FOOD SUPPLEMENTS ON EU MARKET: ILLEGITIMATE, INCAPABLE OF BEING OFFERED OR FOOLISHLY REGULATED PRODUCTS?

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Abstract

The current regulation of food supplements on EU market raises a number of questions. Due to a new EU regulation (Regulation (EC) No. 1924/2006) the possibilities of an efficient marketing of these special foodstuffs have been substantially limited. The new EU law provides for a reliable enforceability of the ban on misleading and scientifically insufficiently evidenced claims on the effects of these foodstuffs. Their efficient offer to consumers, however, is particularly dependent precisely on these claims.

What is then the ultimate aim of EU regulation and what should the legal market of food supplements look like? Are food supplements missing scientific evidence of their effects on human body really illegitimate and shall they be eliminated from the market? Are they only incapable of being offered to consumers? Who else should they be offered to? Or are they only foolishly regulated and EU has imposed irrational effects on food supplements

The authors explain principles of EU regulation of food supplements. They have found room for food supplements on the market, even if no beneficial effects with respect to human body may be commercially communicated.

Key words: Food supplements; EU Law; Regulation; Consumer protection; Regulation (EC) No. 1924/2006;

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Introduction

The market of food supplements in the EU is estimated at some 7 billion EUR nowadays and is expected to rise to 9 billion EUR by the year 2018 (Starling, 2014). The high sales of these products are surprising given the purpose for which they have been foreseen under EU Law. Food supplements are not aimed at alleviating symptoms of any human diseases. Their consumer value consists mostly in nutritional prevention. Their positive effects on human

body can be reasonably expected within a long period of term time once they have been regularly used for years. The theoretical legal principles of food supplements and their consumer value do not correspond to their demand on the market and to the expectations of consumers (Nocella, Kennedy, 2012). Such a contradiction may result from illegal behavior, illegal advertising and offer of these products to consumers. An extensive research of heath claims carried out by the European Food Safety Authority has pointed out at the illegal offer of food supplements to consumers on a massive scale (Vavrečka, Štěpánek, 2012).

The current public discussion has concentrated on misleading consumers by claiming effects lacking sufficient scientific evidence. However, a no less important issue has been set aside. Its principles lie in the general theory of law rather than in natural sciences. And this issue is common to the world market. Therefore, it is interesting to compare the level and the accuracy of these legislative reflections in different systems of law (Guinta, Basile, Tibuzzi, 2010). This problem consists in the legal regulation and principles of mutual demarcation of product categories having physiological functions with respect to the human body. The authors believe that the scope of the practical reflection of this topic remains at a very low level, even though EU Law fully recognizes and employs these principles. This can lead to a number of misunderstandings among legislators, regulators, producers and consumer representatives.

1 Fundamental Principles of Demarcation of Products having Physiological Functions in EU Law

The aim of any legal regulation is to protect humans and/or legal entities. Law should limit the protection of these persons to an extent which is necessary and useful in a society taking into account all circumstances. If EU Law establishes various legal regimes for products having physiological functions, then we can claim that EU creates and contains different regimes and levels of protections of humans and legal entities. Terms and institutes of EU Law, such as medicinal product, foodstuff, food supplement, cosmetic product or medical device, constitute categories of different regimes of legal protection.

Legal practice often mistakenly believes that the objective properties of these products lie behind the legal demarcation of products having physiological functions. In other words, it is believed that the regulation is primarily based on and justified by a specific product. The aim of law, however, is not to distinguish between different products available on the market only because they are different. The aim of law is to provide a proportional level of protection to the natural and legal persons concerned. There has to be something else to justify

differences in legal regulation. There have to be sufficient and arguable differences between persons, who should be protected by different legal regimes. It is fair and in line with the principle of equality to provide the same level of protection to persons in similar situations. Only where certain persons do not require an intensive legal protection, it does not need to be provided.

Using these basic principles we can infer that products having physiological functions have been demarked in particular with respect to consumers. Only different consumers can be legitimately provided a different level of protection with respect to products they use. Consumers of medicinal products, food supplements (foodstuffs), cosmetic products and medical devices display substantial differences. They differ in the quality of their health and they differ in the needs that they wish to meet using the product concerned. A different state of health of consumers and a different urgency of their needs justify a different approach of the society to the level of legal protection provided to them.

If a market of a Member State witnesses a situation in which the same consumers use products of different categories for the same purpose, such a state cannot be justified on the basis of the theoretical premises described above (Grmelová, Vavrečka, 2014). There has been either a fundamental shortcoming at the level of the legislation or the respect for and enforcement of law has failed.

1.1 Food supplements and medicinal products circulating on a common market

The most important clash concerning different categories of products having physiological functions has been witnessed by the legal regulation and correct demarcation of food supplements and medicinal products.

Medicinal products are aimed at patients (i.e. consumers having ill health) to eliminate and alleviate the symptoms of their disease. Consumers having such a non-physiological state have an objective and urgent need to be assisted in changing their current unsatisfactory state of health. If they wish to meet this need by a product (having a pharmacological, immunological or metabolic effect), they enjoy a high level of legal protection. The legal regime of medicinal products provides such a protection to this group of consumers. Therefore, all products foreseeably used by such consumers to meet their urgent needs should be legally qualified as medicinal products.

Food supplements, on the other hand, constitute a special category of foodstuffs. The legal regulation of food supplements provides for a considerably lower level of legal

protection of consumers compared to the legal regulation of medicinal products. Less urgent medical needs are expected to be met by these consumers of food supplements under EU Law. Consumers using food supplements should merely maintain their good state of health. Food supplements should assist them in preventing future possible health problems. Such problems are either not present yet with these consumers at all or they are present, however, they do not signal an acute human disease (such as fatigue, tendency to sweat etc.). Food supplements may also be used to promote a normal development and growth of the body of a child. The protection provided to consumers by the legal regulation of food supplements corresponds to the need of a nutritional prevention of basically healthy population. Consumers having ill health who are using food supplements may use these only to meet the same needs as healthy consumers. Food supplements cannot be used for therapeutic treatment of the very disease and its symptoms.

It is essential to stress that the definition of a medicinal product in EU law (Directive 2001/83/EC) displays two important characteristics. Firstly, it has to be given a priority use (CJEU: Cases C-112/89, C-369/88). This is logical, since this definition provides for the oldest legal protection of consumers. Where there are reasons for an extensive legal regulation of consumers one cannot justify the application of a lower level of legal protection on grounds of meeting the conditions for the application of such a regime as well.

The second crucial feature of EU law is the fact that the definition of a medicinal product in EU law is a composite definition. It is made of two mutually independent definitions: The so-called definion “based on the function” and the definition “based on the presentation” (CJEU: Joint Cases C-211/03, C-299/03, C-316/03 – C-318/03). The definition of a medicinal product “based on the function” makes sure that all medicinal products having an established healing function and an established impact on the functioning of the human body fall within the scope of a strict legal regulation. Consumers of products having a significant impact on the functions of the human body should be provided with a wide scope of legal protection. This provides at the same time for fair and equitable competition of producers of registered medicinal products since their products cannot compete with mere foodstuffs on the market, even if the latter displayed the same physiological functions.

The definition of a medicinal product “based on the presentation” should make sure that consumers having ill health do not use foodstuffs which cannot establish physiological functions instead of suitable medicinal products. This definition precludes misleading presentation of foodstuffs as medicine under a strict sanction of withdrawing the foodstuff

from the market as a non-registered medicinal product, since it does not display an established physiological function at all (CJEU: Case 227/82). At the same time, this definition prevents the breach of equal conditions of competition of manufacturers of registered medicinal products, since consumers may feel effectively addressed also by foodstuffs bearing a misleading presentation.

1.2. The aim of using a product and its significance

The wording of the definitions of these product categories aims at achieving the above objectives of EU law and of the mutual demarcation of the products concerned. This can be discerned from the fact that both the definition of a medical product and that of a food supplement contain the purpose of using these products as a decisive element. The purpose of use is not a property inherent in the very product, it not a property of its composition. The purpose of use is determined by the contents of the information leaflet and the advertisement. It is a subjective decision of the producer to opt for one or the other purpose of its product on a market. It is basically a logical construction. Consumers use products based on what they are aimed at and not based on the knowledge of the objective effects of their composition. The contents of commercial presentation appear to be more decisive than the composition of the product with respect to the manner of its use by consumers.

The manner of use, which is the key element of legal qualification of a product, creates a big problem when applying law in practice. The manner of use of a product offered to consumers may not be constant. It is a fact which may be subject to (substantial) changes in time. Whereas the properties of the composition of a product are static, the purpose of use of the product by consumers may by dynamic. The purpose of use is determined by the contents of the package, label and particularly the advertisement of the product (contents of the commercial presentation). If a product has been introduced to the market correctly as a food supplement, if may not continue being a food supplement in a two years´ time from the point of view of EU Law. Interference with commercial presentation changing the declared manner of use may result in changing its legal qualification. Such inferences, however, need not always come from the producer, but they may be introduced by national distributors (importers) or even by final salespeople if these engage in a large scale advertisement on their own.

1.3 Two levels of breaching EU Law

The breaching of rights and interests of consumers by the contents of commercial presentation displays two different levels. The first level consists in an incorrect qualification of a product from the point of view of EU Law. If a producer introduces a product to the market in a category which does not correspond to the purpose of its use, it will be used by consumers who are entitled to a different level of legal protection The producer thus breaches the consumer´ right to the scope of their legal protection even if the product states only true data and established scientific evidence.

The second level consists in misleading consumers by stating such effects of products which lack established scientific evidence of their effects. If the producer states the manner of their use with these products, yet its effects have not been established by scientific evidence yet, then the producer misleads the consumer in a typical manner.

2 Food supplements and problems of their regulation in the context of the new EU Law

Food supplements constitute products aimed at consumers who do not have an urgent need to use them. The prevention of future diseases and a healthy development of an individual motivate a certain group of consumers. On the other hand, this motivation is weaker compared to consumers who already have and notice specific health issues. Nutritional prevention of the occurrence of future diseases requires a long term and regular consumption of the same effective substance – of the same product. The effects are very slow and dilated in time. This has two logical consequences.

First, a natural need for an effective value which only manifests itself in a distant future is rather low with consumers as a whole. Particularly, higher aged group and seniors are naturally not motivated to initiate distant future prevention. Their needs are targeted at more prompt effects. Nutritional prevention carried out for a short period of time is unable to achieve any substantial changes to the human body. Only therapeutic prevention significantly influencing body functions, such as vaccination, may achieve these objectives. However, therapeutic prevention remains limited to medicinal products in the EU.

Second, the provision of the necessary scientific evidence is very demanding, both technically, and financially. Proving the efficiency of a medicinal product with respect to an existing disease is in a way easier than proving that a long term use of a foodstuff will prevent the occurrence of a certain disease with a healthy individual. It is not only the funding of these long term researches which creates a problem. Another one is the deficient motivation and the

objective incapacity of a high number of producers of foodstuffs to carry out such a scientific research. A legal introduction of successful innovations has been notably limited in this way. If the producer does not provide sufficient scientific evidence of physiological functions of a product with respect to the human body, it does not have a legal possibility to offer a product to consumers for any specific purpose.

2.1 New EU Law– regulation of nutrition and health claims made on food

In 2007 a new EU Regulation (Regulation (EC) No. 1924/2006) came into effect, which governs the conditions for using nutrition and health claims on food. This regulation introduces an exhaustive regulation of health claims having scientific evidence with respect to physiological functions of foodstuffs. The effects of this Regulation have significantly influenced the contents of advertisement and the manner of labelling food supplements and "healthy foodstuffs" with respect to consumers (Vavrečka, Štěpánek, 2012). This Regulation caused an outcry and huge resentment among the producers of food supplements. It has often been presented in public as new highly restrictive regulation. However, these claims on the new EU Law significantly contradict the facts.

Given the scope of the definition of a medicinal product and its preferential application, the producers of food supplements were not able to impute their products neither curative nor preventive effects with respect to human diseases. Regulation (EC) No. 1924/2006 has for the first time, as *lex specialis*, authorized the use of nutritional properties to foodstuffs as a prevention of occurrence of human diseases. This constitutes a notable deregulation of marketing restriction in the EU´s food law.

Regulation (EC) No. 1924/2006 has merely achieved a reliable enforceability of the ban on marketing claims which cannot be imputed to foodstuffs at all or which cannot be considered having sufficient scientific evidence. These requirements have been present in EU for a long period of time. The most important marketing restrictions which result from this regulation should have taken place long ago. However, administrative bodies of the EU Member States were unable to enforce this law in an effective way beforehand. Also, recital 14 of Regulation (EC) No. 1924/2006 makes reference to this fact.

2.2 The Legitimacy of "ineffective" food supplements on the common market of the EU

Expert assessment carried out by the European Food Safety Authority identified a large number of products on the EU market which lack any scientific evidence of beneficial effects

on human body. Therefore, these products cannot be legally offered to consumers for any specific purpose other than common nutrition. This concerns in particular food supplements offered in the form of capsules, tablets, granules, solutions or drops, which are unlikely to be used by a consumer because they taste well or because they extend the consumer´s food choices. This purpose of use which can be legally stated by producers does not raise any interest with consumers. Big sales of "ineffective" food supplements are generally associated with suspicions of using effective unfair commercial practices and breaching the regulatory objective of EU Law (Gongol, 2013). Therefore, it is questionable whether there is a legitimate social interest to successfully introduce food supplements to the EU market where they cannot be offered for any useful purposes.

This situation seems parallel to the regulation of homeopathic medicine. Homeopathic medicine does not require scientific evidence of physiological efficiency. However, the introduction of homeopathic medicine to the market is clearly not being restricted. On the contrary, legislative measures assist in introducing these products to the market. Nevertheless, it is still prohibited to offer consumers homeopathic medicine for therapeutic purposes, which have not been approved for their therapeutic indications. Effective regulation and standard marketing of homeopathic medicine lacking any scientific evidence thus remain at variance with law.

EU Law expects consumers to use homeopathic medicine only following a consultation with a homeopathic specialist. This clarifies the key aspects of regulating the market of products lacking scientific evidence of effects. In a therapeutic relation between a patient and a freely chosen medical doctor, the patient does not chose himself/herself medical products based on the information provided by their producer. Based on the principle of transferred confidence the patient relies on the specialist acting in his or her field to make the choice of the right product. Consequently, homeopathic medicines lacking scientific evidence of effects are placed on EU market on a legitimate basis, for the purpose of pursuing homeopathic treatment by homeopathic specialists. It is a fundamental right of consumers to apply their conviction the free exercise of which may prefer the choice of a homeopathic treatment of a patient. Homeopathic specialists must be allowed to use traditional products in their field. This is why their presence on the market is legitimate and cannot be challenged. If EU does not outlaw homeopathy, the introduction of homeopathic medicine to the market cannot be restricted, even though homeopathic medicines lack scientific evidence of their effects and they cannot be advertised to consumers effectively by means of commercial

communications. Nevertheless, the scope of the legal protection of consumers is defined by the urgency of their needs and that is why homeopathic medicines fall within the category of medicinal products.

The same principles may be applied to the situation of food supplements lacking scientific evidence of their physiological functions. Food supplements may be used as means of a nutritional prevention in a number of different therapeutic relations where the consumer transfers the confidence to a freely chosen specialist in a preventive protection of health. Nutritional therapists and alterative healers may use these products even for purposes which still lack sufficient scientific evidence. These therapists may inform the consumer as to the use of the product based on what they personally expect due to their expertise. It is their opinion which may not be a generally accepted scientific fact. For the purpose of nutritional therapists, but also for medical doctors who do not ignore preventive procedures, also food supplements may be introduced to EU market in a legitimate way, however, their producers may not legally offer them to consumers for any purpose in their commercial communication.

Conclusion

Regulation (EC) No. 1924/2006 which introduced an exhaustive regulation of nutrition and health claims does not constitute a new restriction in EU Law. On the contrary, it brings about significant deregulatory effects. It is merely an effective tool for enforcing EU having a long term existence. This law respects and uses principles of proportional protection of consumers with respect to their state of health and with respect to their needs. It is for this purpose that a demarcation between products having a physiological function on the common market into specific product categories was made. It is not so important, what the objective properties of the product are, but what consumers are likely to use it with respect to its commercially communicated purpose. These principles of EU regulation have not been adequately absorbed by some Member States and by some industries. An insufficient enforcement of this law and an incorrect interpretation thereof have established an incorrect perception that many marketing practices in the field of offering and promoting food supplements are legal. New EU Law which establishes a reliably enforceable ban on practices for which food supplement distributers have not been held liable for so far, gives the impression of a new restrictive regulation. Due to their composition, many food supplements cannot be offered to consumers for any legal purposes in commercial communications of producers on the EU market. Their legal use has been basically restricted for the purpose of nutritional prevention carried out by

specialists based on a conferred confidence by consumers and based on the consumers´ convictions. Also, a good previous experience may play a part when it comes to the demand for these products. The introduction of these products to the Union market is generally legitimate and cannot be challenged either directly or indirectly. However, their high sales turnovers in relation to their low needs give rise to serious doubts; doubts as to the legality of commercial practices which provide for high sales of these food supplements in practice.

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References

1. Court of Justice EU. Joint Cases C-211/03, C-299/03, C-316/03 – C-318/03, *HLH Warenvertrieb a Orthica*. ECR 2005, Volume I, p. 05141.

2. Court of Justice EU. Case C-112/89, *Upjohn*. ECR 1991, Volume I, p. 01703.

3. Court of Justice EU. Case C-369/88, *Dellatre*. ECR 1991, Volume I, p. 01487.

4. Court of Justice EU. Case 227/82, *van Bennekom*. ECR 1983, p. 03883.

5. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use.

6. Gongol, T. (2013). *Právní aspekty nekalé soutěže na internetu*. Karviná: Slezská univerzita v Opavě, Obchodně podnikatelská fakulta v Karviné.

7. Grmelová, N., Vavrečka J, Czech Republic: A New Strategy of EU Producers: Marketing Foodstuffs as Cosmetics and/or Medical Devices. *European Food and Feed Law Review [online]*, 2014, No. 4, pp. 261–262.

8. Guinta, R., Basile, G., Tibuzzi, A., Legislation on Nutraceuticals and Food Supplements: A Comparison between Regulations in USA and EU. *Bio-Fams for Nutraceuticals: Functional Food and Safety Control by Biosensors, 698/2010*, pp. 322-328

9. Nocella, G., Kennedy, O., Food health claims – What consumers understand. *Food Policy, 37(5)/2012*, pp. 571-580.

10. 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.

11. Starling, S., Insider view: European food supplements market set for E2bn jump. *www.nutraingredients.com*, *25. 8. 2014 [online]*.

12. Vavrečka, J., Štěpánek, P., Regulace používání zdravotních tvrzení u potravin. *Právní fórum, 12/2012*, pp. 552-559.

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