ADVERTISING FOOD SUPPLEMENTS IN BULGARIA: A COMPARATIVE ANALYSIS OF REGULATORY FRAMEWORKS

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Abstract: The regulatory framework of food supplements in the European Union follows synchronized rules and imperative guidance while it vastly differs in terms of the practicalities of the manner in which national regulations are structured and enforced. This paper aims to examine in detail the case of Bulgaria, where the rules on advertising food supplements are contained in the Regulation on Food Supplements, complementing the Foods Act of 2020. The recently updated national legislation refers to and implements relevant European Union acts, while introducing certain national criteria applicable to the advertising and labelling of food supplements. Unfortunately, such criteria appear quite inefficient as they have proven to be very limited in terms of their scope and practicability. Besides that, mechanisms established to ensure compliance with national regulations have failed to achieve the intended goals. Because evaluation methods vary significantly across departments of the Bulgarian Foods Safety Agency, inconsistencies have emerged in how national regulations concerned with food supplements advertising are interpreted and applied. As a result, the Bulgarian regulatory framework on the advertising of food supplements has fostered a disorderly environment, rather than one of compliance and consistency. In contrast, and while not perfect, the regulation of medicinal product advertising in Bulgaria has been found effective, easier to comply with, structured, clear and exhaustive enough to provide commercial entities choosing to advertise their medicinal products among end users and medical practitioners with coherent advertising guidance and clear boundaries. In practice, medicinal product advertising regulations ensure both compliance and predictability, clearly defining what is permissible, as well as the limits of the responsible national authority's competency. The key difference between the two systems lies in their enforcement. Food supplement regulations are legally established and compulsory yet rarely enforced by the Bulgarian Food Safety Agency. In contrast, medicinal products regulations require prior permission from the Bulgarian Drug Agency as a prerequisite for publishing any advertisement. The present case study conducts a comparative analysis of national regulatory frameworks in both fields. It argues there is a lack of legal certainty regarding the applicable rules, as well as a lack of clarity concerning the criteria used in assessing compliance of advertising materials for food supplements with national regulations. This article highlights the need to make these criteria and their applicability accessible to advertisers and the wider public, including consumers. It also argues that regulatory transparency in the field of food supplements would contribute significantly to ensuring compliance among commercial operators, reducing the volume of misleading advertising in the sector, and allowing competent national regulatory bodies to hold all violators accountable to the same standards.
Keywords: food supplements, comparison, medicinal products, regulation, compliance

1. INTRODUCTION

Recent consumer studies show that almost nine out of ten Europeans have used food supplements in their lives (Ipsos, 2022). Almost two-thirds of surveyed consumers use food supplements daily, driven by easy access and personal health awareness (EPPA SA/NV, 2025). In such an environment commercial operators compete to position their products as well as possible on a thriving market, actively using elaborate advertising strategies. Since food supplements are regulated as food products, they could be conveniently found in supermarkets, drugstores and websites. Advertisements of all kinds of food supplements could be seen all around us in the physical world, as well as online, relying heavily on nutrition and health claims to attract consumers (Obstfeld & Lohmann, 2025).

In this context the regulatory framework of food supplements in the European Union (EU) includes carefully crafted legislative acts, amongst which regulations, directives and even soft law instruments. The main ones include the General food law (Regulation (EC) No 178/2002), the Food supplements Directive (Directive 2002/46/EC), the Nutrition & health claims Regulation (Regulation (EC) No 1924/2006), and the Regulation on the provision of food information to consumers (Regulation (EU) No 1169/2011). These are complemented by the European Commission's guidance in the area, as well as the European Food Safety Authority's publications. At first glance, these legislative instruments appear to construct a comprehensive regulatory framework, containing detailed and presumably strict requirements related to the marketing of food supplements. Whereas this assumption is generally correct, the EU regulatory framework applicable to the advertising of food supplements remains rather basic. Regulatory gaps could be found in those Member States which have chosen to refrain from supplementing the EU acquis with more detailed national provisions or sector-specific guidance and good practices. Such is the case in Bulgaria. By choosing to automatically implement a few EU general consumer protection principles into its domestic legal system, Parliament has failed to create a reliable and

transparent regulatory framework applicable specifically to food supplements as a special rapidly expanding category of foods (EPPA SA/NV, 2025). Even though the Bulgarian legal framework on labelling and advertising of food supplements refers primarily to Regulation (EU) No. 1169/2011, the national Regulation on Food Supplements of 2021 contains a few explicit requirements applicable to advertisements. Amongst them is the addition of necessary warnings and information on the label of food supplements. In this regulatory environment advertisements for food supplements putting emphasis on human health can be found everywhere. The leadership position, however, is shared with medicinal products (Penkova, 2025). Unlike them, advertisements of food supplements often breach the law because of lack of legal clarity and inconsistency in the approaches competent authorities follow to ensure effective enforcement. This study examines the national rules governing food supplement advertising and their enforcement mechanisms. By comparing them with the more developed regulatory framework for medicinal products, it argues for the expansion of national rules on food supplements advertising. Alongside the revision of regulations, introduction of strengthened control is suggested to ensure fair competition and consumer protection.

2. MATERIALS AND METHODS

This legal case study applies a comparative research methodology aiming to look closely at the regulatory framework applicable to the advertising of food supplements in Bulgaria while examining the differences between such framework and the one applicable to medicinal products. It investigates in depth the strengths and limitations of the current legal regimes applicable to both sectors and identifies regulatory gaps. The analysis is based on the Regulation on Food Supplements of 2021, the Foods Act of 2020, Regulation No.1 for the requirements to advertisements of medicinal products of 2012 and the Medicinal Products in Human Medicine Act of 2007. Secondary sources, including peer-reviewed journals and official reports, are referred to for contextual interpretation. Examined legal instruments are chosen based on their direct applicability and relevance. Specific rules are set out to outline their practical implications and to demonstrate identified similarities, as well as the differences peculiar to each sector.

3. RESULTS AND DISCUSSIONS

The regulatory analysis conducted for the purposes of the present research indicated that in Bulgaria advertising of food supplements is not as strictly regulated as one might expect. The lack of control on part of the Bulgarian Food Safety Agency (BFSA, the Agency) over commercial operators in the sector has fostered an environment tolerating non-compliance. Compliant businesses had found themselves forced to turn to other competent institutions to guarantee conformity with the law of those who abused regulatory gaps. Such was identified to be the case of unfair competition fostered by some commercial operators through misleading or false advertising. The study observed there were several cases before the Competition Protection Commission (CPC) in Bulgaria, as well as national courts. The facts revealed therein demonstrated that all of them share a common theme – misleading the consumer. Inaccurate presentation of advertised products and texts amounting to health claims could be found in almost every case before the CPC the subject of which were advertisements of food supplements. These anticompetitive strategies were used in both print and online media. Some of the disputed advertisements included statements assigning food supplements properties related to the prevention or treatment of human diseases (SDC Decision No. 573, 2017, ACSC Decision No. 15878, 2025). Others contained false statements related to the composition and representation of the products. The CPC found those advertising practices to be entirely misleading the consumer and alerted they could be found via different communication channels. Their presence was established in television, print, electronic and social media (CPC Decision No. 996, 2023), meaning they could be easily accessed by anyone. These cases, however, did not fall under the scope of the Foods Act of 2020, nor the Regulation on Foods Supplements of 2021 (RFS). They were all decided under the Protection of Competition Act of 2008. In fact, only until recently there was no case law on the advertising of food supplements in Bulgaria. In the past months two decisions (SAC Decision No. 3742, 2026, ACSC Decision No. 24941, 2026) concerned with the application of Article 15 of the RFS were delivered by national courts. They were concerned with the administrative approach undertaken by the BFSA when assessing the compliance of food supplements advertisements with the law. Subject to BFSA's control in these cases were statements attributing food supplements the property to heal or to refer to such properties. The court decided while it was not competent to rule on whether such statements were legally made, it could rule on the appeals to acts imposing penalties, as issued by the BFSA. Judgments held that, in adopting administrative acts imposing sanctions on commercial operators, the Agency failed to provide a reasoned legal and factual justification for its conclusion that the regulatory requirements had been infringed. The courts found that the BFSA had not established the factual basis of the alleged violations through legally admissible and sufficient evidence, nor had it adequately demonstrated the applicability of the relevant legal provisions to the established facts. It was concluded that the evidentiary and reasoning requirements governing the lawful exercise of administrative sanctioning powers had not been satisfied on behalf of the Agency, meaning the BFSA did not fail those court cases because it was not legally right (as in fact it was right on the law). The Agency lost the

battle in court because it was unexperienced. The inspectors who conducted the disputed compliance audits were not well prepared on procedural rules and their proper application and presumably lacked key competences. As a result of inappropriate evaluation mechanisms and lack of instruments ensuring effective regulatory compliance, enforcement performance of the BFSA was poor.

The analysis went on to look in more detail at the specific national provisions applicable to the advertising of food supplements. It indicated that while the Regulation on Food Supplements of 2021 is a legal instrument concerned specifically with food supplements, setting out all special legal rules applicable to the said category, it only mentions the term 'advertisement' four times in the entire document. Two of them stipulate precisely forbidden approaches regarding labelling, presentation and advertising of food supplements. Two more refer to Regulation (EU) No. 1169/2011 and compulsory content information concerned with consumer safety.

A look at the European level framework was also necessary at this point. Regulation (EC) No. 178/2002, suggested that national legislation must firstly ensure the public interest in the process of building an effective regulatory framework in the sector. Article 8 of the Regulation specifically refers to the protection of consumers' interests:

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:
(a) fraudulent or deceptive practices;
(b) the adulteration of food; and
(c) any other practices which may mislead the consumer.

Article 16, on the other hand, ensures consumer priority through a rule on product presentation:

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Regulation (EU) No. 1169/2011 confirmed that information given to consumers with regards to food supplements must not be misleading (Article 7, paragraph 1), that it shall be accurate, clear and easy to understand (Article 7, paragraph 2), and must not '*attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties*' (Article 7, paragraph 3). The same rule contained Directive 2002/46/EC, as well (Article 6, paragraph 2). On the other hand, Regulation (EC) No. 1924/2006 allows the use of health claims for food supplements, but only if they were previously approved at the EU level for specific nutrients or substances.

On the national level, the Foods Act of 2020 introduced a registration regime for all food supplements marketed on the territory of Bulgaria. The aim lawmakers had in mind when introducing the Act was to keep the rapidly growing food supplements market under control. However, the obligation of commercial operators to submit a request for a food supplement to be included in the register of the Bulgarian Food Safety Agency is, in practice, mere formality. The legal framework requires certain documentation concerning the content of the product and its labelling to accompany such registration request, but in practice, the BFSA does not conduct any product tests to establish whether such documentation is accurate. Once a food supplement is registered, its importer/distributor must, on its own, ensure compliance with the RFS. In the context of advertising this means compliance with Articles 14 and 15 of the Regulation.

Article 14 of the RFS states:

(1) The provision of information on food supplements by means of labeling, presentation, and advertising shall be carried out in accordance with the requirements of Regulation (EU) No. 1169/2011.
(2) In addition to the information referred to in paragraph 1, the following particulars shall also be mandatorily declared:
1. the names of the categories of nutrients or substances that characterize the product, or an indication of their nature;
2. the recommended daily dose;
3. a warning not to exceed the recommended daily dose;
4. a warning that the product should not be used as a substitute for a varied diet;
5. a warning that the product should be stored out of the reach of young children;
6. the registration number and date of entry of the food supplement in the register under Article 24(1) of the Food Act.

Article 15 of the RFS states:

(1) The labeling, presentation and advertising of food supplements shall not attribute to such products the property of preventing, treating or curing human disease, nor shall they refer to such properties.
(2) The labeling, presentation and advertising of food supplements shall not include any statement or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients.

The provisions of Articles 14 and 15 contain the only rules directly concerned with food supplements advertising at the national level. They were introduced in Bulgarian legislation through a collection of rules

extracted from different EU legal instruments. And while Article 14 is concerned with the safety of the food supplement, Article 15 explicitly forbids commercial operators attributing food supplements the property to heal or to refer to such properties. It also forbids the inclusion of statements implying that the consumer cannot receive necessary nutrients solely through foods. The analysis of their enforcement found these texts insufficient to build a transparent and clear framework of food supplements advertising and leaving so much room for interpretation that, in practice, the rules do not have any impact on commercial operators advertising food supplements in Bulgaria. In addition, without a proper enforcement mechanism, the sector is practically ungovernable.

The failure of the regulatory framework on advertising food supplements was also confirmed by the success of another.

On the very opposite side of the advertising coin stands Bulgarian legislation covering medicinal products. It is contained in the Medicinal Products in Human Medicine Act of 2007, but also in a separate act, namely Regulation No.1 for the requirements to advertisements of medicinal products of 2012. Having their very own special regulation, advertisements concerned with medicinal products were confirmed as following a structured, balanced and competitive regulatory framework, which ensures fairer competition and transparency. As per Article 2 of Regulation No.1 of 2012 it is only after a written approval is issued by the Bulgarian Drug Agency (BDA) that an advertisement could be made accessible to consumers. Compliance of commercial operators with this obligation is guaranteed by high monetary sanctions. Any commercial operator who does not inquire BDA's approval in this context is in breach of the law and could be fined up to 10 000 EUR. Further, it was established that national legislation governing the advertising of medicinal products imposes not only general regulatory requirements but also mandatory instructions, prescribed texts, and technical requirements commercial operators must comply with. For example, Article 5 of Regulation No.1 of 2012, paragraphs 3 and 4 read as follows:

(3) The Bulgarian Drug Agency may require that the composition of combination medicinal products, as well as specific information regarding the safety of the medicinal product's use, also be presented in the advertisement.

(4) In video advertisements, the information referred to in Paragraph 2, items 2, 4, 5, and 6 must be displayed on a freeze-frame in large, legible letters as static text. This text must be read aloud by a narrator.

In addition, Article 6 indicated 13 explicit prohibitions of what is considered unacceptable with regard to the content of advertisements of medicinal products, some of which include: creating the impression that advise from a medical practitioner is not necessary when the medicinal product is consumed, or that the effects following use of the medicinal product are guaranteed or are not accompanied by adverse drug reactions, or where the advertisement refers to recommendations from scientists, medical specialists or other persons who, due to their popularity, could encourage the use of the medicinal product. These rules were found to be largely absent from the regulation of food supplements to the detriment of consumers. Unsurprisingly the analysis established that often direct access to the consumer in the food supplements sector is as easy as it is in a non-regulated environment. The main difference between the analyzed regimes, however, was shown to lay in enforcement. While the BFSA only evaluates an already published advertisement concerning a food supplement because of a claim submitted by a competitor, the BDA assesses whether an advertisement of a medicinal product complies with the applicable law before that advertisement is published and later on acts on competitor's claims and its own compliance audit campaigns.

The findings suggested that regulation on food supplements advertising in Bulgaria is inefficient due to its limited scope and lack of proper enforcement. The fact that it only addresses the provision of information related to the obligation of commercial operators to mention the categories of nutrients or substances that characterize the product, recommended daily dosage and a few safety warnings, shows that the applicable regulation is focused on ensuring the advertised products are compliant with the law in the sense that they provide sufficient information to the consumer about the content of the advertised products and the intake instructions. The explicit prohibitions on including expressions which tell consumers food supplements could cure a disease (a characteristic attributable only to medicinal products) or that they could be a substitute for a balanced diet, do not broaden the scope of the national regulatory framework in any way. They are simply prohibitions which cannot and must not serve as guidelines for commercial operators advertising their food supplements on the market as they are otherwise a must.

Entities advertising food supplements have to be afforded access to the criteria used by the BFSA when considering the lawfulness of an advertisement in the sector. They should also be given the opportunity by the Agency to comply with regulations in a reasonable and effective manner. For this to happen, the BFSA must publish advertising guidelines tailored to the food supplements sector. Such document must include instructions on how the law is applied and ways in which it could be followed properly, relevant examples and real case scenarios from BFSA's practice. Once such guidelines are present, both compliance and enforcement would be much more effective.

Further, lawmakers must admit the fact that in its current state the regulatory framework is unable to ensure compliance with national rules. This would be a step in the right direction as Bulgarian Parliament must swiftly

initiate legislative changes which could update the regulations in line with BFSA's administrative practice and the rapidly developing sector. Special attention in this process should be given to advertising of food supplements online and the present lack of necessary means for their control in BFSA's set of tools. In other words, the Agency must be given powers to sanction wrongdoers online as soon as possible – a measure previously discussed (Ministry of Economy and Industry of the Republic of Bulgaria, 2025), but never implemented.

4. CONCLUSIONS

The analysis of the regulatory framework of food supplements in Bulgaria reveals the unsuccessful attempt of Bulgarian lawmakers to introduce clear standards, if any, applicable to the advertising of food supplements to consumers. This is demonstrated by the exhaustive review of the arrangement of food supplements advertising in the national law, as well as its comparison to regulations applicable to advertisements of medicinal products. In addition, it is argued that the key difference between the two systems lies in their scope and enforcement. This article has found regulations applicable to medicinal products to be more transparent, effective and structured as the Bulgarian Drug Agency controls the entire process of medicinal products advertising – from the approval of the creative idea of the advertisement, to the post-publishing control of advertisements both offline and online. It is, therefore, suggested that advertising of food supplements must be subjected to clear and exhaustive rules, transparent prior approval procedure before the BFSA and comprehensive guidance of commercial operators on behalf of the competent authority. The above could only be achieved by means of swift and adequate legislative changes and effective control. The expected results are enhanced consumer protection, better protected notion of fair competition amongst commercial operators in the sector, as well as the disposal of a dysfunctional regulatory framework.

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