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REVIEW PAPER

Law regulations concerning food supplements, dietetic food and novel food containing herbal substances

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Summary

Food supplements are concentrated sources of nutrients and/or other substances with a nutritional or physiological effect. However, they often contain herbal substances or their preparations. Food supplements belong to category of food and for that reason are regulated by food legislation. European Union regulations and directives established general directions for dietary supplements, dietetic food, which due to their special composition or manufacturing process are prepared for specific groups of people with special nutritional needs, and novel food/novel food ingredients to ensure product safety, suitability and appropriate consumer information.

Key words: *herbal substances, Union food law, dietary supplements, novel food ingredients*

INTRODUCTION

People almost all over the world know that appropriate diet is essential for human health. What is very interesting and surprising, it is estimated that number of people taking food supplements has risen dramatically in recent years and is predicted to increase further over the next five years. Presently, millions of us take one or more dietary supplements either every day or occasionally as supplementation of normal, health diet. Food supplements are easily available to consumers and they are sold in almost all pharmacies, supermarkets and also other shops or *via* Internet. Nowadays, food products, for example dietary supplements containing different herbal substances are very popular also in healthcare. The phenomenon of self-medication with nutritional supplements can be observed because most people think that they are effective in preventing serious diseases and also safe. Most consumers obtain information about food supplements from popular magazines, newspapers and also commercials. The real problem is that sometimes even family doctors and pharmacists can not define the basic difference between dietary supplements (food) and medical products. Therefore, reliable health service education concerning composition of this products, products qualification and law requirements is required. All health professionals should provide reliable opinion on dietary supplemens efficacy, safety and possible serious interactions which may exists.

Moreover, plants and parts of plants or their preparations can also occur in foodstuffs for particular nutritional uses. Dietary supplements and also foodstuffs for particular nutritional uses as food are regulated by European Union regulations and directives and also Polish law. It is clearly defined that foods for particular nutritional uses (dietetic foods) are specially manufactured to satisfy particular nutritional requirements of specific groups of people. Contemporary situation concerning food for particular nutritional uses was in force as regulatory records of Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses [1]. A new Union law as Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009 was prepared [2]. This Regulation should be applied on 20 July 2016. Particular food products placed on the market earlier in accordance with this Directive before 20 July 2016 may be sold after that date until stocks are let out [2]. Therefore, the name of foodstuffs for particular nutritional uses was abolished by the new law. The Regulation No. 609/2013 established the composition and information requirements for infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and also food

for total diet replacement for weight control. Moreover, this new Regulation establishes also a Union list of substances (vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol) that may be added to one or more of abovementioned categories of food [2].

Food supplements

According to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002, on the approximation of the laws of the Member States relating to food supplements, the definition of food supplements states that supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet, alone or combined, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be dispensed in measured small unit quantities [3]. Dietary supplements are products intended to supplement the normal diet of health people, named consumers. Simply, it is defined as food. Definitely, they are not drugs and, therefore, are not intended to treat, diagnose, mitigate, prevent, or cure any diseases. The dietary usually contain vitamins and minerals but also different substances as amino acids, fatty acids, fiber, probiotic microorganisms, honey, different enzymes. More and more frequently crude plant material such as leaves, flowers, fruits, seeds, roots or other plant parts as well as their herbal preparations (for example extracts) are present in these products. Generally, there are no special limitations for amount of herbal substances in food supplements. In practice, it is recommended to use doses of plant preparations which are lower than doses present in medicinal products. On the other hand, for vitamins and minerals harmonised rules were clearly established. According to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002, on the approximation of the laws of the Member States relating to food supplements only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary [3]. Only vitamins and minerals listed in Annex I, in the chemical forms listed in Annex II of Directive 2002/46/EC, may be used in food supplements [3]. Also, in Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, daily reference intakes for vitamins and minerals and reference intakes for energy and selected nutrients (total fat, saturates, carbohydrate, sugars, protein, salt) other than vitamins and minerals for adult persons were established [4]. Moreover, Directorate-General Health and Consumer Protection in UE, in 2007 prepared "Orientation paper on the setting of maximum and minimum for vitamins and minerals in foodstuffs". In this document, minimum and maximum

amounts for vitamins and minerals in food supplements and other foodstuffs as well as tolerable upper intake level (UL) were proposed [5].

General provisions for botanical food supplements are harmonised by Directive 2002/46. However, as compositional criteria in relation to botanicals have not been harmonised yet, particular national rules may still be applicable. As we mentioned above, complete harmonization was provided just for the use of vitamins and minerals. Especially, lack of harmonisation of the use of particular botanical ingredients in food supplements equal for all EU countries is observed. In few countries the use of particular botanicals is generally permitted while in others serious obligatory restrictions are considered as a model. Some Member States have specific rules, including for example positive and negative lists of herbal substances. For example in Belgium, project named PlantLIBRA aims to foster the safe use of food supplements containing plants or botanical preparations, by increasing science-based decision-making by regulators and food chain operators. The main goal of PlantLIBRA project is create the rules for safe use of plant food supplements. It is a project co-financed in the context of the 7th EU Framework Program. In 2011, The BELFRIT Project started in the collaboration of Belgium, France and Italy. The main aim of the project is to define a common positive list of herbals, deriving from the comparison of national lists, and to harmonize eventually their approach to the assessment of plants in food supplements. BELFRIT Project can be used as useful tool for the harmonization of botanicals in food supplements in all EU countries. Moreover, in United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) prepared guidance concerning „Banned or restricted herbal ingredients" published on 18 December 2014. It contains an alphabetical list of herbal ingredients which are subject to various restrictions in the UK [6]. In 2009, European Food Safety Authority (EFSA) published Scientific Opinion named „Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements". The guidance document is focussed on botanicals and botanical preparations intended for use in food supplements. It is not the objective of this opinion to produce a list of safe botanicals or their preparations but rather to provide guidance on how to assess safety of botanical ingrediens placed in food supplements [7]. In addition, in 2009 EFSA also published „Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern". The purpose of the Compendium is to facilitate the implementation of the EFSA guidance for the safety assessment of botanicals and their preparations intended for use as ingredients of food supplements [8]. Without prejudice to the existing legal framework, the compendium has no legal status and may not be used as support or evidence in any disagreement or dispute pertaining to the legal classification of products or substances. The Compendium should be periodically updated by EFSA. Moreover, in 2012 EFSA published a „Compendium of botanicals reported to contain naturally occuring substances of possible concern for human health when used in food and food supplements" [9]. The purpose of the Compendium is to assist risk assessors responsible for the evaluation of specific ingredients in food supplements. This new

"Compendium of botanicals reported to contain naturally occuring substances of possible concern for human health" replaces the first version published in 2009; it lists in alphabetical order botanicals without any judgment on whether they are suitable or not suitable for food applications in Europe; it has no legal or regulatory force pertaining to the legal classification of products or substances.

Additional Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives harmonises the use of food additives in foods in the Community [10]. However, community list of food additives approved for use in foods and conditions of use was established in Commision Regulation (EU) No. 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives [11]. Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC is also important and cover flavourings, source materials for flavourings and foods containing flavourings [12].

Many herbal products are marketed as "natural", which may lead consumers to assume the products are safe, even when taken along with prescription medicines. Natural does not equal safe. The real problem is that a lot of interactions can arise between herbal medicines, dietary supplements, prescription synthetic drugs and also regular food leading to serious clinical consequences. Sometimes only a few limited data on pharmacological interactions with other medicinal products are available for particular plant preparation. Moreover, most dietary supplements have not been tested for safety in pregnant women, nursing mothers, or children. Because safety profile of many herbal substances during pregnancy and lactation has not been established because of lack of appropriate data, as a precautionary measure use during pregnancy and lactation is not recommended. Additionally, persons with hypersensitivity to active substance of plants should not use them as well as its preparations. The main objective of EU policy is food safety. In the Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 gives general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food was assessed [13]. In Europe, European Food Safety Authority (EFSA) is working on evaluation the safety and bioavailability of nutrient sources proposed for addition to the list of permitted substances of the food supplements. Moreover, EFSA's NDA Panel is concentrated on comprehensive evaluation of possible adverse health effects of individual micronutrients at intakes exceeding the dietary requirements, and also on evaluation of the safety of nutrient substances added to food supplements. In 1979, the Rapid Alert System for Food and Feed (known as RASFF) was created. Members of RASFF network are as follow: from European Union – European Commission/Health and Consumer

Protection Directorate-General, European Food Safety Authority (EFSA), European Free Trade Association (EFTA) and member countries of EU. RASFF system was developed to create an effective tool to exchange information between countries or EU institutions about serious risks detected in relation to food or feed. Definitely, exchange of important informations helps Member States to act more rapidly in case of problems with health caused by any food. RASFF system provide also useful informations for consumers of all member countries. For consumers RASFF portal was created with important informations or alerts about dangerous food. RASFF consumers' portal is a consumer-friendly, very useful internet tool providing important information on food, especially about public health warnings issued by food safety authorities and food companies.

Responsibility

Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or labeled falsely. That means that these companies are totaly responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004. Food information law should prohibit the use of information that would mislead the consumer in particular as to the characteristics of the food, food effectiveness or properties, or attribute medicinal properties to foods and also food presentation. Food labels should be clear and understandable in order to assist consumers who want to be professionally informed about food properties. Main food information must contain the name of the food, the list of all ingredients, the quantity of certain ingredients or categories of ingredients, the date of minimum durability, any special storage conditions and/or conditions of use, the name or business name and address of the food business operator, and also nutrition declaration. According to Regulation (EU) No. 1169/2011 foods placed on the market or labelled prior to 13 December 2014 which do not comply with the requirements of this Regulation may be marketed until the stocks are run out. The mandatory nutrition declaration should include energy value, the amounts of fat, saturates, carbohydrate, sugars, protein and salt. The content of the nutrition declaration may be supplemented with an indication of the amounts of the following substances: mono-unsaturates, polyunsaturates, polyols, starch, fibre, vitamins or minerals [4].

Novel food and novel food ingredients regulations

Nowadays, the real problem exists that a lot of substances of plant origin present in herbal products are regarded as "novel food". Novel food is food not consumed to a significant degree in the European Union prior to 15 May 1997. However, other specific legislation may restrict the placing on the market of particular product as a food or food ingredient in some Member States. Therefore, it is recommended to check all available informations with the national competent authorities. According to informations presented by UE Commission about legislation regarding „novel food" all data about novel food have been harmonised when Regulation (EC) 258/97 was first adopted [14]. The Novel Food Regulation 258/97 required that all food or food ingredients that have not been used for human consumption in the UE before May 15, 1997 according to the information available to Member States' competent authorities were considered as novel food or a novel food ingredient. Therefore, before it may be placed on the market in the EU as a „novel food", a safety assessment under the Novel Food Regulation was required. As next step, in 2013, the Commission presented a proposal for a new Regulation. In the draft of this document, novel food would be subject to a simpler and more efficient authorisation procedure, which should enable safe and innovative food to be placed on the EU market. A new Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001 concerning novel food was adopted on 25 November 2015 [15]. In the Regulation EU 2015/2283 the novel food is clearly defined as well as procedure for determination of novel food status, requirements for placing novel foods on the market within the Union and authorisation procedures for a novel food.

Novel food ingredients must be safe for consumers, properly labelled in order to not to mislead them and cannot be nutritionally disadvantageous. Regulations concerning novel food does not cover food additives, flavourings for use in foods, extraction solvents used in the production of foods and also GMOs for food and feed. Only authorised novel foods may be placed on the market in European Union. Companies must apply to a EU country authority for authorisation, presenting the scientific information and safety assessment report. Authorization is specific to a particular product. Only the applicant is allowed to place the product on the market. However, a complete positive list of novel foods and ingredients does not yet exist. But, The Novel Food Catalogue published in European Commission website lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States (http://ec.europa.eu/food/safety/novel_food/catalogue). Examples of foods that Commission Implementing Decision may be placed on the

EU market are among others: DHA and EPA rich oil from the microalgae *Schizochytrium*, lipid extract from antarctic krill (*Euphausia superba*), magnolia bark extract, synthetic zeaxanthin, bovine lactoferrin, chia seed, yeast beta-glucans, fermented black bean extract, a chitin-glucan from *Aspergillus niger*, puree and concentrate of the fruits of *Morinda citrifolia* (Noni), a leaf extract from lucerne (*Medicago sativa*), trans-resveratrol, coriander seed oil, UV-treated baker's yeast (*Saccharomyces cerevisiae*) or lycopene. There are of course a few refusals of authorization of novel food ingredients by Commission Decisions, for example plants and dried leaves of *Stevia rebaudiana* Bertoni (Commission Decision of 22 February 2000), Nangai nuts – *Canarium indicum* L. (Commission Decision of 19 December 2000) or betaine (Commission Decision of 25 July 2005).

CONCLUSIONS

There are numerous food supplements containing different substances (parts of plants, herbal preparations, novel food ingredients) on the market; they are also called dietary or nutritional supplements. Supplement use varies in separate European countries but increasing food supplements intake is still observed. First of all it is necessery to define a common positive list of herbals and to harmonize botanicals in food supplements in all European Union countries.

Moreover, establishing of botanicals list that have been considered to contain toxic, addictive, psychotropic or other substances dangerous for human health will help in safety assessment of this category of food products. It is known that in some products present on the market ingredients listed have been found to be different from the contents, a lot of supplements were also found to contain unsafe or illegal substances. Moreover, most of the supplements studied were of low quality. Some reports performed pay attention to an unsafe levels of arsenic, cadmium, lead and mercury or high level of microorganisms in these products. Therefore, more restricted law is definitelly required in this category of food. Additionally, effects of most dietary supplements have not been determined in randomized clinical trials and their health claims are incorrect. That is why the self-medication is unsafe, not all supplements are useful for everybody. Individuals should pay particular attention to reading the label and assure that particular product is suitable for them. The next real problem is that borderline between food supplements and pharmaceutical products containing herbal substances or preparations is not clearly defined which leaves consumers, health professionals and the herbal industry confused about the status of herbal products. Therefore, also detailed European Union regulations concerning borderline herbal substances as dietary supplement's constituents and theit safety amounts are required.

Ethical approval: The conducted research is not related to either human or animal use.
Conflict of interest: Authors declare no conflict of interest.

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REGULACJE PRAWNE DOTYCZĄCE SUPLEMENTÓW DIETY, ŻYWNOŚCI DIETETYCZNEJ I NOWEJ ŻYWNOŚCI ZAWIERAJĄCEJ SUBSTANCJE ROŚLINNE

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S t r e s z c z e n i e

Suplementy diety są skoncentrowanym źródłem substancji odżywczych i/lub innych substancji wykazujących efekt odżywczy lub fizjologiczny. Produkty te bardzo często zawierają w swoim składzie surowce roślinne lub ich przetwory. Suplementy diety należą do kategorii żywności i z tego powodu podlegają przepisom prawa żywnościowego. Dyrektywy i inne przepisy Unii Europejskiej określają główne wytyczne prawne dla suplementów diety, dietetycznych środków spożywczych, które ze względu na specjalny skład lub sposób przygotowania są przeznaczone do zaspakajania szczególnych potrzeb żywieniowych określonych osób, a także nowej żywności/nowych składników żywności. Gwarantują one bezpieczeństwo produktu, jego przydatność oraz właściwe przekazywanie konsumentom informacji na temat żywności.

Słowa kluczowe: *surowce roślinne, prawo żywnościowe UE, suplementy diety, nowe składniki żywności*