

REVIEW

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Under the procedure for the award of the academic and scientific degree of 'Doctor' in Field of Higher Education 3. Social, Economic and Legal Sciences, Professional direction 3.6 Law, Doctoral Programme 'Administrative Law and Administrative Procedure'

Hosting unit: Faculty of Law, Plovdiv University 'Paisii Hilendarski'

Primary unit: Department of Public Law

Candidate: Maria Ilieva Zlatanova

Supervisor: Prof. Darina Peeva Zinovieva, Doctor of Law

This opinion is presented by a member of the academic jury appointed by Order No. RD22/1462 of 22 July 2026 of the Rector of Plovdiv University "Paisii Hilendarski"

Dear members of the academic jury,

I hereby submit this assessment, having been tasked with preparing a review by a decision of the academic jury at its first meeting, as recorded in Minutes No. 1 of 23 July 2026.

Insofar as the candidate's eligibility from a scientometric perspective, in accordance with the minimum national requirements, has already been assessed by a decision of the academic jury as set out in the aforementioned protocol, I hereby present my conclusions regarding the substance of the procedure.

Maria Zlatanova's doctoral thesis, entitled 'The Administrative Law Regime of Food Supplements', makes a significant contribution and is highly original, insofar as these issues have practically not been researched in our legal system and there is no comprehensive academic work on the subject. The topic has remained outside the scope of legal doctrine.

The thesis comprises a total of 202 pages, including the title page, the required declaration of originality and contributions, the table of contents, a list of legislative acts and abbreviations used, an introduction (referred to as such rather than a 'preface', which I do not consider to be an error), three chapters and a conclusion.

The main analytical text of the three chapters totals 171 pages. Following the main text are tables containing appendices from the empirical studies included in the thesis. Fourteen sources in Bulgarian and eight in English have been used, as well as three online sources in English. Numerous European Union legal acts, on which the research is based, are cited. I consider the bibliography to be satisfactory given the highly specific and narrow subject matter of the research, which has practically never been conducted in Bulgaria before and is based on the framework of Community law.

The abstract presented accurately and concisely reflects the content, structure, main conclusions and contributions of the doctoral thesis. Four independent academic publications

(one in press) have been produced on the subject of the thesis, which meet the minimum national requirements under the Law on the Promotion of Academic Staff in the Republic of Bulgaria and the Regulations for its implementation.

Relevance and significance of the topic: the topic of the thesis is highly topical, significant and rapidly evolving in both a national and a European context. The significant expansion of the food supplements market over the last two decades has brought to the fore a number of administrative and legal issues – the legal classification of so-called ‘borderline products’ and their distinction from medicinal products and medical devices, control over their presentation and advertising, as well as the effectiveness and coordination of control mechanisms in the context of widespread e-commerce.

The legal framework in this area is characterised by a complex two-tier structure comprising national law and EU law; the author examines in detail the directly applicable EU regulations (Regulation 178/2002, Regulation 1924/2006, Regulation 1169/2011, Regulation 2017/625, Regulation (EC) No 1333/2008, Directive 2002/46/EC) and national legislation (the Food Act, the Agri-Food Chain Management Act, the 2021 Food Supplements Regulation). In this regard, the thesis offers a timely, comprehensive and systematic analysis of the administrative and legal framework, filling a significant gap in legal scholarship. The structure follows a rigorous scientific and logical sequence.

Chapter One, ‘Concepts and Regulatory Framework’, lays the theoretical and conceptual foundations of the work. The author provides a detailed distinction between the related concepts of ‘food supplements’, ‘foods’, ‘food additives’, ‘medicinal products’, ‘medical devices’, ‘narcotic substances’ and ‘novel foods’, which share similarities and differences. The evolution of the regulatory framework is traced, and the key stakeholders – the ‘business operator’ and the ‘consumer’ – are examined, together with a comparative analysis of the regulatory regimes in non-EU countries (the USA, Canada and Japan). The position of food supplements within the food law system as a specific category of food is clarified, and the specific features of the administrative and legal regime applicable to them are analysed. The legal definitions established in European Union law, their interrelationship and their significance for the classification of individual product categories have been examined. The nature of the regime governing the placing of food supplements on the market has been examined, and the distinction between the notification and authorisation regimes has been clarified. This chapter provides a solid conceptual foundation for the study. A particular strength is the systematic distinction drawn between food supplements and neighbouring categories — foods, nutrients and ‘other substances with a nutritional or physiological effect’, food additives, foods for specific groups, medicinal products and medical devices, and narcotic substances. The author correctly identifies the terminological confusion between ‘food supplements’ and ‘food additives’ — an error which is not merely a linguistic inaccuracy but a source of real difficulties in law enforcement, as the categories in question are subject to substantially different legal regimes.

A distinction has been appropriately drawn between food supplements, medicinal products and medical devices, taking into account the criteria established in the case law of the Court of Justice of the European Union.

Another strength of this chapter is the careful analysis of the case law of the Court of Justice of the European Union on the distinction between food supplements and medicinal products (Cases C-319/05, C-140/07, C-219/91 and others), in which the author systematically analyses the two distinct criteria for classifying a product as a medicinal product – ‘by

presentation’ and ‘by function’ – as well as their significance for distinguishing medicinal products from food supplements.

The analysis of the judgment in Case T-302/21 is a prime example of the ability to draw a more general structural conclusion from specific case law – regarding the limits of the European Commission’s powers under Article 8 of Regulation (EC) No 1925/2006.

Particular mention should be made of the comparative law review of regimes outside the European Union (the US, Canada, Japan, Australia, New Zealand, China), which is not a mere listing of foreign systems but is organised around an analytical typology — the liberal model, the authorisation model and hybrid models — and concludes with a clear positioning of the European regime within this typology. Particularly successful is the analysis of the Japanese system, in which the author demonstrates how a more differentiated regulatory approach allows health claims to be graded according to their scientific validity.

I consider the following to be its main contributions:

- A critical analysis of the definition in § 1, item 21 of the Supplementary Provisions of the Food Act (FA) and its comparison with Article 2 of Directive 2002/46/EC, with an emphasis on the terminological inaccuracy in the translation and the confusion between ‘food supplements’ and ‘food additives’.
- A precise distinction between food supplements, medicinal products (in terms of function and presentation), medical devices, foods for specific groups (Regulation 609/2013), novel foods (Regulation 2015/2283) and narcotic substances.
- An outline of the theoretical tension between the regulatory definition of food supplements as foods and the specific characteristics of their actual nature, form and intended use, as well as a critical analysis of their inclusion as a separate ‘food group’ under Section 1(4) of the Supplementary Provisions to the Food Act.
- An excellent comparative legal analysis of three main global models: liberal (USA – DSHEA, based on post-market control), authorisation-based (Canada – NHP, prior licensing regime) and hybrid (Japan – FNFC/FFC/FOSHU, tiered regulation according to scientific claims).

Chapter Two, ‘Legal Framework Governing the Manufacture, Placing on the Market and Provision of Information on Food Supplements’, is devoted to the substantive legal framework governing the manufacture and placing on the market (notification procedure) of food supplements, as well as the requirements regarding their composition and labelling. Central to this is a detailed analysis of the legal regime governing nutrition and health claims, the precautionary principle (Article 7 of Regulation 178/2002) and the role of the European Food Safety Authority (EFSA) and the Bulgarian Food Safety Agency (BFSA). This chapter is the most extensive and analytically dense part of the work. It begins with a clear and systematic overview of the general principles of food law — a high level of health protection, the free movement of goods, legal certainty, proportionality and the precautionary principle — and skilfully distinguishes these principles from the specific legal instruments for their implementation under Regulation (EC) No 178/2002. The analytical value of this distinction lies in the fact that it enables the author to go on to examine the extent to which the stated principles are actually realised through the mechanisms in place. The analysis of the institutional balance between the European Commission and the European Food Safety Authority (EFSA) represents a particularly valuable contribution. The author puts forward the argument that,

although the EFSA does not formally possess regulatory powers, and its opinions are non-binding, in practice they function as a de facto regulatory standard, as the Commission systematically follows negative scientific assessments without itself independently justifying the proportionality of the measures taken. This argument is convincingly supported by an analysis of the General Court's case law in Cases T-302/21 and T-274/21, in which the Court held that scientific uncertainty cannot, in itself, serve as a basis for a ban. The conclusion that the distinction between 'risk assessment' and 'risk management', introduced by Regulation (EC) No 178/2002, loses its practical significance when the Commission's decisions are in fact bound by the scientific assessment of the EFSA, is an original contribution of real analytical depth and ties in directly with the issue of the institutional balance under Article 13(2) of the TEU.

The section devoted to the national competent authorities deserves special attention for its critical yet well-reasoned analysis of the distribution of powers between the Bulgarian Food Safety Agency (BFSA), the Minister of Agriculture and Food, the Minister of Health, the Executive Agency for Medicines, the Commission for Consumer Protection (KZP), the Commission for Protection of Competition (KZK) and the scientific advisory bodies (the National Food Council, the Centre for Risk Assessment in the Food Chain, and the National Centre for Public Health and Analyses). The observation regarding a 'complex, multi-layered but poorly coordinated system' is supported by specific examples of overlapping competences, whilst the *de lege ferenda* proposal to centralise control functions at ministerial level demonstrates not only critical but also constructive legal thinking geared towards practical benefit.

The comprehensive analysis of the regime governing nutrition and health claims under Regulation (EC) No 1924/2006 is one of the strongest parts of the entire study. The distinction between nutrition and health claims is precisely outlined, and the systematisation of the types of health claims under Articles 13 and 14 of the Regulation is supplemented by the author's own, analytically grounded classification according to degree of specificity and method of presentation. The review of case law (Cases C-544/10, C-19/15, C-299/12) concerning the context-dependent threshold for classifying a given statement as a health claim demonstrates maturity in working with primary sources and an ability to identify general trends from seemingly disparate case law.

The main contributions of this chapter are:

- An analysis of the precautionary principle (Article 7 of Regulation (EC) No 178/2002) and EFSA's scientific assessments as a regulatory factor in legitimising health claims.
- A detailed analysis of the legal framework governing nutrition and health claims under Regulation (EC) No 1924/2006 and the strict requirements for labelling, presentation and advertising (Regulation 1169/2011).
- An analysis of the case law of the Court of Justice of the European Union (CJEU) concerning the limits of the European Commission's powers under Article 8 of Regulation 1925/2006 (including Case T-302/21 *Aboca SpA*), highlighting the problem of regulating complex plant-based 'preparations' rather than individual 'substances'.
- Defence of the argument that the fundamental principle of proportionality between consumer protection and the freedom of economic initiative and the free movement of goods must be upheld.

Chapter Three, 'The Legal Framework for Control and Sanctions in Relation to Food **Supplements**', examines the control mechanisms and the system of sanctions. A detailed review

is provided of coercive administrative measures (CAMs), administrative liability under the Administrative Offences and Penalties Act (ZANN), as well as the overlap with the provisions of the Competition Protection Act (unfair competition) and the Consumer Protection Act (unfair commercial practices). Particular attention is paid to the functioning of the Rapid Alert System for Food and Feed (RASFF). This chapter is devoted to one of the most complex and least-studied issues in Bulgarian legal literature — the system of coercive administrative measures and administrative penalties applicable to food supplements. A strength of the exposition is the careful distinction drawn between the various legal bases for the application of coercive administrative measures — the Food Act, the Agri-Food Chain Management Act, the Consumer Protection Act and the Competition Protection Act — and their systematic comparison with the requirements of Regulation (EU) 2017/625 and Regulation (EU) 2019/1020.

Particularly useful is the analysis of the procedure under Article 26 of the Food Act (instruction and order to suspend operations), in which the author carefully examines the administrative procedure requirements and reaches well-founded conclusions regarding the nature of the prescribed time limits (the indicative time limit for the Director of the Regional Food Safety Agency) and on the applicability of the general requirements of the Administrative Procedure Code regarding the statement of reasons for administrative acts. Also worthy of note is the precise analysis of the concept of ‘serious risk’ under Article 88 of the Consumer Protection Act as an element of the factual basis for a discretionary power involving an element of assessment — a distinction which has direct practical significance for the scope of judicial review of these acts.

A significant contribution is the finding regarding the regulatory ambiguity that arose following the 2026 amendments to the Consumer Protection Act concerning the applicability of the market surveillance mechanisms provided for therein and the role of the Bulgarian Food Safety Agency (BFSA) within the system of competent authorities, insofar as food supplements are foods subject to the separate regime of official controls under Regulation (EU) 2017/625 and fall outside the traditional market surveillance regime under Regulation (EU) 2019/1020 and Regulation (EU) 2023/988.

The main contributions of this chapter are:

- A systematic analysis of the application of coercive administrative measures (CAMs) and administrative penalties under the Administrative Offences and Penalties Act (ZANN), the Food Act (ZH) and the Food Safety Act (ZAHV).
- An examination of the intersections between consumer protection (under the Consumer Protection Act) and competition protection (under the Competition Protection Act), with regard to misleading advertising and unfair commercial practices.
- A critical analysis of the practice of the Commission for Protection of Competition (CPC) and the courts (the Supreme Administrative Court and the Administrative Court of Sofia City), revealing institutional gaps and a lack of sufficient coordination between the Bulgarian Food Safety Agency (BFSA), the Commission for Consumer Protection (CCP) and the CPC.
- An assessment of the role of the Rapid Alert System for Food and Feed (RASFF) in risk prevention at European and national level. An assessment of health claims as a regulatory filter – an in-depth analysis of the significance of the EFSA’s scientific assessment as a regulatory factor in legitimising health claims under Regulation 1924/2006.

Overall assessment and contributions:

In summary, Maria Zlatanova's doctoral thesis represents an in-depth, original and methodologically sound study of the administrative and legal regime governing food supplements. The contributions of the thesis can be summarised as follows:

- The development of a comprehensive concept of the legal regime governing food supplements as an independent subsystem of food law, characterised by its interdisciplinary nature and the intersection of food, consumer and competition law.
- An in-depth critical analysis of the institutional balance between the European Commission and the European Food Safety Authority (EFSA), which reveals structural tensions between the formal allocation of competences and the actual functioning of the regulatory mechanism.
- A systematisation of the criteria for distinguishing between food supplements and medicinal products based on the case law of the Court of Justice of the European Union, as well as a classification of food and health claims according to several analytical criteria.
- A comprehensive analysis of the fragmentation of national supervisory powers and the formulation of specific, practically applicable *de lege ferenda* proposals to address it.
- A valuable comparative law review of regulatory models outside the European Union, which allows for a more accurate positioning of the European regime within a broader global context.
- Criteria for classifying 'borderline products': Drawing on the extensive case law of the Court of Justice of the European Union (including Cases C-308/11, C-319/05, C-140/07 and the current case T-302/21 Aboca) and national courts, the author identifies and systematises the functional and formal characteristics for distinguishing food supplements from medicinal products (in terms of 'presentation' and 'function').
- The overall style is one of precise terminological systematisation and distinction: the author convincingly clarifies the conceptual differences between the distinct category of food ('food supplements') and technological ingredients ('food additives'). Critical reference is made to terminological inaccuracies in Bulgarian legislation and translations of EU law, which create the conditions for incorrect application of the law.
- Legislative proposals (*de lege ferenda*): The paper contains specific and well-reasoned proposals for improving the Food Act, the Agri-Food Chain Management Act and the Food Additives Regulation (including the reformulation of § 1, item 4, sub-point 'sh' of the supplementary provisions of the Food Act and the harmonisation of the legal definitions of 'economic operator'/'business operator').

The merits of this work set out above clearly exceed the usual requirements for a doctoral thesis for the award of the academic and scientific degree of 'Doctor'. The research is distinguished by the originality of its thesis, the depth of its analysis, the wealth of sources used, and the practical applicability of the conclusions and proposals made.

I also highly value the empirically derived conclusions, systematised in the appendices (particularly Table 5: Comparative analysis of the interpretation of the concept of 'health claim' in the case law of the ECJ). These enable this academic work to be used as a methodological guide in practice

In view of the above, I find that, given the quality of the doctoral thesis entitled 'The Administrative-Legal Regime Governing Food Supplements', Maria Ilieva Zlatanova deserves to be awarded the academic and scientific degree of 'Doctor' in Field of Higher Education 3. Social, Economic and Legal Sciences, Professional direction 3.6 Law, doctoral programme 'Administrative Law and Administrative Procedure', and I propose that the members of the

examination board vote accordingly at the open final meeting of the academic examination board.

Sincerely,

(Assoc. Prof. Dr Konstantin Pehlivanov)

03.09.2026

Plovdiv