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THE ADMINISTRATIVE LAW REGIME OF FOOD SUPPLEMENTS

AUTHOR'S ABSTRACT

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1 INTRODUCTION

The subject matter of the present study is the legal framework governing the production, placing on the market, and provision of information concerning food supplements, as well as the exercise of control in this regard.

The study analyses a comparatively new object of legal regulation, one that is developing dynamically in conditions of a free market, advances in nutritional science and biotechnology, and growing consumer demand.

The need for such a study is dictated by the fact that the prevailing literature examines food supplements from a medical, pharmacological, or technological perspective, while legal analysis remains fragmented and is usually confined to isolated aspects of food law. Despite the significant expansion of the food supplements market, the current regulatory framework remains fragmented and inconsistent. At the national level, terminological inaccuracies, regulatory gaps, and difficulties in applying European standards persist, giving rise to inconsistent administrative and judicial practice.

Analysis of the applicable normative acts reveals a search for balance between consumers' rights and traders' rights in the context of the free market. Viewed as two separate variables, their regulation – the creation of restrictions or of guarantees and safeguards – proves to be proportionally interdependent. Within that relationship, in regulating the social relations connected with food, and food supplements in particular, a third variable intervenes: science and scientific achievement, which influences the market through the products thereby created and through the capacity to meet consumers' health-related needs through food. Visualised, these interdependencies may be represented in a coordinate system in which the X-axis represents consumers' rights, the Y-axis represents the rights of economic operators together with the principles of competition and the free movement of goods, and the Z-axis represents scientific achievement. The advent of new technologies may improve products or expand the scope of their impact on human health. Traders who manufacture and place such products on the market require an appropriate legal framework that does not impede the relevant achievements. Standing opposite is the constant of human health, which must be protected. It is precisely the interplay of these dependencies within this coordinate system that constitutes the subject of the study.

The aim of the dissertation is therefore to systematise the current regulatory framework and to assess its effectiveness in regulating the social relations within the area under examination.

In order to achieve this aim, the following tasks have been set: analysis of the principal legal concepts and their delimitation; examination of the applicable national and European regulatory framework; analysis of the regime governing production, placing on the market, labelling, advertising, and the use of health claims; examination of the mechanisms for administrative control and the imposition of sanctions; and the formulation of *de lege ferenda* proposals.

The study employs the historical, comparative-legal, systemic, and formal-legal (doctrinal) methods. Particular attention is devoted to the case-law of the Court of Justice of the European Union, as well as to national administrative and judicial practice.

The thesis advanced is that food supplements formally form part of the legal regime governing food, but their specific characteristics place them within a borderline regulatory zone between foodstuffs and medicinal products. This gives rise to regulatory gaps, inconsistency in the application of the law, and difficulties in exercising effective control.

The study defends the understanding that the principle of proportionality should be the guiding criterion in assessing regulatory choices within the area under examination, and that the balance between health protection, the free movement of goods, and economic initiative should be grounded in scientific justification. In this process of interaction, EFSA plays an essential role, since its scientific assessments have a direct bearing on permissible health claims and on regulatory decisions.

The structure of the dissertation follows the logic of administrative-law analysis. Chapter One examines the basic concepts and the regulatory framework. Chapter Two analyses the legal regime governing the production, placing on the market, labelling, presentation, and advertising of food supplements. Chapter Three examines the mechanisms of control, coercive administrative measures, administrative-penal liability, and the problems connected with the allocation of competences among the supervisory authorities.

2 CHAPTER ONE. Concepts and Regulatory Framework

2.1 The concept of food supplements

The study analyses the statutory definition of the concept of “food supplement” contained in § 1, item 21 of the Supplementary Provisions of the Foodstuffs Act and in Article 2 of Directive 2002/46/EC.

It is established that the concept comprises several core elements: membership in the category of “foodstuffs,” a purpose of supplementing the normal diet, a specific composition, a dosed form, and intake in pre-determined quantities.

The conclusion is drawn that, although food supplements are formally classified as foodstuffs, their factual characteristics bring them closer to products used in medicine, dietetics, and pharmacy, which gives rise to tension between their normative classification and their actual functional purpose.

2.2 Distinctions from other concepts

This part draws distinctions between food supplements and similar legal categories, with a view to clarifying the boundaries of the applicable legal framework and overcoming terminological inaccuracies.

2.2.1. Foodstuffs

The statutory definition of food under Regulation (EC) No 178/2002 is analysed. It is established that food supplements formally fall within the category of foodstuffs, but their dosed form, concentrated composition, and specific purpose distinguish them from ordinary foodstuffs. Questions are raised as to the systematic consistency of the Foodstuffs Act with regard to the classification of categories of food.

2.2.2. Nutrients and other substances with a nutritional or physiological effect

The distinction between traditional nutrients and the category of “other substances with a nutritional or physiological effect” is examined. It is established that it is precisely with regard to this second category that the greatest degree of normative indeterminacy and the absence of full harmonisation at EU level are observed. Unlike vitamins and minerals, for which positive lists exist, the remaining substances are often admitted to the market owing to the absence of an express prohibition rather than following a prior positive safety assessment.

2.2.3. Food additives

A distinction is drawn between food supplements and food additives, it being established that there is a degree of terminological conflation in national practice and in certain translations of European acts, notwithstanding the differing legal regimes applicable to the two categories. Thus, in the national regulatory framework and in certain translations of acts of EU law, a conflation is observed between the concepts of food supplements and food additives, even though these designate different categories of products subject to different legal regimes.

2.2.4. Food for specific groups

A distinction is drawn between food supplements and food intended for specific groups under Regulation (EU) No 609/2013. The conclusion is reached that, in respect of food for specific groups, the legislature applies materially stricter prior control over composition and placing on the market, whereas a significantly more liberal regime has been adopted for food supplements.

2.2.5. Medicinal products and medical devices

The distinction between food supplements and medicinal products is examined through the criteria developed in the case-law of the CJEU concerning medicinal products by function and medicinal products by presentation. The conclusion is drawn that, in its case-law, the CJEU seeks to balance the protection of public health against the free movement of goods, avoiding both an excessive extension and an unjustified restriction of the scope of medicinal product legislation.

The criteria developed by the CJEU concerning medicinal products by function and by presentation are analysed. It is established that it is precisely within this borderline zone that the most serious practical problems arise, particularly in respect of products containing high doses of active substances, plant extracts, and suggestions of therapeutic effect.

The distinction from medical devices, where the mechanism of action differs, is also examined.

2.2.6. Narcotic substances

The distinction between food supplements and products containing narcotic substances or substances with a potentially prohibited effect is examined.

It is established that, in respect of certain categories of products – particularly supplements aimed at athletic performance, weight reduction, and physical conditioning – practical problems arise in connection with the inclusion of prohibited or high-risk substances, which raises questions as to the effectiveness of prior control.

The overall conclusion drawn from the analysis in this part is that, notwithstanding the formal normative classification of food supplements as foodstuffs, their characteristics place them at the intersection of several distinct legal regimes, which creates the preconditions for subsequent problems in regulation and control.

2.3 Other concepts relevant to the area under examination

Additional concepts of relevance to the proper application of the regime governing food supplements, and to determining the subjects of liability, are analysed.

2.3.1. Official control and other official activities

The regulatory framework governing official control under EU law is examined; it is established that, with regard to food supplements, control is predominantly ex post and directed at identifying non-conformities after the products have been placed on the market.

2.3.2. Business operator or economic operator in the food industry

This is one of the principal subjects in the legal relationships connected with the production, processing, and distribution of food supplements. It does not constitute an independent type of legal subject, but rather a functional legal category by means of which the bearers of specific rights, obligations, and liabilities are identified. The concept originates in EU law and is laid down in Article 3(3) of Regulation (EC) No 178/2002 (“food business operator”), rendered in the Bulgarian translation as “economic operator in the food industry.” The analysis shows that a broader approach has been adopted in national law, since Article 9 of the Foodstuffs Act encompasses not only persons controlling food-production undertakings but also subjects engaged in distribution and trading activities.

A terminological inconsistency is also established, in that various national normative acts use, in parallel, the concepts of “business operator” and “food undertaking operator,” notwithstanding that both derive from the same term – “food business operator.” Further

difficulties arise in distance selling of food, where it is not always clear which subjects bear the relevant obligations and administrative-penal liability.

The conclusion is drawn that this terminological and substantive inconsistency creates difficulties in the application of the law and requires more precise and consistent use of the concepts with a view to ensuring legal certainty.

2.3.3. Consumer

The concept is examined in the context of food legislation. It is established that the perception of the average consumer is of material significance in assessing the presentation and advertising of food supplements.

2.3.4. Food business undertaking within the meaning of Regulation (EC) No 178/2002

The content of the concept and its significance for determining the scope of administrative control and the subjects bearing liability in the production process are clarified.

2.4 Regulatory framework in the field of food supplements

2.4.1 The legal framework of the European Union

This part establishes that the legal regime governing food supplements at EU level is not laid down in a single normative act but constitutes a system of interacting horizontal and sectoral norms, founded on Regulation (EC) No 178/2002 as the general framework of food law, supplemented by Directive 2002/46/EC, Regulation (EU) No 1169/2011, and Regulation (EC) No 1924/2006, which are likewise analysed.

A terminological inconsistency is established in the Bulgarian-language version of Directive 2002/46/EC, in which the concept of food supplements is in certain instances rendered in a manner liable to be confused with the concept of food additives.

The analysis shows that only partial harmonisation exists, since exhaustive regulation at EU level exists solely in respect of vitamins and minerals, whereas no uniform positive regime exists for “other substances with a nutritional or physiological effect.”

The conclusion is drawn that the current European legal framework is fragmented and leaves significant regulatory questions to the national level, which creates the preconditions for divergence in the application of the law.

2.4.2 National regulatory framework

The development of the national regulatory framework is characterised by delayed normative response, lack of systematic coherence, and terminological inconsistency. In the early stages, food supplements were not treated as an independent legal category, and various normative acts from the 1990s either failed to regulate them at all or addressed them only indirectly, alongside other products.

A protracted terminological conflation is also established among the concepts “food supplements,” “additives to foodstuffs,” and “additives in foodstuffs,” whereby the same term has been used to denote categories that differ in their legal nature, creating difficulties in the interpretation and application of the legal framework.

The first attempt at independent regulation was made through the 2003 amendments to the Foodstuffs Act, while a more systematic framework was introduced by Ordinance No 47 of 2004, which transposed EU requirements and established a specific regime for food supplements.

Even at that stage, however, practical problems were identified in connection with the presentation of food supplements as an alternative to medicinal products, their aggressive advertising, and the lack of clarity as to the legal status of market participants.

The conclusion is drawn that the national regulatory framework has developed reactively and has not fully overcome the conceptual and terminological deficiencies that arose at the outset, some of which continue to affect the current legal regime.

2.4.3 Comparative analysis of the regulation of food supplements outside the EU

A comparative analysis is carried out of models outside the EU, including those of the United States, Canada, Australia, New Zealand, and Japan.

It is established that different legal systems adopt differing degrees of prior control, underscoring the absence of a universal regulatory model.

The principal conclusion is that, even at the conceptual and normative level, preconditions exist for subsequent problems in the application of the law – unclear boundaries between legal categories, a fragmented regulatory framework, and the absence of a fully consistent regulatory model. The formal treatment of food supplements as a mere subcategory of

foodstuffs fails adequately to take account of their specific characteristics and creates preconditions for problems in placing on the market, advertising, and control.

3 CHAPTER TWO. The Legal Regime Governing the Production, Placing on the Market, and Provision of Information on Food Supplements

3.1 General principles

The study traces the relationship between the general principles of EU law, the mechanisms of risk management, the regime governing market access, the rules on product composition, and the restrictions on the provision of information.

The legal framework governing food supplements is built upon several core principles: a high level of protection of human health; the free movement of goods; legal certainty; and proportionality.

These principles are enshrined in EU primary law and find concrete expression in Regulation (EC) No 178/2002.

There exists a lasting structural tension between the principle of health protection and that of the free movement of goods, which is particularly apparent in the case of food supplements owing to their borderline character between foodstuffs and products with a pronounced physiological action.

Of particular significance is the precautionary principle under Article 7 of Regulation (EC) No 178/2002, which permits restrictive measures in conditions of scientific uncertainty connected with a risk to health. The analysis shows that this principle frequently performs a compensatory function owing to the absence of sufficiently effective prior control over certain categories of food supplements.

3.2 Instruments for implementing the principles

Regulation (EC) No 178/2002 establishes the mechanisms through which the abstract principles are translated into a concrete regulatory framework. The following are examined as such mechanisms: risk analysis; scientific risk assessment; the exchange of information; traceability; the liability of economic operators; and mechanisms for the withdrawal of dangerous products.

3.3 National competent authorities

Competence for the regulation of food supplements in Bulgaria is distributed among multiple authorities whose powers frequently overlap, resulting in inefficiency of control. A central role is played by the Bulgarian Food Safety Agency (BFSA), which exercises official control over the safety, composition, labelling, registration, and placing on the market of food supplements, and which applies coercive administrative measures and administrative penalties.

At the level of state policy, competences are vested in the Minister of Agriculture and Food and the Minister of Health, the latter being of particular significance with regard to products with a potential pharmacological action. In this connection, a structural problem is identified with regard to borderline products, since the Bulgarian Drug Agency has competence to determine whether a given product is a medicinal product, while the Foodstuffs Act lacks a mirroring mechanism for coordination with the BFSA, which creates a regulatory asymmetry.

Supervisory functions in relation to presentation and commercial practices are also exercised by the Commission for Consumer Protection (CCP) and the Commission for Protection of Competition (CPC), while the Risk Assessment Centre along the Food Chain and the National Centre of Public Health and Analyses perform a scientific-advisory role. The conclusion is that the current model is functionally fragmented, weakly coordinated, and creates preconditions both for ineffective control and for inconsistent application of the law.

3.4 Authorisation regime, procedure, and requirements as to the qualitative and quantitative composition of food supplements

The regime governing the placing of food supplements on the market is laid down in the Foodstuffs Act and in the Ordinance on Food Supplements. It is established that the regime is one of notification/registration rather than prior authorisation, the principal procedure being conducted before the Executive Director of the BFSA.

A significant regulatory problem is presented by the possibility for a food supplement to be placed on the market before its final entry in the register has been completed. This creates a risk that a product of disputed composition or unclear legal status may reach consumers before the administrative review has been concluded. A further difficulty arises

from the inconsistency between the provisions permitting prior placing on the market and those presupposing placing on the market only following registration.

Uncertainty is also established in the regulation of restrictive measures. The Ordinance on Food Supplements provides for the possibility for the BFSa temporarily to prohibit or restrict the marketing of a food supplement, but it is not sufficiently clearly regulated as to which products this measure applies – those already registered, those undergoing the registration procedure, or those subject to the mutual-recognition regime under Regulation (EU) 2019/515. This leads to the conclusion that, *de lege ferenda*, the types of coercive administrative measures available to the BFSa authorities at the various stages of the market-access regime should be expressly regulated.

As regards qualitative and quantitative composition, it is established that, with regard to vitamins and minerals, a relatively detailed framework exists through positive lists, permitted forms of the substances, and maximum permissible quantities. The category of substances with a nutritional or physiological effect, including botanical substances and botanical preparations, is significantly more problematic, there being no comparable degree of harmonisation or prior assessment.

Substances with a pharmacological, stimulant, or psychoactive action, as well as substances falling within the scope of narcotic-substances legislation, are of particular significance. Control over such ingredients remains at the boundary between the competence of the BFSa and that of the authorities of the Ministry of Health, which creates a risk of institutional gaps. It is precisely in respect of such products that the problem of classifying food supplements as foodstuffs is most clearly manifested, notwithstanding that they may in fact contain substances with an effect characteristic of more strictly regulated categories of products.

A further normative problem arises from the use of differing concepts in the national and European frameworks. The Ordinance on Food Supplements uses concepts such as “botanical substances,” “botanical preparations,” “substances,” and “products,” whereas Regulation (EC) No 1925/2006 operates with the concepts of “substance” and “ingredient.” This divergence may create difficulties in the imposition of prohibitions and restrictions.

In this context, the judgments of the General Court in Cases T-302/21 and T-274/21, concerning hydroxyanthracene derivatives, are analysed. They show that restrictive measures under Article 8 of Regulation (EC) No 1925/2006 must be directed at substances and ingredients for which an actual risk has been established, rather than at entire preparations or finished products falling outside the scope envisaged by the Regulation.

The principal conclusion is that the regime governing the placing on the market and control of the composition of food supplements contains certain unsatisfactory normative solutions: a notification-based regime allowing for prior market access, unclear regulation of restrictive measures, terminological inconsistency, and insufficient coordination as regards substances with a pharmacological or prohibited effect. This confirms that the current model is reactive rather than preventive in character.

3.5 The European institutional framework for the regulation of food supplements

At EU level, competence for the regulation of food supplements is distributed among several institutions and bodies whose functions rest upon the distinction between legislative activity, scientific risk assessment, and risk management.

The European Parliament and the Council adopt the principal normative acts in the field of food on a proposal from the European Commission. Scientific risk assessment is carried out by EFSA, while risk management – including the adoption of measures, restrictions, or prohibitions – is entrusted to the European Commission, assisted by the Standing Committee on Plants, Animals, Food and Feed.

Coordination and the exchange of information among Member States are carried out through the Rapid Alert System for Food and Feed (RASFF), which is of considerable importance whenever risks connected with food supplements arise. In certain cases, other bodies are also of significance, such as the European Medicines Agency and the European Chemicals Agency, particularly with regard to borderline products or substances with a potential pharmacological or toxicological action.

The European institutional framework formally establishes a clear distinction between scientific expertise and administrative decision-making; in practice, however, EFSA's scientific opinions carry substantial weight in the final regulatory decisions, raising the

question of the actual relationship between science and law within the regime governing food supplements.

3.6 The role of the European Commission (EC) and the European Food Safety Authority (EFSA)

This part analyses the functional allocation of competences between the European Commission and EFSA in the regulation of food supplements.

It is established that the Commission exercises risk-management powers through the adoption of delegated and implementing acts, the amendment of technical annexes, the management of lists of authorised substances, the authorisation or refusal of health claims, and through coordination of and oversight over the application of EU law by the Member States.

In the absence of full harmonisation, Member States retain a limited national competence, which must be exercised in compliance with the principles of the free movement of goods, health protection, and proportionality. In this connection, the case-law of the CJEU in Case C-446/08 is analysed, which set out the limits of national autonomy in determining maximum amounts of vitamins and minerals.

The role of EFSA as an independent body for scientific risk assessment is examined. It is established that EFSA possesses no rule-making or supervisory powers and that its opinions are formally non-binding.

It is nonetheless established that, in practice, EFSA's scientific opinions function as a de facto binding regulatory standard, particularly in the field of health claims. Where a scientific opinion is negative, the Commission as a rule refuses authorisation of the relevant claim, and national authorities treat such assessments as a practically insurmountable criterion.

Rigorous scientific assessment performs a compensatory function owing to the absence of sufficiently effective prior control over food supplements. This cannot, however, justify the automatic conversion of scientific uncertainty into a ground for excessive restrictions.

Nor does the structural problem stem from the very existence of EFSA, but rather from the absence of sufficiently flexible mechanisms for subsequent risk management, which results in the scientific assessment being overburdened with regulatory functions.

3.7 Nutrition and health claims

The regime governing nutrition and health claims under Regulation (EC) No 1924/2006 is analysed as one of the central elements of the legal framework governing food supplements. Since food supplements are foodstuffs, the rules on claims apply to them; however, the specific nature of their form, composition, and purpose creates a heightened risk of borderline statements that approach medicinal claims.

The Regulation introduces the general concept of a “claim” as any message or representation, including pictorial, graphic, or symbolic representation, which states, suggests, or implies that a food has particular characteristics. In this sense, what is legally relevant is not only the express statement but also the overall impression created in the mind of the consumer.

A distinction is drawn between nutrition claims and health claims. Nutrition claims relate to the energy value or content, the reduced, increased, or absent quantity of nutrients or other substances. Health claims, for their part, establish a link between a food, a category of food, or one of its constituents and health, and therefore carry a significantly higher regulatory risk.

It is established that, in respect of health claims, what is decisive is not the formal structure of the statement but its overall communicative effect on the average consumer. In the case-law of the CJEU, the concept of “health claim” is interpreted broadly and contextually, taking into account the type of product, the addressee of the message, and the overall presentation. This is of particular importance for food supplements, where the name, packaging, visual elements, and advertising context often have a stronger effect than the verbal formulation itself.

The study systematises the principal types of health claims: function claims under Article 13 of Regulation (EC) No 1924/2006, which relate to normal physiological functions of the body; claims under Article 14 concerning the reduction of disease risk; and claims relating to children’s development and health. Further analytical criteria of distinction are derived according to the degree of specificity, the manner of presentation, regulatory status, the object affected, and the addressee of the claim.

Of material significance is the distinction between authorised, rejected, and pending claims. Regulation (EU) No 432/2012 adopted a partial list of authorised function health

claims, while a substantial proportion of claims – particularly those relating to botanical substances – remain in so-called “pending” status. An asymmetric regime is thereby created: a relatively clear and functioning model exists for vitamins and minerals, whereas prolonged regulatory uncertainty continues to exist with regard to botanical substances. This uncertainty gives rise to serious practical problems. On the one hand, the Regulation establishes a principled prohibition on the use of unauthorised health claims. On the other, the transitional regime and the continued non-completion of the assessment of a large number of claims create conditions conducive to the use of formulations that lie at the borderline of what is permissible.

Several principal types of non-conformity are observed in practice: deviation from the conditions of use of authorised claims; the use of health claims in the absence of authorisation; and circumvention of the prohibition through general, implicit, or marketing formulations that suggest a health effect. Particularly problematic are cases in which authorised claims relating to vitamins or minerals are used as a vehicle for suggesting effects that are not authorised for the remaining ingredients of combined food supplements.

Melatonin is examined as an example, in respect of which an authorised function health claim exists subject to strictly defined conditions. Deviation from those conditions – whether through the use of higher doses or through the addition of statements as to the absence of habituation – results in departure from the permissible regime and an approach toward a medicinal characterisation.

Particularly problematic are claims relating to probiotic strains, botanical substances, immunity, weight control, “fat burning,” “detoxification,” or “support for the body.” Such claims frequently employ borderline formulations that are formally descriptive or general in appearance but, in the context of the overall presentation, create a health implication.

In this connection, the case-law of the CJEU is analysed, including the judgment in Case C-386/23, in which it was held that specific health claims relating to botanical substances may not be used until the Commission has completed their assessment and they have been included in the relevant lists. The Court likewise confirmed that general, non-specific health benefits may not be used on their own unless accompanied by an authorised, specific health claim.

This approach strengthens consumer protection but, at the same time, raises the question of the proportionality of the regime where a significant number of claims remain pending for years. In this context, account is also taken of the significance of the case-law in *Bionorica* and *Diapharm*, in which a broad margin of discretion was recognised for the Commission as regards the non-completion of the assessment of claims relating to botanical substances.

The principal conclusion is that the regime governing health claims is built upon a high standard of scientific justification, while at the same time creating significant normative uncertainty as regards botanical substances and borderline marketing formulations. Thus, a strict formal regime exists in parallel with a market practice that frequently relies on suggestion, general statements, and contextual presentation in order to circumvent the restrictions. This calls into question the effectiveness of the framework and demonstrates the need for clearer criteria for assessing permissible claims, particularly with regard to food supplements containing botanical and other substances with a physiological effect.

3.8 Provision of information on food supplements. Labelling, presentation, and advertising

The regime governing the provision of information on food supplements through labelling, presentation, and advertising is not exhausted by the formal content of the label, but extends to all means by which information reaches the consumer and shapes the consumer's perception of the product.

The legal framework is constructed through the interaction of Regulation (EU) No 1169/2011, Directive 2002/46/EC, and Regulation (EC) No 1924/2006.

Regulation (EU) No 1169/2011 establishes the horizontal rules on accuracy, clarity, intelligibility, and the avoidance of misleading information, whereas Regulation (EC) No 1924/2006 introduces a special regime for cases in which the information contains nutrition or health claims.

Directive 2002/46/EC lays down additional special requirements for food supplements, including their mandatory designation as a “food supplement,” the recommended daily dose, a warning not to exceed that dose, and a warning that the product should not be used as a substitute for a varied diet.

The regime governing health claims does not exist independently but constitutes a special framework within the general regime governing the provision of food information. Accordingly, in assessing the permissibility of a given statement, regard must be had not only to its formal content but also to its actual effect on the perception of the average consumer.

Of particular significance is the prohibition on attributing to a food supplement, through its label, presentation, or advertising, properties of preventing, treating, or curing a human disease, or on suggesting that a balanced and varied diet cannot provide adequate quantities of nutrients. This prohibition establishes a clear boundary between the food supplement and the medicinal product.

Inconsistencies are established in the national regulatory framework. First, Article 16 of the Ordinance on Food Supplements employs the term “substances” [“substantsii”] in a manner that does not correspond to the terminology of Directive 2002/46/EC and Regulation (EC) No 1924/2006. It would be more precise to use the expression “substances with a nutritional or physiological effect.” The use of the term “substantsii” creates a risk of conflation with medicinal-law terminology and of an overly broad interpretation of the scope of the provision.

Second, the relationship between Annex XIII to Regulation (EU) No 1169/2011 and the annexes to Directive 2002/46/EC is analysed. It is established that the former performs an informational function and sets reference values for labelling-declaration purposes, whereas the annexes to Directive 2002/46/EC are of a regulatory character and determine which vitamins and minerals may be used in the manufacture of food supplements. The absence of a given substance from Annex XIII cannot be interpreted as a prohibition on its use, nor as grounds for restricting market access.

In this connection, the question of the minimum content of 15% of the reference values under Article 9 of the Ordinance on Food Supplements is also examined; this requirement is relevant to the regime governing the provision of information and labelling declarations, and not to the permissibility of incorporating the substance in question. The contrary interpretation would conflate the labelling regime with the compositional regime and could lead to unjustified restrictions on the free movement of goods.

The liability for the provision of food information under Article 8 of Regulation (EU) No 1169/2011 is analysed; this provision introduces a differentiated model under which primary liability for the presence and accuracy of the information rests with the operator under whose name or business name the food is marketed, or, where that operator is not established within the Union, with the importer. The remaining operators in the chain bear limited liability, applicable only where they know or may be presumed to know that the information does not comply with the requirements.

An inconsistency exists between this functional model of liability and the national provisions, which permit a broader engagement of the liability of the “business operator” or “trader,” without always taking into account whether the relevant subject created, controlled, or was in a position to influence the content of the information. This gives rise to a risk of disproportionate engagement of liability, particularly in respect of traders who offer an already packaged and labelled product without having participated in the creation of the information.

Where a discrepancy exists between declared and actual product characteristics, a misleading commercial practice may be present; the subject of liability should, however, be the person who created or presented the inaccurate information. The mere capacity of “trader” offering the product to the end consumer does not in itself constitute sufficient grounds for engaging liability in the absence of knowledge, or the possibility of knowledge, of the non-conformity.

This problem is also connected with the risk of overlapping competences between the authorities under the Foodstuffs Act and the Consumer Protection Act. In situations where the same conduct simultaneously constitutes both a breach of the labelling rules and a misleading commercial practice, parallel exercise of powers by the BFSa and the CCP is possible. This creates a risk of duplication of sanctions and raises questions concerning the principle of *ne bis in idem*.

Comparison with the regime governing medicinal products shows that, in the case of medicinal products, control over advertising is direct and expressly regulated, whereas, in the case of food supplements, restrictions are achieved indirectly – through the prohibition on unauthorised health claims and the general rules against misleading information. Food supplements thus occupy an intermediate regulatory position: formally, a relatively liberal

regime applies, but in fact their presentation is significantly constrained by the rules on health claims and the prohibition on therapeutic suggestion.

The principal conclusion is that the provision of information on food supplements constitutes a complex regime built upon three cumulative standards: the information must enable an informed choice by the consumer; it must not mislead; and, where health claims are present, it must be scientifically substantiated and authorised. These standards do not fully coincide in content and purpose, which creates tension in the application of the law.

In summary, the legal risk attaching to food supplements frequently arises not solely from the composition of the product but from the manner in which it is presented to the consumer. It is precisely the presentation that functions as an independent criterion for determining the applicable legal regime, since, through it, a given piece of information may remain a permissible description of the product, or may become a health claim, a misleading commercial practice, or even a medicinal presentation.

A functional asymmetry in health protection is thereby revealed: the communicative risk connected with deception through statements and suggestion is subject to stricter and more immediate control, whereas the material risk arising from composition is regulated through a more complex and more mediated mechanism. This confirms the need for a clearer distinction between labelling, presentation, advertising, and health claims, as well as for better coordination among the competent authorities.

4 CHAPTER THREE. The Legal Regime of Control and Sanctions Applicable to Food Supplements

4.1 Coercive administrative measures and administrative penalties in proceedings under the Administrative Violations and Penalties Act

This part analyses coercive administrative measures and administrative-penal liability as the principal instruments of administrative control over food supplements. The study covers the provisions of the Foodstuffs Act, the Official Controls of Food Act, the Consumer Protection Act, and the Protection of Competition Act.

It is established that the national system of administrative coercion has been shaped under the influence of EU law, Regulation (EU) 2017/625 requiring that sanctions be effective, proportionate, and dissuasive. The analysis shows that, despite the broad range of coercive

measures provided for, the practical effectiveness of the system is limited by normative fragmentation and an unclear allocation of competences.

The Foodstuffs Act provides for measures such as prescriptions, the temporary suspension of activity, and removal from the register. It is established that the regulatory framework employs inconsistent terminology and contains systematic ambiguities as to the applicability of individual provisions to food supplements. This creates difficulties both for the administrative authorities and for the addressees of the measures.

Particular attention is devoted to the Official Controls of Food Act, which provides an exceptionally broad range of coercive administrative measures – restricting or prohibiting the placing of products on the market, the withdrawal of products, the alteration of labels, the temporary suspension of activity, and others. The conclusion is drawn that the broad discretion enjoyed by the administrative authorities requires particularly strict compliance with the principle of proportionality and with the duty to state reasons for administrative acts.

Analysis of the Consumer Protection Act reveals a further layer of complexity in the control system. Overlapping competences are established among the BFSA, the CCP, the Ministry of Health, and the municipal authorities. This creates preconditions both for duplication of supervisory action and for institutional inaction.

As regards administrative-penal liability, it is established that the sanctioning provisions frequently refer to multiple European regulations and national norms, which complicates the correct legal classification of the violations. In certain cases, the legislative technique creates a risk that the same conduct may fall under different sanctioning regimes.

Particular difficulties arise in electronic commerce in food supplements, where it is often difficult to identify the actual liable subject among the manufacturer, the distributor, and the operator of the online platform.

The overall conclusion is that the problem in the area under examination is not the absence of legal mechanisms of control, but rather their fragmentation, the lack of clearly delineated competences, and the difficulties encountered in their practical application, which creates a risk both of excessive administrative interference and of insufficiently effective control.

4.2 Unfair competition and unfair commercial practices concerning food supplements

4.2.1 General remarks

This part examines the interaction between the regime for the protection of competition and the regime for the protection of consumers in the marketing of food supplements.

It is established that an infringement in the area under examination is not exhausted by a formal breach of the labelling rules or by the use of unauthorised health claims. What is legally relevant is the overall presentation of the product, in so far as it may affect the consumer's economic behaviour through suggestion, context, or incomplete or misleading information. Accordingly, the same conduct may simultaneously trigger the different legal regimes under the Foodstuffs Act, the Consumer Protection Act, and the Protection of Competition Act.

A distinction is drawn between unfair competition and unfair commercial practices under the Protection of Competition Act and the Consumer Protection Act respectively. It is established that no conflict exists between the two regimes, but rather a functional distinction grounded in their differing protected interests.

Nevertheless, practice shows that, in respect of food supplements, the dispute is frequently examined primarily through the prism of relations between competing traders, while consumer protection remains in the background.

The conclusion is drawn that the parallel existence of several supervisory regimes does not automatically guarantee a higher degree of protection, and that, in the absence of coordination, it may result both in an overlap of powers and in incomplete enforcement.

4.2.2 Unfair competition and unfair commercial practices under the Protection of Competition Act

This part analyses the application of the Protection of Competition Act to infringements connected with the marketing and advertising of food supplements. Particular attention is devoted to the general prohibition on unfair competition under Article 29 of that Act and to the specific provisions of Articles 30–34.

It is established that, in the food-supplements sector, infringements most frequently manifest themselves through the presentation of products in a manner that creates false or misleading impressions as to their properties, including through suggestions of a

therapeutic, prophylactic, or pharmacological effect. The study shows that the same conduct may simultaneously harm the interests of competitors, mislead consumers, and breach the special rules of food legislation.

The procedural particularities of proceedings before the CPC are analysed, including the possibility of initiating proceedings on the Commission's own initiative, its broad evidentiary powers, and the possibility of imposing interim measures where there is a risk of serious harm.

It is established, however, that proceedings under the Protection of Competition Act are structured predominantly with a view to protecting the competitive environment and the interests of economic operators. The consumer does not have an independent, central procedural role within this mechanism.

The conclusion is drawn that, in practice, this results in a shift of focus away from protection against the misleading effect on the consumer and toward the resolution of disputes between competitors.

Accordingly, the conclusion is reached that, in the case of food supplements, the independent application of the mechanisms under the Protection of Competition Act is not sufficient to achieve full protection of the public interest, which requires a parallel analysis of the regime under the Consumer Protection Act.

4.2.3 Unfair commercial practices under the Consumer Protection Act

This part analyses the application of the Consumer Protection Act to the marketing and advertising of food supplements. Unlike the regime under the Protection of Competition Act, the consumer and the consumer's economic behaviour are placed at the centre of legal protection here.

It is established that the regime governing unfair commercial practices allows for the sanctioning not only of expressly false statements but also of formally accurate information where, by reason of the manner of its presentation, it creates a misleading effect on the average consumer. In the field of food supplements, this is of particular significance, since the misleading effect frequently does not arise through a direct statement of a curative claim but through the product's name, visual design, suggestion, incomplete information, or marketing context.

Cases are analysed in which the overall presentation of the product creates an impression of a therapeutic or prophylactic effect in the absence of legally permissible grounds for such statements.

Borderline situations frequently arise with food supplements in which a given statement formally falls within the scope of a permissible health claim but, in the specific context, creates a significantly stronger suggestion of a health effect. This creates a practical difficulty, since there is no breach of the special regime governing health claims, while at the same time it is difficult to prove a misleading effect under the general regime. A normative and practical gap is established with regard to these borderline cases.

The relationship between Regulation (EC) No 1924/2006 and Directive 2005/29/EC is also examined; on the basis of CJEU case-law, the conclusion is drawn that the special regime governing health claims takes precedence, while the norms of the Consumer Protection Act retain independent significance with regard to the broader range of misleading practices.

The parallel application of the Foodstuffs Act, the Consumer Protection Act, and, in certain cases, the Medicinal Products in Human Medicine Act, creates a risk of overlapping competences, while at the same time revealing instances of incomplete control.

The principal conclusion is that the overall presentation of the product remains one of the most weakly regulated and most difficult to control areas within the food-supplements sector.

4.3 Examples from practice – the Rapid Alert System for Food and Feed (RASFF) and the practice of the Commission for Protection of Competition as a manifestation of the structural problems in control

This part analyses practical manifestations of the normative problems examined, drawing on data from the Rapid Alert System for Food and Feed (RASFF).

The system constitutes an EU mechanism for the exchange of information among Member States and the Commission upon the identification of a direct or indirect risk to consumer health connected with food and feed.

Analysis of the notifications relating to food supplements reveals recurring infringements connected with excessive quantities of substances, the presence of unauthorised ingredients, the use of novel foods without authorisation, misleading labelling, the absence of mandatory warnings, and the use of unauthorised health claims.

Particularly illustrative are cases of products presented as “natural” or “herbal,” in which substances with a proven pharmacological action – including sibutramine, sildenafil, and tadalafil – have been identified. These cases show that, in certain instances, products in fact fall outside the category of foodstuffs, notwithstanding that they are formally marketed as food supplements.

The conclusion is drawn that the current control model functions predominantly after the product has been placed on the market. RASFF limits the consequences of a risk that has already materialised but does not perform a preventive function.

This confirms the central thesis of the study, namely that, notwithstanding the broad regulatory framework, control over food supplements remains predominantly reactive rather than preventive.

Analysis of the practice of the CPC confirms the structural problems identified in the study with regard to control over food supplements.

It is established that proceedings before the CPC are directed primarily at the protection of competition among economic operators, rather than at the protection of consumers. Accordingly, even where the factual circumstances contain evidence of the use of unauthorised health claims or suggestions of a therapeutic effect, such questions frequently remain outside the subject matter of the proceedings.

The study establishes that the same conduct may simultaneously breach the rules of competition, mislead consumers, and contravene the special legislation in the field of food. Nevertheless, the individual aspects of the conduct are often examined by different authorities, according to different criteria, and in certain cases remain outside effective control.

A particular difficulty also arises in the allocation of liability among the various participants in the supply chain where advertising content is created and disseminated by multiple subjects.

The principal conclusion is that the practice of the CPC confirms the existence of fragmented enforcement, in which the overall commercial conduct connected with the presentation of food supplements is frequently not subject to a unified and consistent legal assessment.

5 CONCLUSION

The present study establishes that the legal regime governing food supplements constitutes an independent subsystem within food law, characterised by the intersection of several regulatory regimes – food law, consumer law, competition law, and, in certain cases, the law of medicinal products.

The first principal result of the study is the clarification of the conceptual apparatus and the formulation of criteria for distinguishing food supplements from similar legal categories, including medicinal products. It is established that the boundary between food supplements and medicinal products is not fixed by normative provision but is determined by a combination of criteria relating to the function of the product, its presentation, and consumer perception.

The second principal result is the systematisation of the regime governing nutrition and health claims and the clarification of the relationship between Regulation (EC) No 1924/2006 and Regulation (EU) No 1169/2011. It is established that even formally permissible statements may create a misleading effect through the manner in which the product is presented.

The third result of the study is the identification of a regulatory asymmetry within the current model. Access to the food-supplements market is comparatively liberal, while the scientific standards applicable to health claims are exceptionally strict. This results in a situation in which prior control is limited while subsequent control is reactive in character rather than constituting a systematic mechanism of intervention.

The fourth result is the clarification of the role of EFSA as a factor of de facto regulatory significance. It is established that, although the Authority's scientific opinions are formally non-binding, they function in practice as a determinative standard in the Commission's regulatory decisions.

The fifth result is the identification of fragmentation in the control mechanisms at national level. The analysis shows an overlap of competences among the BFSa, the CCP, the CPC, and other competent authorities, which gives rise both to a risk of duplicated enforcement and to instances of incomplete control.

The practical analysis, including the practice of RASFF and of the national supervisory authorities, confirms that the current model functions predominantly after a risk has arisen, rather than through sufficiently effective prevention.

On the basis of the analysis carried out, *de lege ferenda* proposals are formulated, directed at a clearer delineation of competences among the supervisory authorities, the refinement of national terminology in line with EU law, clearer regulation of coercive administrative measures, and an increase in the effectiveness of control over the presentation and advertising of food supplements.

The overall conclusion of the study is that the problem within the current regime is not exhausted by isolated normative imperfections but concerns the internal structure of the regulation itself. The formal treatment of food supplements as part of the category of foodstuffs does not adequately take into account their specific characteristics, which creates a lasting tension between health protection, the free movement of goods, and the effectiveness of legal control.

PUBLICATIONS RELATED TO THE TOPIC OF THE DISSERTATION:

1. M. Zlatanova, "Are Food Supplements Food?", *Medical Law and Healthcare*, No. 3/2025, pp. 12–23, ISSN 2738-7054 (Online), 2738-7070 (Print).
2. M. Zlatanova, "The Administrative Law Regime of Food Supplements – Coercive Administrative Measures and Administrative Penalties", *Medical Law and Healthcare*, No. 1/2025, pp. 15–41, ISSN 2738-7054 (Online), 2738-7070 (Print).
3. M. Zlatanova, "The Legal Regime Governing Health Claims for Food Supplements under European Law", *STUDIA IURIS*, No. 1/2026, pp. 66–73, ISSN 2367-5314.