REVIEW

Regulatory Requirements for Food Supplements in the European Union and Bulgaria

Elina S. Petkova-Gueorguieva1, Ilko N. Getov2, Kalin V. Ivanov3, Stanislava D. Ivanova3, Stanislav R. Gueorguiev1, Violeta I. Getova1, Anna A. Mihaylova1, Vasil G. Madzharov1, Radiana A. Staynova1

1 Department of Pharmaceutical Sciences, Faculty of Pharmacy, Medical University of Plovdiv, Plovdiv, Bulgaria
2 Department of Social Pharmacy and Pharmacoconomics, Faculty of Pharmacy, Medical University of Sofia, Sofia, Bulgaria
3 Department of Pharmacognosy and Pharmaceutical Chemistry, Faculty of Pharmacy, Medical University of Plovdiv, Plovdiv, Bulgaria

Correspondence:
Elina S. Petkova-Gueorguieva,
Department of Pharmaceutical Sciences, Faculty of Pharmacy, Medical University of Plovdiv, 15A Vassil Aprilov Blvd., 4000 Plovdiv, Bulgaria
E-mail: elinapetkova@abv.bg
Tel: +359888614647
Received: 25 Feb 2018
Accepted: 01 Apr 2018
Published Online: 30 July 2018
Published: 31 Mar 2019

Key words: food supplements, legislation, quality control, health, safety

Citation: Petkova-Gueorguieva ES, Getov IN, Ivanov KV, Ivanova SD, Gueorguiev SR, Getova VI, Mihaylova AA, Madzharov VG, Staynova RA. Regulatory requirements for food supplements in the European Union and Bulgaria. Folia Med (Plovdiv) 2019;61(1): doi: 10.2478/folmed-2018-0032

INTRODUCTION

Currently the European Economic Community is strongly concerned about the quality of food supplements (FS) due to the fact that they require a large internal market and reliable protection of customers’ health against low quality products. The data presented by the European Commission revealed that public expenditures for food supplements over the last decade have been constantly increasing. Evidence provided by the International Marketing Agencies show that the global FS market, which has been estimated to be USD 132.8 billion in 2016, is expected to reach around USD 220.3 billion in 2022. At the same time, the fact that the current European legislation has assigned the responsibility for protection of FS safety to the manufacturers and distributors is alarming. On this ground numerous authors support the opinion that in countries with insufficient production control there is a strong possibility of having distribution of low quality products.

MATERIALS AND METHODS

The aim of the present work was to analyze and interpret the major regulations concerning food supplements in the European Union and in Bulgaria from the viewpoint of customers’ safety provision.

The following tasks were fulfilled in order to
achieve the objective of the study:
1. Discussion of the EU Strategy for food supplements safety and systematization of the relevant EU Regulations.
2. Survey of the national regulations, introducing the provisions of the EU legislation for FS safety and of the additional requirements for Bulgarian manufacturers.
3. Evaluation of the food supplements market. The relevant regulations were investigated by a documentary method.

RESULTS AND DISCUSSION

LEGISLATIVE FRAMEWORK FOR FOOD SUPPLEMENTS IN THE EUROPEAN UNION

The classification of the major regulations of the European Community was laid in Art. 249 of the EC Treaty, stating that “the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions”.

The main function of a Regulation is to establish binding, general application in all Member States. A Directive is an act that has not generally a binding effect, i.e. it regulates the result, but leaves to the national authorities to choose the form and methods for its achievement. A Decision is an individual administrative act binding in its entirety upon those to whom it is addressed.

In 2002 the European Parliament enforced Regulation (EC) 178/2002 establishing the European Food Safety Agency (EFSA). With this Regulation the EU outlined the general principles and requirements of the Food Law. The food supplements safety for human health was adopted as the leading principle in the field of food supplements. The key task of EFSA and the member states was the elaboration and exchange of scientific expert opinions based on scientific evidence.

In 2006, according to Commission Directive 2006/37/EC, the Management Board of EFSA adopted a Strategy for cooperation and establishment of a network of focal centers for exchange of scientific information on health risk assessment between EU member states.

EFSA introduced the term “novel foods”, subject to special regulation. This term covered all foods, insufficiently consumed or without demonstrated significant benefits by 15 May 1997. Those foods are still subject to strict pre-market assessment. The same term also covered vitamins and minerals permitted for use (Regulation (EC) 1170/2009), but produced from sources subject to Regulation (EC) 258/97. Each nutrient, produced by a genetically modified source is also a subject of precise health safety assessment before being listed in the Positive list of Regulation (EC) 1170/2009.

Regulation (EC) No 1924/2006 of the European Parliament and Council on nutrition and health claims made on foods has been in force since 20 December 2006. The Regulation has been applied in EU member states since 1 July 2007. According to the Regulation “health claim” means any claim (statement) that states or implies that a relationship exists between a food group, or one of its constituents, and health.

Aiming to provide a harmonized scientific assessment, the European Food Safety Agency performs analysis and assessment of the applications for approval of health claims submitted by the member states implementing high standards. The European Commission published a positive list of health claims permitted for use, including characteristics of the active substance, conditions of use (amounts, target groups) as well as a regulation with health claims rejected after being scientifically assessed.

According to Directive 2002/46/EC of the European Parliament “food supplements” are concentrated sources of nutrients or other substances with a nutritional or physiological effect, aiming to supplement the normal diet. They are marketed in dose form, namely forms such as tablets, capsules, liquids etc.

Art. 5 of the Directive set requirements to the maximal and minimal amounts of vitamins and minerals in food supplements based on scientific evidence concerning health safety.

In 2006, according to Commission Directive 2006/37/EC, the Management Board of EFSA adopted a Strategy for cooperation and establishment of a network of focal centers for exchange of scientific information on health risk assessment between EU member states.

EFSA introduced the term “novel foods”, subject to special regulation. This term covered all foods, insufficiently consumed or without demonstrated significant benefits by 15 May 1997. Those foods are still subject to strict pre-market assessment. The same term also covered vitamins and minerals permitted for use (Regulation (EC) 1170/2009), but produced from sources subject to Regulation (EC) 258/97. Each nutrient, produced by a genetically modified source is also a subject of precise health safety assessment before being listed in the Positive list of Regulation (EC) 1170/2009.

In 2002 the European Parliament enforced Regulation (EC) 178/2002 establishing the European Food Safety Agency (EFSA). With this Regulation the EU outlined the general principles and requirements of the Food Law. The food supplements safety for human health was adopted as the leading principle in the field of food supplements. The key task of EFSA and the member states was the elaboration and exchange of scientific expert opinions based on scientific evidence.

In 2006, according to Commission Directive 2006/37/EC, the Management Board of EFSA adopted a Strategy for cooperation and establishment of a network of focal centers for exchange of scientific information on health risk assessment between EU member states.

EFSA introduced the term “novel foods”, subject to special regulation. This term covered all foods, insufficiently consumed or without demonstrated significant benefits by 15 May 1997. Those foods are still subject to strict pre-market assessment. The same term also covered vitamins and minerals permitted for use (Regulation (EC) 1170/2009), but produced from sources subject to Regulation (EC) 258/97. Each nutrient, produced by a genetically modified source is also a subject of precise health safety assessment before being listed in the Positive list of Regulation (EC) 1170/2009.

In 2006, according to Commission Directive 2006/37/EC, the Management Board of EFSA adopted a Strategy for cooperation and establishment of a network of focal centers for exchange of scientific information on health risk assessment between EU member states.

EFSA introduced the term “novel foods”, subject to special regulation. This term covered all foods, insufficiently consumed or without demonstrated significant benefits by 15 May 1997. Those foods are still subject to strict pre-market assessment. The same term also covered vitamins and minerals permitted for use (Regulation (EC) 1170/2009), but produced from sources subject to Regulation (EC) 258/97. Each nutrient, produced by a genetically modified source is also a subject of precise health safety assessment before being listed in the Positive list of Regulation (EC) 1170/2009.

In 2006, according to Commission Directive 2006/37/EC, the Management Board of EFSA adopted a Strategy for cooperation and establishment of a network of focal centers for exchange of scientific information on health risk assessment between EU member states.

EFSA introduced the term “novel foods”, subject to special regulation. This term covered all foods, insufficiently consumed or without demonstrated significant benefits by 15 May 1997. Those foods are still subject to strict pre-market assessment. The same term also covered vitamins and minerals permitted for use (Regulation (EC) 1170/2009), but produced from sources subject to Regulation (EC) 258/97. Each nutrient, produced by a genetically modified source is also a subject of precise health safety assessment before being listed in the Positive list of Regulation (EC) 1170/2009.
lists all nutrition claims and the conditions for use applying to them. It also contains a list of rejected health claims and reasons for their rejection. One of the aims of Regulation (EC) No 1924/2006 was to guarantee that the health claims were truthful, clear, reliable and useful for the consumer.

An Expert Council to the European Food Safety Agency has developed guidelines, including criteria used in scientific support of the health claim. Six major criteria have been established for the assessment of health claims and specific requirements for each criterion have also been elaborated.

**Criterion 1.** The food or food component to which the claimed effect is attributed should be well characterised. This assessment is made through a database enabling the evaluation of the validity of the research. The positive or negative effect at intake should be associated with a particular food ingredient.

**Criterion 2.** The substantiation of a claim must be based on data from epidemiological studies: cross-sectional, case-control, cohort studies and intervention studies.

**Criterion 3.** When the true endpoint of a claimed benefit cannot be measured directly, studies should use markers. This approach is applied in cases, when a longer study period is necessary.

**Criterion 4.** Markers should be biologically and methodologically valid; they must be biologically verified to have a known (evidenced) relationship with the final outcome and that they have a known relationship to the final outcome and their variability within the target population is known. Their methodological validity is assessed with respect to their analytical characteristics.

**Criterion 5.** Within a study the target variable should change in a statistically significant way and the change should be biologically meaningful for the target group consistent with the claim to be supported. Appropriate statistical methods, providing the correctness of the results referring to their reliability, biological significance, and stability shall be implemented.

**Criterion 6.** A claim should be scientifically substantiated and not controversial to generally accepted principles of healthy nutrition. Before producing a final opinion, the weight of the evidence is discussed: convincing, probable, possible.

The developed list of permitted health claims of the foods according to Art. 13.1 together with all necessary conditions for their use are contained in the Register of the European Commission. The food supplements, permitted for use, must be labelled. The label on the food must show: claim for the importance of the food for human health; daily intake dose and way of intake of the product producing the expected beneficial effect; precautions to individuals for whom this product is inappropriate, contraindications (if applicable); warning for risk at over-intake of the particular product (if any). Additionally, regulations regarding vitamins and minerals were issued: Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods and Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.

**Bulgarian legislation on food supplements**

In the capacity of an EU member state Bulgaria applies the European legislation associated with regulation of requirements for foods. The national legislation concerning regulation of food supplements is harmonized with the legislation acting in the EU.

The top-down hierarchy of the regulations in the Bulgarian legislation incorporates legislative acts (constitution, code, law) and regulations (Decree of the Council of Ministers, rules, ordinance, instructions).

The safety of food supplements is regulated by three laws: “Health Law” (2004), “Food Law” (2004) and “Law on medicinal products in human medicine” (2007).

According to the Food Law, food supplements are foods, thus the requirements for manufacturing, marketing, labeling, control rules and specific regulations are applicable to them. The Law envisages that, upon finding that the product labels, package or leaflet are incompatible, it shall be re-labeled or the distribution and marketing of the supplement is fully discontinued. It is absolutely banned to cite preventive or curative claims on the FS label. The admissible wordings could only state that FS “improves the state or supports the normal function of organs or systems”.

The composition of food supplements could incorporate herbal ingredients or they could be formulated on herbal basis as a whole, but they should be marketed in strictly determined, pre-
labeled and dosed small amounts – in conformity with the provisions of Par. 72 of the Supplementary orders of the Food Law. Herbal teas are not food supplements.

Food supplements are intended to complement the normal human diet. Food supplements are not administered with therapeutic purposes and they cannot state claims for prevention of a particular disease, for treating or capacity to treat a certain disease. Products with curative claims must be registered by the Executive Drug Agency.

Food supplements are sold in shopping cites registered according to the Food Law, but, according to the provisions of Art. 219 Par. 1 of the Law for medicinal products, food supplements may be sold in pharmacies without additional registration.26

Although FS are not directly cited in the Health Law, this Law stipulates that the state executes health control on all foods. This control is realized by the Regional Inspectorates for Protection and Control of Public Health (RIPCPH).27

The main legal act regulating the requirements for food supplements in Bulgaria is Ordinance № 47 of the Ministry of Health on “Requirements for Food Supplements.”28 More requirements are laid also in Ordinance № 23 of the Ministry of Health on the requirements for food labeling and presentation29 and Ordinance № 5 of the Ministry of Health on food hygiene30.

Art. 4. (amended – State Gazette (SG) No. 90 (2005), SG, No. 44 (2007): Manufacturers or merchants intending to launch food supplements for the first time on the Bulgarian market shall notify the relevant local Regional Health Inspectorate before placing the product on the market. In order to legalize the food supplements the company placing the product on the market and offering it to consumers has to file a notification. The regime is notifying and not licensing. It is more liberal than the registration regime and enables the introduction of many new FS to the pharmaceutical market within a very short time.

All foods within the EU follow the line for free movement of goods and food supplements follow this route as well.31 Nevertheless, they are subjected to control and a notification has also to be filed for them because the requirements for FS of the particular European countries differ to a certain extent.

The most frequent infringes identified by the National Sanitary Control authorities are: poor current hygiene, offering of products with expired shelf life, lack of documents for the origin of the products at the shopping site that have to ensure their follow-up, a misleading label. The label of the food supplements must not state that they can be administered for treatment of any disease or for health prevention.

EVALUATION OF THE FOOD SUPPLEMENTS MARKET
The last few years marked an enhanced consumers’ interest in healthy foods and FS as the consumers identified the relationship between FS and health. The factors, substantiating the growth of this market are: higher interest of consumers who wish to enrich their diet; high consumption by athletes and physically active consumers; promotion strategies and approaches launched by manufacturers and distributors; liberal legal framework; liberal distribution and sales regime. The global legislation enables the quick introduction of a new FS – most countries require only a notification (USA, Mexico, Australia, Bulgaria, etc.) while others demand a registration (Brazil, Canada, Russia). The FS market is growing faster than that of medicinal products (MP) because of the liberal regime of production and registration.32–35

The recent data (2016) the greatest market for FS is the Asia-Pacific region (India, Japan, China, Republic of Korea). Consumers’ awareness of FS benefits and the active large-scale supply of the products are the main engines of the market in the Asia-Pacific region.36–40 While globally the FS market is growing faster than that of MP, the Bulgarian statistics reveal a trend to increase of both MP and FS sales. The total market growth rate in the period 2012–2016 (Fig. 1) amounted up to 37.62%. The average annual growth rate was about 7.5%.

Food supplements contributed a smaller percentage rate of the overall sales of the pharmaceutical market - in 2016 MP sales were esteemed to 2797 billion BGN, while FS contributed 717 million. BGN, compared to the MPs growth rate in the same period amounting up to 31.87%. We analyzed the FS sales growth in Bulgaria by number of sold packages. The total growth rate in the period 2012–2016 (Fig. 2) was 13.64%.

It is obvious that the difference in terms of money of the market share of FS and MP was in favor of MP and FS contributed only a small part.

In terms of consumer packages 297 million consumer packages of MP were sold in 2016 (Fig. 3) while the sales of FS in the same period amounted up to 125 million consumer packages. The same analysis accounting for consumer packages identified
FS as important pharmaceutical products because each three sold MP corresponded to 1 FS (Fig. 3).

Although the total market share of MP and over the counter (OTC) products is much greater than that of FS, it is seen that, measured in number of consumer packages MP OTC have a much smaller market share than FS. Eighty-five million consumer packages of OTC MP and 125 million consumer packages of FS were sold in Bulgaria in 2016. This fact additionally highlights the need of a stricter FS regulation.

CONCLUSIONS

The analyzed data showed that public expenditures for food supplements grew incessantly in most countries, including Republic of Bulgaria. This is due to a great extent to the legislation that enables fast introduction of a new FS – most countries require just a notification (USA, Mexico, Australia, Bulgaria and others), others demand a registration (Brazil, Canada, Russia). Numerous authors support the opinion that there is a real risk for distribution of low quality products in countries where the production control is inadequate.

Currently the European Community is concerned about food products, including FS, launched on the market because the citizens require reliable protection of their health. This concern provoked the European Parliament and the Council to undertake a number of legislative initiatives in the field of production and control of food products.

Our national legislation presents 6 regulations with different legal force for provision of healthy and safe food supplements on the market. They comply with the specificities of our country and the international legislative requirements in the field. Quality and post-marketing control of FS should not be neglected. It is necessary to set more precise quality and safety criteria in future strategies associated with those products.

REFERENCES

1. http://europa.eu/legislation
2. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002), p. 0001-0024.
3. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approxi-
mation of the laws of the Member States relating to food supplements (Text with EEA relevance) (OJ L 183, 12/07/2002), p. 0051-0057.
4. Duleva V. [Aspects of regulation of food supplements in the European Union. National Center of Public Health and Analyses], Sofia, 2013 (Article in Bulgarian).
5. FDA. Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues. Retrieved January 15, 2013, from http://www.fda.gov/food/guidancecompliance-regulatoryinformation/guidancedocuments/dietary-supplements/ucm257563.htm; 2011.
6. European Food Safety Authority. E. Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA J 2012;2012:10.
7. Ivanova S. [Pharmacoanalytical control of food supplements with androgenic effect] [PhD thesis]. Plovdiv: Medical University; 2016 (Bulgarian).
8. Bagchi D, editor. Nutraceutical and functional food regulation in the United States and around the United States. 2nd ed. Elsevier Inc; 2014, ISBN: 978-0-12-405870-5.
9. European Commission. Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. Official Journal of the European Union L 314/36, 2009.
10. European Commission. Novel foods and novel food ingredients. Food and Feed Safety Retrieved January 15, 2013. Available from http://ec.europa.eu/food/food/biotechnology/novel-food/index_en.htm; 2012.
11. European Commission. Novel Food catalogue Search. Food and Feed Safety Retrieved January 15, 2013. Available from http://ec.europa.eu/food/food/biotechnology/novel-food/index_eng.htm; 2012.
12. FDA. New Dietary Ingredients in Dietary Supplements Background for Industry. Retrieved January 15, 2013. Available from http://www.fda.gov/Food/DietarySupplements/ucm109764.htm; 2012.
13. ANVISA. Registration of Products: Manual covering procedures for registration and exemption from registration of imported products. Retrieved January 15, 2013. Available from http://www.anvisa.gov.br/eng/food/registration.htm; 2000.
14. Corrigendum to 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. Official Journal of the European Union. 18.1.2007, p. 1-16
15. Asp NG, Bryngelsson S. Health claims in Europe: new legislation and PASSCLAIM for substantiation. J Nutr 2008;138(6):1210S-5S.
16. Getov I, Grigorov E, Lebanonova H. Food supplements- marketing and health claims analysis. Archives of the Balkan Medical Union 2011; 46(4, Suppl.1):26-29.
17. Natural Health Products Directorate. Compendium of Monographs. Drugs and Health Products. Retrieved January 15, 2013. Available from http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index-eng.php.; 2009.
18. New function health claims under Article 13.5 of the EU Regulation. Available from http://www.efsa.europa.eu/en/topics/topic/article13-5.htm
19. Claims regarding disease risk reduction and child development or health under Article 14 of the EU Regulation. Available from http://www.efsa.europa.eu/en/topics/topic/article14.htm
20. Aggett PJ, Antoine JM, Asp N-G, et al. PASSCLAIM Process for the assessment of scientific support for claims on foods. Consensus on criteria. Eur J Nutr 2005;44 Suppl 1:1/1-1/30.
21. TGA. Australian Guidelines for Complementary Medicines (ARGCM) Part II: Listed Complementary Medicines, 2011.
22. Asp NG, Cummings JH, Mensink RP, et al, editors. PASSCLAIM. Process for the assessment of scientific support for claims on foods. Phase 1: Preparing the way. Eur J Nutr 2003;42 Suppl 1:1/1-1/119.
23. Asp NG, Cummings JH, Howlett J, et al, editors. PASSCLAIM. Process for the assessment of scientific support for claims on foods. Phase 2: Preparing the way. Eur J Nutr 2004;43 Suppl 2:II/1-II/183.
24. Asp NG, Bryngelsson S. Health claims in Europe: new legislation and PASSCLAIM for substantiation. J Nutr 2008;138(6):1210S-5S.
25. Food Law, Bulgaria, State Gazette No. 70 of 10 August 2004 [in Bulgarian].
26. Law for medicinal products in human medicine, Bulgaria, SG, No. 31 of 13 April 2007 [in Bulgarian].
27. Health Law, Bulgaria, SG No. 70 of 10 August 2004 [in Bulgarian].
28. Ordinance No. 47 of the Bulgarian Ministry of Health on requirements for food supplements, SG No. 5/2005 [in Bulgarian].
29. Ordinance No. 23/2001 of the Bulgarian Ministry of Health on conditions and requirements for presenting nutritional information on food labels, SG 53/2001 [in Bulgarian].
30. Ordinance No 5 of the Bulgarian Ministry of Health on food hygiene, SG 55/07.07.2005 [in Bulgarian].
31. European Commission, “Food Supplements,” European Commission Food Safety. Available from https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en

32. TGA. The regulation of complementary medicines in Australia an overview: Pre-market assessment. Retrieved January 15, 2013. Available from http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm#pre.; 2012

33. TGA. Australian Guidelines for Complementary Medicines (ARGCM) Part II: Listed Complementary Medicines, 2011.

34. Dietary Supplement Quality: The Meaning of the USP Verified Mark. Available from http://www.pharmacytimes.com/publications/issue/2014/april2014/r636_april2014

35. Global Dietary Supplements Market will reach USD 220.3 Billion in 2022: Zion Market Research. Available from https://globenewswire.com/news-release/2017/01/11/905073/0/en/Global-Dietary-Supplements-Market-will-reach-USD-220-3-Billion-in-2022-Zion-Market-Research.html

36. Halsted CH. Dietary Supplements. Am J Clin Nutr 2000;71(2):399-400.

37. Mason P. Handbook of Dietary Supplements. USA: Blackwell Science Ltd; 1998.

38. ASEAN. Harmonization of Standards and Technical Requirements in ASEAN. Retrieved January 15, 2013. Available from http://www.asean.org/news/item/harmonizationof-standards-and-technical-requirements-in-asean. 2012.

39. ASEAN. Profile of Definition, Terminology, and Technical Requirement of Traditional Medicines and Health Supplements among ASEAN Member Countries. 2006.

40. ASEAN. Guiding Principles for Inclusion of Active Substances into the Restricted List for Traditional Medicines and Health Supplements (TMHS). 2010.
Нормативные требования к пищевым добавкам в Европейском Союзе и Болгарии

Елина С. Петкова-Георгиева 1, Илко Н. Гетов 2, Калин В. Иванов 3, Станислав Д. Иванова 3, Станислав В. Георгиев 1, Виолета И. Гетова 1, Анна А. Михайлова 1, Васил Г. Маджаров 1, Радиана А. Стайнова 1

1 Кафедра фармацевтических наук, Факультет фармации, Медицинский университет - Пловдив, Пловдив, Болгария
2 Кафедра социальной фармации и фармакоэкономики, Факультет фармации, Медицинский университет - София, София, Болгария
3 Кафедра фармакогнозии и фармацевтической химии, Факультет фармации, Медицинский университет - Пловдив, Пловдив, Болгария

Данные, предоставленные Европейской комиссией, показывают, что государственные расходы на пищевые добавки постоянно растут в течение последнего десятилетия.

Целью настоящего исследования является анализ основных нормативных актов о пищевых добавках в Европейском парламенте и в Болгарии. Был проведен поиск и найдена публикация по данной теме в MEDLINE / PubMed, базе данных Scopus, Web of Knowledge, а также в Интернете по предварительно заданным ключевым словам. Многочисленные авторы поддерживают мнение, что существует реальный риск того, что продукты низкого качества могут распространяться в странах с плохим контролем производства. В болгарском национальном законодательстве существует 6 нормативных актов, имеющих разную юридическую силу, для обеспечения на рынке безопасных для здоровья пищевых добавок. В настоящее время Европейское сообщество уделяет особое внимание продуктам питания, в том числе ПД, поставляемых на рынок, поскольку граждане настаивают на надежной защите своего здоровья. Эти обстоятельства спровоцировали Европейский парламент и Совет Европы предпринять ряд законодательных инициатив в области производства и контроля продуктов питания. Необходимо установить более точные критерии качества и безопасности в будущих стратегиях, связанных с этими продуктами.