https://orcid.org/0000-0003-1539-3065; Anna Fabisiak https://orcid.org/0000-0003-4725-5679; Dorota Nowak https://orcid.org/0000-0002-5450-8294

✉ dorota_nowak@sggw.pl

sible food which enables the efficient preparation of a meal at any time and in different situations related to human activity has become the reason for the search for new methods of processing and preserving raw food materials. A significant increase in interest from consumers is associated with a change of diet and with the attachment of more and more importance to the quality of the food. This gives great opportunities to increase the attractiveness of multiple products. The impact of diet on health and well-being and the knowledge of specific food components have allowed to design healthy food, which has begun to contribute to well-being, improve health, reduce the risk of chronic diseases and obesity. It has been called "functional food" or "designed food" and is a modification of traditional food, which has a beneficial effect on health compared to non-modified products [Verchueren and Contor 2005, Corbo et al. 2014].

THE CONCEPT OF FUNCTIONAL FOODS

The concept of functional foods was first developed in Japan in the 1980s. It is defined as the food which reduces the risk of specified health hazards. This term was the result of the work program entitled "Foods For Specified Health Uses" (FOSHU) in 1991. A detailed characterization of functional foods appeared in 1998, in the document entitled "Scientific Concepts of Functional Foods in Europe" (Consensus Document) [Diplock et al. 1999]. In 1991, the Japanese Ministry of Health and Welfare launched the world's first legalization of functional foods. The first product bearing the term FOSHU was hypoallergenic rice.

In 2001, the Japanese government introduced a new system of regulating functional foods, in which a new, broader term was adopted: foods with special dietary declarations (Food with Health Claims – FHC). This food was divided into two groups:

– FNFC (Food with Nutrient Function Claims) – food which contains the additives (ingredients) of 13 vitamins, 6 minerals and folic acid. It can be processed and distributed without special registration or notification of relevant legal authorities, provided that it meets the established requirement standards.
– FOSHU – food officially approved, exerting a positive physiological effect on the human body. This food contains ingredients with health-promoting properties that are officially recognized as having physiological effects on the human body. This declaration is approved by the Minister of Health and the European Commission "Functional Food Science in Europe" (FUFOSE). In connection with such a large variety of products included in the group of functional foods, there is no legally sanctioned definition of the food in Europe. With regard to functional foods, preferably operating on human health, many often overlapping concepts apply, e.g.: Designer Foods, Agromedical Foods, Medifoods, Medical Food, Fortified Foods, Food Fitness, Wellness Food, Vitafoods, Therapeutic Food, Performance Food, Pharma Food, Nutraceutical [Ashwell 2002].

In the European Union, the definition of functional foods was established within the framework of the European research project "Functional Food Science in Europe" (FUFOSE). According to the aforementioned definition, food may be considered to be functional if what is proven is its beneficial effect on one or more functions of the organism beyond its nutritional effect, whose end result is to improve the health and well-

-being and/or to reduce the risk of diseases. Functional foods must resemble conventional food forms and show their beneficial effects on the overall intake of part of the daily diet in amounts which are expected to be normally consumed with the diet – not as tablets or capsules, but part of a normal diet, if it contains one or more components that are not nutrients, the operation of which causes a selective and positive effect with regard to the specific functions of the human body [Arvanitoyannis and Houwelingen-Koukaliaroglou 2005]. According to the "Healthy Eating Concept", functional foods, called physiological functional foods, have biochemical and physiological properties. The increased health quality of these foods is mainly due to the presence in their composition of bioactive substances that stimulate the desired course of the metabolism and possess physiologically optimal proportions of individual components. According to U.S. National Institutes of Health, functional food is enriched or modified, which in addition to providing nutrients can have a beneficial effect on health [Berner and O'Donnell 1998]. However, according to the International Life Science Institute (ILSI), functional food is food that due to its physiologically active ingredients makes it possible to provide health benefits, regardless of their function, i.e. proper nutrition [Corbo et al. 2014].

Another definition was adopted by the U.S. Council of Food and Nutrition. According to them, functional food is food modified or any component thereof to provide greater health benefits [Thomson et al. 1999]. Functional food is also called food planned for specific needs of the body (designer foods, tailored foods). It may be in a traditional or technologically modified form. Food designed in the traditional form is generally produced by conventional methods. The concept of functional foods is a marketing concept. In addition to all aspects of health, nutritional functional food is a product which in addition to recipes (R&D), the declaration of nutrition identifying the benefits of health, nutrition and marketing has two more important elements: branding and profit, because they are the driving force behind all activities related to the introduction of new products and new categories [Bradford 2016]. Difficulties in creating legal regulations for this group of food have diverse reasons. Legal regulations for food producers are related to compliance with the requirements to enter the functional food market. Due to the lack of a legal definition of food, the variety of terms is the result of different divisions. On account of its specific composition, food can be grouped into: enriched, low-energy, probiotic, reduced sodium or cholesterol, energizing food. Whereas, on account of satisfying the specific needs of the body, food can be divided into the following groups: reducing the risk of cardiovascular diseases, cancers, osteoporosis, for individuals coping with stress, inhibiting aging, diets for people with impaired metabolism and digestion, and influencing mood and psychomotor performance [Corbo et al. 2014].

A detailed and interesting classification of functional foods, nutraceuticals, biofortified foods and cosmetics has been proposed lately [Syngai et al. 2016, Alamgir 2017, Banerjee 2017]. Nutraceuticals are medicinal foods, nutritional supplements, dietary supplements, or food components made from herbal or botanical raw materials that can deliver health benefits beyond basic nutrition, modulate immunity, and/or prevent and cure specific diseases and increase life expectancy [Alamgir 2017].

Nutraceuticals are classified as traditional or natural nutraceuticals (e.g. nutrients, herbals, phytochemicals, probiotic microorganisms, nutraceutical enzymes) and non-traditional or artificial nutraceuticals (e.g. fortified and recombinant nutraceuticals). They

may have a form of herbal products, biofortified crops, genetically modified or processed food products.

Functional foods today have two meanings. The first one includes foods with proven health-promoting properties, and the second one has a very broad meaning, including products that contain or are fortified with health-promoting ingredients. Currently, defining functional foods with a health-related function is a result of a marketing strategy. In functional foods, in addition to food for special purposes, we can include healthy foods, dietary supplements, BFY (Better for You) food, organic food and natural food. However, only fortified foods in terms of health ingredients and foods for particular nutritional uses are laid down by law.

The last years have brought new knowledge on some plants and products containing bioactive components. Amongst them are:

- argan oil that contains squalene and tocopherols suggesting potential preventing hypocholesterolema, obesity and characterised by anticancer activity [Guillaume and Charrouf 2016];
- cactus pear, that could provide protective effect such as anticancer, antiviral, anti-inflammatory, anti-diabetic, neurological and cardiovascular actions [Gupta 2012];
- seaweeds, which depending on species, can provide a range of different functional properties. Generally activities such as anticancer, anti-inflammatory, antioxidant, antiviral and stimulation of the immune system are proposed [Holdt and Kraan 2011, Bellou et al. 2014];
- grape seeds – recently their activity against cancer, high blood pressure, the Alzheimer's disease, diabetes, retinopathy and vascular fragility has been discovered [Patel 2015a];
- vacon, which is an Andean tuberous root that contains fructooligosaccharides (FOS), inulin and phenolic compounds; FOS and inulin as probiotics improve the growth of bifidobacteria, enhance mineral absorption, gastrointestinal metabolism, regulation of cholesterol, the work of the immune system, resistance to infections and allergy [Choque Delgado et al. 2013];
- lotus root fermented sugar syrup, which was reported in a research centre that was aimed to explore the physicochemical, nutritional and microbiological properties of lotus root fermented sugar syrup as a source for human health benefits [Shukla et al. 2017];
- chia seed which is an emerging plant material containing dietary fiber, proteins, ω-3 fatty acids, antioxidants, vitamins and essential minerals, and has antidiabetic and anticancer properties [Patel 2015b].

LEGISLATION IN THE EUROPEAN UNION AND POLAND

The development of food production has become the reason for the introduction of regulations on food quality and safety, regardless of its formation and processing. One of the main priorities of the European Union (EU) is to provide food safety (Act of 25 August 2006 on food and nutrition safety). General rules for additives which have been positively evaluated by the Food and Agriculture Organization of the United

Nations (FAO) and the World Health Organization (WHO) are contained in the "Codex Alimentarius". The effect of diet on many diseases, including the illnesses of the cardiovascular system, was included in the project of the European Community (FUSFOSE). However, the European Commission, in 2002, drafted the control of food regulations, health requirements and functional SANCO 1832/2002 [EU Commission DG SANCO 2002]. There is also a regulation introduced on nutrition and health claims made on foods (Regulation (EC) 1924/2006).

In the European Union, it is necessary in each case to confirm a beneficial nutritional or physiological substance on which the health claims can be made by the European Union only after a scientific evaluation is carried out each time by the European Food Safety Authority (EFSA) [Aggett et al. 2005]. In the European Union and in Poland currently there are no regulations on functional foods. In the European Union functional food can be classified in accordance with the Regulation (EC) 258/97 concerning novel foods and novel food ingredients. There is also a regulation introduced on nutrition and health claims made on foods Regulation (EC) 1924/2006.

In Poland, however, under the existing laws there are a number of regulations on food safety and nutrition, which also form the basis for regulating production and distribution of functional foods. Among a large group of regulations is the Act of 25 August 2006 on food safety and nutrition, Regulation of the Minister of Health of 16 September 2010 on substances added to food, Regulation (EC) 258/97, Regulation (EC) 1924/2006 [Błaszczak and Grześkiewicz 2014].

LEGISLATION IN THE US

In the United States until the 1980s, a general ban was enforced on food labels with reference to the relationship of food to the reduction of disease risk. This prohibition resulted from the position adopted by the US Food and Drug Administration (FDA) that any statement suggesting that the consumption of food can prevent disease, qualifies the substance as a drug and is prohibited until the appropriate procedure provided for the approval of drugs is performed [EFSA 2011a].

The first act regulating in a comprehensive manner the conditions for admission to the market of nutrition and health claims on food products was the Nutrition Labeling and Education Act of 1990 (NLEA). According to the act on the labeling and advertising of foodstuffs, only nutrition and health claims which have been approved or regulated by the FDA and regulations contained in the code of Federal Regulation (CFR) may be used.

These nutrition and health claims may be approved by the FDA if the credibility of the statements (significant scientific agreement standard) is supported by scientific research of the unit. The NLEA also established procedures for the creation of adequate regulation by the FDA, both in relation to nutrition and health. Not only food manufacturers can apply for these statements but also organizations promoting a healthy diet, protecting the rights of consumers as well as consumers themselves. The amendment of existing food regulations, the Drug and Cosmetic Act was the result of the new approval of procedures for nutrition and health, included in the Food and Drug Administration Modernization Act (FDAMA). Another group of claims in the US legal system are the statements

(structure/ function claims) which do not refer to diseases, but describe the impact that a particular substance has on the structure or function of the body or general well-being. This category includes statements that indicate the work component mechanism in maintaining the structure and function of the body (e.g. calcium helps build strong bones). These statements do not require the FDA authorization. It is required only that they are true and do not cause confusion. Additional requirements were defined only in relation to food supplements. They concern the procedure for market introduction and labeling [Arai 1996, EFSA 2011c].

According to the studies mentioned in the Functional Foods Report [2014], in the future particular attention should be paid to the labeling of functional foods, in order to ensure the effectiveness of information provided to consumers. Forecasts for chronic diseases (type 2 diabetes) can be a good investment for the functional food market.

MARKERS OF FUNCTIONAL FOODS

Roberfroid stresses that the measurements of "functional foods markers" are the main element of the discovery and development of new functional foods. In this context, the author points out that these markers will be predictors of the value of potential functional food benefits. It is important that the functional food markers should be specific, valid, feasible, reproducible and sensitive. It will be perfect if these factors are biochemical, physiological or psychological in nature [Roberfroid 2002]. These markers should relate to:

- exposure to the food component under study by measuring the biological material (such as serum, faecal, urine or tissue level) in context of the food component itself or its metabolite(s);
- target function(s) or biological response, such as the change in serum or other body fluids;
- an appropriate endpoint of an improved state of well-being and health and/or reduction of a disease risk such as cardiovascular diseases, overweight/obesity, dyslipidaemia, hypertension, type 2 diabetes, osteoporosis and dental caries;
- individual susceptibility or genetic polymorphism controlling the metabolism and/or the effect of the food component.

Functional food has been benefited in various ways such as: β-carotene, lutein, lycopene, fatty acid, soy protein, probiotics and vitamins (Table 1).

Table 1. Classification of functional components [Jitendra and Amit 2015]

Tabela 1. Klasyfikacja składników funkcjonalnych [Jitendra i Amit 2015]

Name Nazwa	Functional components Składnik funkcjonalny	Function – Funkcja
Carotenoids Karotenoidy	β-carotene β-karoten	neutralizes free radicals, which may damage cells neutralizuje wolne rodniki, które mogą uszkadzać komórki
	lutein, zeaxanthin luteina, zeaksantyna	may contribute to maintenance of healthy vision może przyczynić się do utrzymania prawidłowego wzroku
	lycopene likopen	may contribute to maintenance of prostate health może przyczynić się do prawidłowej pracy prostaty

cont. Table 1
cd. tabeli 1

Fibre Błonnik	soluble fiber rozpuszczalny błonnik	may contribute to maintenance of a healthy digestive tract może przyczynić się do prawidłowej pracy przewodu pokarmowego
	insoluble fiber nierozpuszczalny błonnik	may reduce risk of coronary heart disease (CHD) and some types of cancer może zmniejszyć ryzyko choroby wieńcowej i niektórych rodzajów raka
	β-glucan β-glukan	may reduce risk of CHD może zmniejszyć ryzyko choroby wieńcowej
	whole grains pełne ziarna	may contribute to maintenance of healthy blood glucose levels mogą przyczynić się do utrzymania zdrowych poziomów glukozy we krwi
Fatty acid Kwas tłuszczowy	ω-3 fatty acids kwasy tłuszczowe ω-3	may contribute to maintenance of mental and visual function mogą przyczyniać się do prawidłowego funkcjonowania umysłu i wzroku
Flavonoids Flawoidy		neutralize free radicals, which may damage cells; bolster cellular antioxidant defences neutralizują wolne rodniki, które mogą uszkadzać komórki; wzmacniają antyoksydacyjne mechanizmy obronne komórki
Probiotics Probiotyki		may improve gastrointestinal health mogą przywrócić prawidłową pracę przewodu pokarmowego
Vitamins Witaminy		may contribute to maintenance of healthy vision, immune function, and bone health mogą przyczynić się do utrzymania prawidłowego wzroku, funkcji układu odpornościowego i zdrowia kości
Soy protein Białko sojowe		may reduce the risk of cardiovascular disease może zmniejszyć ryzyko choroby sercowo-naczyniowej

COMPONENTS OF FUNCTIONAL FOODS

There are a lot of food components which are an important part of a healthful lifestyle and have a positive influence on human health. Currently, there are about 385 functional food products on the European market[1], which contain about 503 different "functional" ingredients. It should be noted that this list is very incomplete. According to the report "Functional Food in the European Union" [Stein and Rodriguez-Cerezo 2008], there are about 168 companies on the EU market which have at least one functional food product. A significant majority of these companies are in Germany, the UK and Spain. The Netherlands, France, Italy, Austria, Finland, Belgium, Denmark and other European countries play an important role on the market of functional food products too. It should be stressed that a global market volume in foods of EUR 23,490 million includes EUR 1,270 million worth of functional food products [Özen et al. 2014]. According to this popularity of

[1] The European market includes both the EU Member States and other European countries.

functional food products, there have been attempts to prepare the classification of their main components. For example, Pravst [2012] stresses that all components of functional foods could be divided into five groups, such as: vitamins, minerals and trace elements; fats, fatty acids and fatty acid composition; carbohydrates and dietary fibre; prebiotics and others. According to the report "Functional Food in the European Union" [2008], the most popular ingredients of functional foods are: bacteria cultures (mostly probiotics) – about 173 products contained them; saccharides (mostly prebiotics) – about 78 products contained these ingredients; plant extracts (in 53 products); terpenes (in 41 products); miscellaneous (in 37 products); fibres (in 35 products); phenols (in 33 products); peptides (in 30 products); lipids (in 23 products).

According to the Global Analysis Report [Acheson 2016], functional foods in 2015 accounted for three main segments: dairy, confectionery and bakery products. While functional foods as a whole have been gaining popularity, the most significant segment has been the dairy segment. Its main subcategory, probiotic dairy-based yogurt, is expected to increase 19.7% in retail value from 2016 to 2020. Although retail sales of functional beverages have been stagnant over the past five years, it is anticipated that these products will see growth during the forecast period (2016–2020), particularly the energy drinks subcategory, which is expected to increase 20% in retail value from 2016 to 2020. The dairy segment is expected to continue to develop, growing 14% by 2020. The fruit and vegetable juices segment is expected to continue increasing throughout the forecast period (2016–2020), but at a slower compound annual growth rate of 2% (www.agr.ca). According to the report "Functional Foods and Beverages", a growing body of research points to dairy's key role in sports nutrition, and these ingredients can help provide digestible, high-quality protein for building and repairing muscle, carbohydrates for energy, and vitamins and minerals to strengthen bones and replace electrolytes [Natural Products Insider 2014]. Schouw Andersen particularly called dairy proteins flagship ingredients in the functional sector [Schouw Andersen 2017]. In particular, he said that protein offers benefits that cut across all generations – from consumers in their teens to people in the later stages of their lives.

The 2013 "Food & Health Survey" carried out by the International Food Information Council looked at consumer attitudes towards food safety, nutrition, and health. The survey found that "taste" was the most important factor impacting consumers in their food and beverage choices (89%). This was followed by "price", with "healthfulness" ranking as the third most important factor. The respondents in Europe attach great importance to the attributes associated with the information on the label concerning the freshness of the product and information on its healthful properties and nutritional value. Buyers expect products with a pleasant taste. Consumers show the greatest interest in the attributes associated with the strengthening of the immune system and preventing certain cancers [Kraus 2015].

VITAMINS, MINERALS AND TRACE ELEMENTS

The first group of vitamins and minerals which have the properties of functional foods are antioxidants. There are a lot of studies which emphasize that antioxidants are indeed included in the antioxidant defence system of the human body, the protection of DNA, and proteins and lipids from oxidative damage [Bjelakovic et al. 2008]. The most known

antioxidants are vitamin C, vitamin E, riboflavin, copper (Cu), manganese (Mn) and selenium (Se). A positive influence on the immune system was also recognised for various vitamins (such as vitamins A, D, B6, B12, C and folate), copper (Cu), and selenium (Se) [EFSA 2009, EFS 2010]. Currently, many researchers have analysed the relationship between the brain or nervous system function and some vitamins on the one hand, and minerals on the other hand. The current evidence supports that some vitamins (such as thiamine, riboflavin, niacin, pantothenate, vitamin B6, Folate, vitamin B12, biotin and vitamin C) as well as minerals, such as: copper (Cu), iron (Fe), iodine (I), potassium (K), magnesium (Mg) and zinc (Zn), positively affect the nervous system [EFSA 2010]. The effect of nutrition on bone health is well established. Positive influence on the function of bone or teeth has been noted for magnesium (Mg), zinc (Zn), manganese (Mn), potassium (K), copper (Cu) and phosphorus (P) as well as vitamins D and K.

There are some studies which point out that some nutrients have a positive effect on the function of skin, hair or connective tissues. These are vitamins (such as vitamin A, riboflavin, niacin, biotin) and minerals, such as: copper (Cu), iodine (I), selenium (Se), and zinc (Zn) [EFSA 2010]. There is some evidence which has shown that vitamin A, riboflavin, and zinc (Zn) have a positive influence on the function of vision [EFSA 2010]. The muscle weakness is associated with vitamin D deficiency, because this vitamin is necessary in the maintenance of normal muscle function. Dietary intake of calcium (Ca), magnesium (Mg), potassium (K) and copper (Cu) was also connected with muscle function. Some studies have shown that several nutrients have received positive reviews for their function in blood, especially formation of haemoglobin and oxygen transport. The most common components of functional foods in this case are vitamins (vitamin A, vitamin K, riboflavin, vitamin B6, folate, vitamin B12, vitamin C) and some minerals, such as: calcium (Ca), copper (Cu) and iron (Fe) [EFSA 2010].

Other specific functions of vitamins and minerals are: participation in the evaluation process, such as a role in cell division and differentiation, regulation of hormones and metabolism of nutrients. Additionally, there are some vitamins which play an important role in the regulation of hormones, especially pantothenic acid and vitamin B6. In addition to these vitamins, there are some important minerals such as iodine (I), selenium (Se), and zinc (Zn). The researchers also point out that some nutrients are important in the context of their function in metabolism of nutrients, for example homocysteine metabolism and normal lipid metabolism. In this context, the most important vitamins are: thiamine, riboflavin, niacin, pantothenate, vitamin B6, vitamin B12, biotin, vitamin C, and some minerals such as calcium (Ca), iron (Fe), magnesium (Mg), zinc (Zn), iodine (I), copper (Cu), potassium (K), chromium (Cr), molybdenum (Mo), and manganese (Mn) [EFSA 2011a, c].

FATS, FATTY ACIDS AND FATTY ACID COMPOSITION

Fats are a major source of total energy intake in human diets. Two fatty acids, linoleic acid and alpha-linolenic acid, are particularly important in the human diet, because these two acids cannot be synthesised in mammalian tissues. There are some studies which point out that linoleic acid and alpha-linolenic acid have a positive influence on management of cholesterol. The role of these two acids in cholesterol management have received

positive reviews. The best effect is observed where a food contains at least 15% of the proposed labelling reference intake. Another very important nutrient are plant sterols, which are also important in cholesterol management. There is some recommendation that the consumption of about 0.8 g plant sterols per day has a positive health effect. Most studies concerning cholesterol have shown that a daily intake of 1.5–2.4 g plant sterols/ /stanols could lower blood cholesterol and reduce a risk of coronary heart disease. It should be stressed that some studies have demonstrated the beneficial health effects of preformed n-3 long-chain polyunsaturated fatty acids (DHA – docosahexaenoic acid, EPA – eicosapentaenoic acid), especially in the context of cardiovascular risk factors, such as a reduction in plasma triacylglycerol concentrations and blood pressure [EFSA 2011b]. The proposed daily dose for the management of blood triglycerides and the management of blood pressure is 2–4 g of DHA and 3 g of EPA. Most studies have shown that a daily intake of 250 mg DHA/EPA has a positive influence on normal cardiac function, normal vision and brain function [EFSA 2011a].

CARBOHYDRATES

Glycaemic carbohydrates are the most common components of functional foods. These ingredients are digested and absorbed in the human small intestine. Glycaemic carbohydrates provide glucose to body cells. The clinical studies point out that an intake of 130 g of dietary glycaemic carbohydrates per day for adults is estimated to cover the glucose requirement of the brain. There is a cause-and-effect relationship between the consumption of glycaemic carbohydrates and the maintenance of normal brain function [EFSA 2011a]. Some studies have shown that sugar replacement in foods (such as xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose or polydextrose) has a positive effect on the reduction of post-prandial blood glucose responses [EFSA 2011b].

DIETARY FIBRE

There are some studies which stress that water-soluble dietary fibre has beneficial health effects. This type of fibre has the ability to improve viscosity of the meal bolus in the small intestine on the one hand and delay the absorption of nutrients on the other hand. Scientists also emphasize the important role of fibre in cholesterol management, especially beta-glucans, chitosan, glucomannan, hydroxypropyl methylcellulose (HPMC), pectins and guar gum, which reduce blood cholesterol. This effect is achieved by a daily intake of 3 g of chitosan per day, 4 g of glucomannan per day, 3 g of beta-glucans per day, 5 g of HPMC per day, 6 g of pectins per day, and 10 g of Guar gum per day. But some fractions of fibers are involved in the management of glycaemic response such as beta glucans, hydroxypropyl methylcellulose, pectins, arabinoxylan, and resistant starch. Dietary fibres, both water-soluble and water-insoluble dietary fibres, are known to support gut health. It is associated with changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools [EFSA 2011b].

PREBIOTICS

A lot of studies have shown that an intake of prebiotics could modulate the colonic microbiota. It is associated with an increase in the number of specific bacteria on the one hand and the change in the composition of the colonic microbiota on the other hand. Al--Sheraji et al. [2013] prepared a publication about prebiotics as functional foods. In this publication, the authors presented some prebiotics which have a beneficial health effect such as acute gastroenteritis, reduction of cancer risk, increased mineral absorption, and lipid regulation. The most common prebiotics are: Fructooligosaccharides, Isomaltulose, Xylooligosaccharides, Galactooligosaccharides, Cyclodextrins, Raffinose oligosaccharides, Soybean oligosaccharide, Lactulose, Lactosucrose, Isomaltulose, Palatinose, Maltooligosaccharides, Isomaltooligosaccharides, Arabinoxylooligosaccharides, and Enzyme--resistant dextrin.

FUNCTIONAL FOOD PRODUCTS

Functional foods have been developed in virtually all food categories. The functional property can be included in numerous different ways as it can be seen in Table 2.

These products have been mainly launched on the dairy, confectionery, soft drinks, bakery and baby-food market. The most prominent types of functional products are: baby

Table 2. Prominent types of functional food [Siró et al. 2008]

Tabela 2. Główne rodzaje żywności funkcjonalnej [Siró i in. 2008]

Type of functional food Typ żywności funkcjonalnej	Definition – Definicja	Example – Przykład
Fortified products Produkty wzmocnione	A food fortified with additional nutrients Potrawy wzbogacone o dodatkowe składniki odżywcze	Fruit juices fortified with vitamin C Sok wzbogacony witaminą C
Enriched products Produkty wzbogacone	A food with added new nutrients or components not normally found in a particular food Żywność z dodatkiem nowych składników odżywczych lub składników, które normalnie nie występują w danym pożywieniu	Margarine with plant sterol ester, probiotics, prebiotics Margaryna z estrem sterolu roślinnego, probiotykami, prebiotykami
Altered products Produkty zmodyfikowane	A food from which a deleterious component has been removed, reduced or replaced with another substance with beneficial effects Żywność, z której usunięto szkodliwy składnik, zredukowano go lub zastąpiono inną substancją o korzystnych skutkach	Fibers as fat releasers in meat or ice cream products Błonnik jako środek uwalniający tłuszcze w produktach mięsnych lub mrożonych
Enhanced commodities Ulepszone towary	A food in which one of the components has been naturally enhanced through special growing conditions, new feed composition, genetic manipulation, or otherwise Żywność, w której jeden ze składników został naturalnie wzmocniony poprzez specjalne warunki wzrostu, nową kompozycję paszy, manipulację genetyczną lub w inny sposób	Eggs with increased ω-3 content achieved by altered chicken feed Jaja o zwiększonej zawartości ω-3 uzyskane przez zmieniony pokarm dla kurcząt

food, bakery products (biscuits, breakfast cereals), confectionery (sugar confectionery, medicated confectionery), dairy products (flavoured milk drinks, fromage frais and quark, milk, yogurt, spoonable yogurt), functional spreadable oils and fats, vegetable and seed oil, soup, snack bars, energy and nutrition bars [Siró et al. 2008].

THE EUROPEAN UNION AND THE FUNCTIONAL FOOD MARKET

Projects related to the functional foods can be carried out in Europe in the framework of Horizon 2020 and Norway Research Council (the Norway Grants and EEA Grants, Norway). Horizon 2020 is the biggest EU Research and Innovation programme ever with nearly EUR 80 billion of funding available over 7 years (2014–2020). Norway Research Council coordinates the Norwegian participation in research cooperation programmes with other European countries.

The European Union plays a main role in public research funding in the context of functional foods, for example, Co-operative Research (CRAFT) and Collective Research for Small and Medium-sized Firms, specific support actions like the Functional Food Net (FFNet), Specific Targeted Research Projects (STREPs), and Specific Support Actions (SSA). It should be stressed that the number of research related to functional food has risen significantly in Europe. The EU has also increased the budget of these projects. The EU research funding of functional food projects was implemented in 6th FP: Food quality and safety (total budget EUR 753 million); 5th FP: Key Action 1 Food, nutrition and health (total budget EUR 204 million); 4th FP: Agriculture and fisheries incl. agro-industry – FAIR (total budget EUR 110 million); 3rd FP: Agro-industrial research – AIR (total budget EUR 62 million) and 2nd FP: Food-linked agro-industrial research – FLAIR (total budget EUR 25 million). There are also some national funding programmes in Ireland, Germany, the United Kingdom, Poland and France, under which functional food projects might receive funding [Stein and Rodriguez-Cerezo 2008]. For example, the project entitled "Innovative functional foods based on sweet lupin protein for cardiovascular prevention" (LUPICARP; Project reference: 285819) was implemented by a research team from Italy. The aim of this project was to assess the health benefits on dislipidemia prevention of innovative food products based on lupin proteins, starting from some preliminary results provided by two past European collaborative projects (Healthy-Profood & Bioprofibre). Another project entitled "Improving Research Capacity of TUBITAK MRC Food Institute on Functional Foods, Nutraceuticals, and Natural Health Products" (NUTRAHEALTH; Project reference: 316012) was coordinated in Turkey. The aim of this project was:

– to improve research capacity of existing functional foods, nutraceuticals, and NHP research laboratory (herein referred to as the Nutra HEALTH) within Food Institute,
– to coordinate networking and co-operative activities in this fostering field through a number of scientific and technical events,
– to integrate FP7 projects.

In Spain, the project entitled "Development and human validation of new healthier food products using low-cost functional ingredients" (FOFIND; Project reference: 315349) was realized. The aim of the FOFIND project was the development of new affordable daily consumed functional foods (biscuits, breads and juices) and nutritional supplements, using innovative low cost functional ingredients derived from milk and potato fibre. These new products will be intended for population with specific nutritional needs that cause hypertension, hypercholesterol, osteoporosis, anemia and bowel problems. Another interesting research project about functional food was the MARIFUNC – an acronym for the Nordic Network for Marine Functional Food, which was realized by 15 partners from industry environments and research institutions in Finland, Sweden, Denmark, Iceland and Norway. The aim of this project was the development of foods which are healthier because they have been fortified with health-promoting ingredients. The project is financed by the Nordic Innovation Centre. Currently, the EU PROJECT PATHWAY-27 is realized entitled "Pivotal Assessment of the Effects of Bioactives on the Health and Wellbeing, From Human Genome to Food Industry", which includes 25 partners from Europe. The EU Consortium consists of different organisation types, namely: universities, research institutes and SMEs. The PATHWAY-27 project sets out to tackle the diverse scientific understanding of the role and mechanisms of bioactive compounds in influencing human health.

THE NEW US PERSPECTIVE ON FUNCTIONAL FOODS

It should be stressed that the US perspective on functional food studies is focused on two main research areas. Firstly, bioactive components of functional foods as health promoters [Reynolds and Martirosyan 2016]. Secondly, the interaction of nutrients and their association with genetics (the so-called nutrigenomics approaches to functional foods). These approaches to functional foods are especially important, because current research in the field of medicine and nutrition has shown that some nutrients may have a key role in the gene expression of some diseases. For example, there are some studies which suggest a role for carotenoids in the gene expression of obesity [Bonet et al. 2016].

It should be noted that some researchers suggest that there is the inter-individual variability in responses to some bioactive components of food, and it has a genetic basis. Therefore, the knowledge of the individual's genetic constitution may allow for an individual tailoring of dietary advice for the use of food products [De Caterina and El-Sohemy 2016]. Not only are there studies which analyse the relationship between functional foods and the genome in the context of health and disease, but also there are studies which want to develop new foods, for example crops. In this context, there are two main American projects which involve providing genetic, genomic, and bioinformatic tools, information, and genetic resources for developing new food crops and which are improving the nutritional quality and health-promoting properties of food crops. These are: the National Program (NP) 301 "Plant Genetic Resources, Genomics, and Genetic Improvement", and the National Program (NP) 302 "Plant Biological and Molecular Processes" [Kochian

et al. 2015]. The National Program 301 supports research that expands, maintains, and protects genetic resource base, and broadens the knowledge of plant genes, genomes, and biological and molecular processes. Through novel tools and approaches, it manages and delivers vast amounts of genetic, molecular, biological, and phenotypic information.

CONCLUSIONS

Functional foods are becoming increasingly popular in both the United States and the European Union. Nevertheless, the lack of the definition of functional foods causes the image of this food to be inconsistent in consumer perception. Nowadays, functional foods are used in the prevention of diet-related diseases such as diabetes, cardiovascular disease, certain cancers, obesity. For this reason, the advantages of functional foods create new developments. In this context, studies which analyse the relationship between functional foods and the genome are a new research area.

Consequently, there is a need to develop uniform research and analysis methods to assess the health benefits of functional foods. An important aspect is also standardizing terminology and legal regulations concerning this food. It is noted that the development of reliable and valid biomarkers of functional foods is an important aspect of functional food studies. It is also worth noting that comprehensive themes for functional foods and a variety of studies tend to create a future base serving further development of this subject.

Acknowledgements
Paper prepared with support of Warsaw School of Tourism and Hospitality Management – Szkoła Główna Turystyki i Rekreacji (SGTiR) (project 217906/E/S/217).

REFERENCES

Acheson J., 2016. Functional foods and beverages in Japan. Agriculture and Agri-Food Canada. Retrieved from: http://www.agr.gc.ca/resources/prod/Internet-Internet/MISB-DGSIM/ATS-SEA/PDF/6739-eng.pdf [accessed: 10.01.2019].

Aggett P.J., Antoine J.M., Asp N.G., Bellisle F., Contor L. et al., 2005. PASSCLAIM –Consensus on criteria. Eur. J. Clin. Nutr. 44, 5–30.

Alamgir A.N.M., 2017. Classification of Drugs, Nutraceuticals, Functional Food, and Cosmeceuticals; Proteins, Peptides and Enzymes as Drugs. In: Therapeutic Use of Medicinal Plants and Their Extracts. Vol. 1. Progress in Drug Research 73. Springer International Publishing AG.

Al-Sheraji S., Ismail A., Manap N., Shuhaimi M., Yusuf R., Hassan F., 2013. Prebiotics as functional foods: A review. J. Funct. Foods 5 (4), 1542–1553.

Arai S., 1996. Studies on functional foods in Japan. Review. Biosci. Biotechnol. Biochem. 60, 9–15.

Arvanitoyannis I.S., Houwelingen-Koukaliaroglou M., 2005. Functional foods: A survey of health claims, pros and cons, and current legislation. Crit. Rev. Food Sci. Nutr. 5, 385–404.

Ashwell M., 2002. Concepts of functional foods. ILSI, Brussels.
Banerjee E.R., 2017. Nutraceuticals – Prophylactic and Therapeutic Role of Functional Food in Health. In: Perspectives in Translational Research in Life Sciences and Biomedicine. Springer Nature, Singapore.
Bellou S., Baeshen M.N., Elazzazy A.M., Aggeli D., Sayegh F., Aggelis G., 2014. Microalgal lipids biochemistry and biotechnological perspectives. Biotechnol. Adv. 32, 8, 1476–1493.
Berner L.A., O'Donell J.A., 1998. Functional foods and health claims legislation: application to dairy foods. Int. Dairy J. 8, 355–362.
Bjelakovic G., Nikolova D., Gluud L.L., Simonetti R.G., Gluud C., 2008. Antioxidant supplements for prevention of mortality in healthy participants and patients with various diseases. Cochrane Database Systematic Rev. 2. Art. CD007176.
Błaszczak A., Grześkiewicz W., 2014. Żywność funkcjonalna – szansa czy zagrożenie dla zdrowia? Medycyna Ogólna i Nauki o Zdrowiu 20, 214–221.
Bonet M.L., Canas J., Ribot J., Palou A., 2016. Carotenoids in Adipose Tissue Biology and Obesity. Sub-cell. Biochem. 79, 377–414.
Bradford B., 2016. Benefit Claims of Functional Food. In: F. Hock (ed.), Drug Discovery and Evaluation: Pharmacological Assays. Springer International, Basel.
Choque Delgado G.T., Pastore G.M., da Silva Cunha Tamashiro W.M., Maróstica Junior M.R., 2013. Yacon (*Smallanthus sonchifolius*): A Functional Food. Plant Foods Hum. Nutr. 68, 222–228.
Corbo M.R. et al., 2014. Functional beverages: the emerging side of functional foods commercial trends research and health implications. Compr. Rev. Food Sci. Food Saf. 13, 1192––1206.
De Caterina R., El-Sohemy A., 2016. Moving towards Specific Nutrigenetic Recommendation Algorithms: Caffeine, Genetic Variation and Cardiovascular Risk. J. Nutrigenet Nutrigenomics 29, 9 (2–4), 106–115.
Diplock A.T. et al., 1999. Scientific Concepts of Functional Foods in Europe (Consensus Document). Brit. J. Nutr. 81 (1), 1–27.
EFSA, 2009. Guidance of the Scientific Committee on use of the benchmark dose approach in risk assessment. EFSA Journal 7, 1150.
EFSA, 2010. Scientific opinion on establishing food-based dietary guidelines EFSA Journal 2010, 8, 3, 1460.
EFSA, 2011a. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal 9, 4, 2135.
EFSA, 2011b. Guidance on the scientific requirements for health claims related to gut and immune function. EFSA Journal 9, 4, 1984.
EFSA, 2011c. Scientific and technical guidance for the preparation and presentation of an application for authorization of a health claim (revision 1). EFSA Journal 9, 5, 2170.
EU Commission DG SANCO, 2002. Draft proposal for regulation of the European Parliament and of the Council on nutrition, functional and health claims made on foods. Working document 1832/2002.
Guillaume D., Charrouf Z., 2016. Functional Food and Sustainable Development Once Met in the Argan Forest: The Tale of the Argan Oil. In: K. Kristbergsson, S. Ötles (eds.), Functional Properties of Traditional Foods, Integrating Food. Science and Engineering Knowledge Into the Food Chain). Springer Science + Business Media, New York
Gupta R.C., 2012. A Wonder Plant; Cactus Pear: Emerging Nutraceutical and Functional Food. In: M.M. Srivastava M.M., L.D. Khemani, S. Srivastava (eds.), Chemistry of Phytopotentials: Health, Energy and Environ-mental Perspectives. Springer, Berlin–Heidelberg.

Holdt S.L., Kraan S., 2011. Bioactive compounds in seaweed: functional food applications and legislation. J. Appl. Phycol. 23, 543–597.
Jitendra K., Amit P., 2015. An overview of prospective study on functional food. Int. J. Sci. Res. 7, 5497–5500.
Kochian L., Ort D., Vance C., 2015. National Program 302: Plant Biological and Molecular Processes – the last 5 years. Retrieved from: https://slideplayer.com/slide/4791682/ [accessed 02.11.2018].
Kraus A., 2015. Development of functional food with the participation of the consumer. Motivators for consumption of functional products. Int. J. Consum. Stud. 39, 2–11.
National Program 301. Plant Genetic Resources, Genomics, and Genetic Improvement, FY 2015 Annual Report. Retrieved from: https://www.ars.usda.gov/ARSUserFiles/np301/NP%20301%20-%20Annual%20Report%20FY15%20-%20FINAL.pdf [accessed 02.11.2018].
Natural Product Insider, 2014. Functional Foods and Beverages.
Özen A., Bibiloni M.M. et al., 2014. Consumption of functional foods in Europe: a systematic review. Nutr. Hosp. 29 (3), 470–478.
Patel S., 2015a. Grape Seeds: Agro-Industrial Waste with Vast Functional Food Potential. In: Emerging Bioresources with Nutraceutical and Pharmaceutical Prospects, Applied Environmental Science and Engineering for a Sustainable Future. Springer International, Basel.
Patel S., 2015b. Newest and Robust Entrant to the Functional Food Sector: Chia Seeds. Emerging Bioresources with Nutraceutical and Pharmaceutical Prospects, Applied Environmental Science and Engineering for a Sustainable Future. Springer, Basel.
Pravst I., 2012. Functional Foods in Europe: A Focus on Health Claims, Scientific, Health and Scientific Concepts of Functional Foods in Europe. Consensus Document. Br. J. Nutr. 81, 1–27.
Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 043 of 14.02.1997, pp. 0001––0006.
Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404 of 30.12.2006, p. 9.
Reynolds T., Martirosyan D.M., 2016. Nutrition by design: a review of biotechnology in functional food of plant origin. Funct. Food Health Dis. 6 (2), 110–120.
Roberfroid M.B., 2002. Global view on functional foods: European perspectives. Br. J. Nutr. 88, 133–138.
Rozporządzenie Ministra Zdrowia z dnia 16 września 2010 r. w sprawie środków spożywczych specjalnego przeznaczenia żywieniowego [Regulation of the Minister of Health of 16 September 2010 on substances added to food]. Journal of Laws 2010 No 180, item 1214.
Schouw Andersen P., 2017. Sport nutrition – 5 key trends for 2017. Dairy Reporter.com. Newsletter 16.
Scientific Concepts of Functional Foods in Europe Consensus Document, 1999. Brit. J. Nutr. 81, l–27.
Shukla S., Park J., Park J.H., Lee J.S., Kim M., 2017. Development of lotus root fermented sugar syrup as a functional food supplement/condiment and evaluation of its physicochemical, nutritional and microbiological properties. Published online: 30 November 2017.
Siró I., Kápolna E., Kápolna B., Lugasi A. 2008. Functional food. Product development, marketing and consumer acceptance – a review. Appetite 51 (3), 456–457.
Stein J.A., Rodriguez-Cerezo E., 2008. Functional Food in the European Union, Institute for Prospective Technological Studies (IPTS). Technical report series EUR 23380 EN-2008.

Syngai G.G., Gopi R., Bharali R., Dey S., Alagu Lakshmanan G.M., Ahmed G., 2016. Probiotics – the versatile functional food ingredients. J. Food Sci. Technol. 53 (2), 921–936.
Thomson C., Block A.S., Hasler C.N., 1999. Position of the American Dietetic Association: Functional Foods. J. Am.. Diet. Assoc. 99, 1278–1285.
Ustawa z dnia 25 sierpnia 2006 r. o bezpieczeństwie żywności i żywienia [Act of 25 August 2006 on food and nutrition safety]. Journal of Laws 2010 No 136, item 914.
Verchueren P.M, Contor L., 2005. FUSE. Functional food science in Europe. FAIR-95-0572: ILSI Europe.

RYNEK ŻYWNOŚCI FUNKCJONALNEJ – UWARUNKOWANIA PRAWNE I PERSPEKTYWY ROZWOJU

Streszczenie. Koncepcja żywności funkcjonalnej została po raz pierwszy opracowana w Japonii w latach 80. XX wieku. Jest to żywność, która może wspierać organizm przed określonymi zagrożeniami dla zdrowia. W Unii Europejskiej definicja żywności funkcjonalnej powstała w ramach europejskiego projektu badawczego „Functional Food Science in Europe" (FUFOSE). W artykule niniejszym przeglądzie przedstawiono aktualne prawodawstwo stosowane w Unii Europejskiej i Stanach Zjednoczonych. Celem tego artykułu było dostarczenie ugruntowanej wiedzy na temat funkcjonalnych markerów żywności i składników żywności funkcjonalnej, które są ważne dla zdrowego stylu życia i mają pozytywny wpływ na zdrowie ludzi. Scharakteryzowano składniki żywności funkcjonalnej, takie jak witaminy, minerały i pierwiastki śladowe; lipidy i określone kwasy tłuszczowe; węglowodany; błonnik pokarmowy i prebiotyki oraz inne związki bioaktywne. Przedstawiono rynek żywności funkcjonalnej w Unii Europejskiej. W podsumowaniu wskazano na konieczność nowego podejścia do badań żywności funkcjonalnej, które powinny uwzględniać interakcje składników żywieniowych i ich związek z genetyką.

Słowa kluczowe: żywność funkcjonalna, ustawodawstwo, rynek żywności funkcjonalnej, składniki funkcjonalne