

OPINION

From: Prof. Dr Veselina Kanatova-Buchkova

Institute of State and Law at the Bulgarian Academy of Sciences 'Public Law Sciences' Section
Administrative Law and Administrative Procedure

On: doctoral thesis for the award of the academic and scientific degree of 'Doctor' in
'Administrative Law and Administrative Procedure' at Plovdiv University 'Paisii Hilendarski',
Plovdiv

Basis for submitting this opinion: participation as a member of the academic jury for the defence
of a doctoral thesis for the award of the academic degree of 'Doctor' in the academic discipline of
'Administrative Law and Administrative Procedure' within professional direction 3.6 Law at
Plovdiv University 'Paisii Hilendarski', Plovdiv, in accordance with Order No. RD-22-1462/22
July 2026 of the Rector of Paisii Hilendarski University, Plovdiv

Author of the doctoral thesis: Maria Ilieva Zlatanova

Thesis topic: 'The Administrative and Legal Regime Governing Food Supplements'

Supervisor: Prof. Darina Zinovieva, PhD

I. Information about the doctoral candidate.

The doctoral candidate was born on 25 May 1974 in Plovdiv. She completed her law degree at Sofia University "St. Kliment Ohridski". After completing her higher education, she worked for one year as a solicitor, after which she served successively as a junior judge, a judge at the Plovdiv District Court and the Plovdiv Regional Court, and from 2013 to the present day she has been a judge at the Plovdiv Administrative Court.

She has four publications on the subject of her thesis.

II. General description of the thesis.

The thesis complies with the requirements of Article 27 of the Regulations for the Implementation of the Promotion of Academic Staff in Republic of Bulgaria. It is structured into three chapters, with the thesis totalling 202 pages, including appendices and the bibliography. The bibliography comprises a limited number of academic publications in Bulgarian and foreign languages.

The subject of the research is the legal regime governing food supplements from the perspective of production, distribution, advertising, trade and consumption, examining the established administrative and legal regimes, unfair competition and unfair commercial practices, and the supervision of such activities. The topic is topical, and the research approach adopted by the author makes it possible to highlight the specific aspects of the legal framework and the challenges facing the administrative regulation of legal relationships, arising from a lack of precision and consistency of the concepts with the European legislative framework.

The topic is divided into three chapters.

The first chapter examines the key legal concepts and definitions relating to food supplements, drawing a distinction between food supplements and similar categories, namely food additives, foods, medicinal products, as well as foods for specific groups and narcotic substances. I find that this part of the study makes a valuable contribution, in particular the well-founded distinction between food supplements and ‘food additives’, which is essential given the confusion between these concepts in Bulgarian legislation. As the author points out, the different categories of products require the application of different legal regimes; consequently, the lack of a clear distinction between them creates conditions for the incorrect interpretation and application of the law.

It is noted that, in view of the legal definitions of food supplements at both European and national levels, food supplements are foods, which determines the applicability of the general legal regime governing food, as set out in the Food Act, and the corresponding competence of the Bulgarian Food Safety Agency. Compared to foodstuffs, food supplements form part of the broader category of ‘food’, and therefore all the general principles and requirements of food law apply to them, including those laid down in Regulation (EC) No 178/2002. The author points out that the regulatory approach adopted does not fully correspond to the nature of the social relations under consideration, insofar as food supplements, by virtue of their origin and intended use, are linked to a significantly greater extent with medicine, dietetics and pharmacy.

This is because, historically, they emerged as a means of addressing deficiencies and malnutrition, and their development as concentrated substances is closely linked to scientific discoveries in the field of vitamins and metabolic processes. The distinction between food supplements, medicinal products and medical devices is based on their mechanism of action, with food supplements having a nutritional or physiological effect, medicinal products having a pharmacological, immunological or metabolic effect for the purposes of treatment, prevention or diagnosis, whilst medical devices exert their primary effect through physical or mechanical means. It is noted that, in certain cases, a food supplement may be classified as a medicinal product in view of its claimed effect, and that the distinction in such cases is of direct significance for determining the applicable legal regime and the competence of the regulatory authorities.

The second chapter of the thesis is devoted to the regulatory framework relating to what the author terms the ‘placing on the market’ of food supplements, the requirements regarding the qualitative and quantitative composition of food supplements, nutritional and health claims, as well as the provision of information on food supplements, labelling and advertising. It is pointed out that the legal regime governing food supplements is subject to general principles enshrined in primary EU law, namely the principle of a high level of health protection, the principle of the free movement of goods, and the principles of legal certainty and proportionality. The application of the precautionary principle is also highlighted as a specific mechanism for managing the risk of harmful effects on consumers’ health. The powers and functions of national and European authorities in the field of safety, quality and requirements for food and food supplements are examined. I do not share the view expressed that, since the law provides for challenges only to refusals of registration, third parties who can demonstrate a legal interest cannot challenge a decision to enter a specific food supplement in the registers, as the right to challenge cannot be restricted by a provision of this nature.

With regard to the European legal framework, it is noted that the regulation of food supplements falls within the scope of shared competence, but the regulatory burden is concentrated at EU level. The European Commission adopts secondary legislation - implementing regulations, technical annexes, and requirements concerning the composition, labelling and use of food supplements; it manages the lists of authorised substances and maintains the positive lists of vitamins and minerals, which Member States may not extend. In the absence of harmonisation, Member States retain national competence, which must be exercised in accordance with general European principles.

A key contribution of the research in this chapter is the analysis of claims - both

nutritional and health-related - as well as the distinction between health claims and the general regime for the provision of information. The author concludes, in this regard, that Regulation (EC) No 1924/2006 takes precedence over Regulation (EU) No 1169/2011. It is pointed out that the concept of a 'health claim' is applied in practice, including by the General Court of the EU, through a varying margin of discretion which depends on the type of product, the target audience, the overall context and the perception of the average consumer, leading to practical differences in the scope of application of the Regulation across different categories of food, including food supplements, where presentation is often the decisive factor in legal classification. It is concluded that, at present, the prolonged delay in the assessment and the lack of a final decision on a significant proportion of health claims are leading to a state of legal uncertainty, which calls into question the effectiveness of the legislation and the achievement of its main objectives. Under the pretext of applying the general principle of precaution, a situation is being created in which the key characteristics of the precautionary approach are lacking, namely the temporary nature of the measures and clear criteria for review.

Chapter Three examines issues relating to the control and sanctions concerning food supplements, in particular the coercive administrative measures imposed by the competent authorities and the administrative penalties for administrative offences under the Food Act and the Agri-Food Chain Management Act. It is pointed out that the orders under Article 26(11) of the Food Act constitute a type of coercive administrative measure and are also subject to judicial review in accordance with the Administrative Procedure Code. It is concluded that, insofar as the application of the Agri-Food Chain Management Act undoubtedly also concerns food supplements, the administrative authorities therefore have the competence to apply coercive administrative measures in cases concerning food supplements as well. The Agri-Food Chain Management Act refers to the coercive measures under Article 138(2) of Regulation (EU) 2017/625, which provides for a wide range of actions, both to determine the origin and extent of the non-compliance and to establish the operator's liability, and to ensure that the operator in question rectifies the non-compliance and prevents its recurrence. I agree with the observation that, despite the provision in Article 25(3) of the Consumer Protection Act (ZPAV) that only the coercive administrative measure under Article 25(1) is subject to appeal, a refusal to revoke a measure that has already been imposed will also be subject to judicial review.

I find that the reasoning under Article 88 of the Administrative Procedure Code regarding the nature of the administrative authority's competence is incomplete and should be further developed with regard to the introduction of a new category of administrative acts, namely

‘administrative acts involving a technically determined assessment’. The conclusion regarding judicial intervention in the administrative authority’s discretion should also be substantiated where the act is issued under operational autonomy, in cases of ‘arbitrariness or manifest lack of justification’. Rather, the possibility of intervention in the authority’s operational discretion is linked to the requirement of legality when issuing acts under operational autonomy, as laid down in Article 6(4) of the Administrative Procedure Code. Nor do I share the view that there is no possibility of a separate appeal against the provisional enforcement of a precautionary administrative measure under Article 60 of the Administrative Procedure Code, irrespective of whether the act is contested, since such an appeal is permitted under the special law; in this regard, the opinion of Prof. K. Lazarov and Prof. I. Todorov in this regard is unfounded. In this case, the issue is not the application of procedural law by analogy, but preliminary enforcement by virtue of law, whereby the legislature has from the outset accepted that one of the alternative scenarios for the preliminary enforcement of an administrative act, as set out in Article 60(1) of the Administrative Procedure Code, is present. This is why, even in cases of provisional enforcement by virtue of a special law, no specific reasoned order is issued under Article 60 of the Administrative Procedure Code. This does not mean, however, that a request cannot be made for its suspension under the procedure of Article 60 of the Administrative Procedure Code, irrespective of the challenge. As I have repeatedly pointed out, the proceedings under Article 60 of the Administrative Procedure Code, and indeed Article 166 of the Administrative Procedure Code, are of a protective nature, which requires, contrary to established practice, requires the court to assess not only the possibility of the interested party suffering significant or irreparable harm, but also the probable merits of the appeal lodged and the associated probable unlawfulness of the administrative act issued. That is why it is not necessary, by analogy with the Civil Procedure Code, to apply the institution of interim relief in respect of a future claim in order to provide for the possibility of suspending the provisional enforcement of an administrative act, as permitted by a provision of a special law.

In conclusion: The content of the thesis complies with Article 6(3) of the Law on the Promotion of Academic Staff in the Republic of Bulgaria and Article 27(2) of the Regulations for the Implementation of the Law on the Promotion of Academic Staff in the Republic of Bulgaria.

The study constitutes a substantial piece of academic work, demonstrating the author’s ability to analyse in detail the legal institutions forming part of the subject matter, to highlight key points, to identify problems, to make well-founded critical observations, and to draw their own legal conclusions. For this reason, in addition to the aforementioned contributions, the study also

makes a contribution through its proposals de lege ferenda, which are based on an in-depth legal analysis.

In view of the above, I strongly recommend that the academic jury award the academic and scientific degree of 'Doctor' in the scientific speciality 3.6 'Law' to Maria Ilieva Zlatanova, a PhD candidate undertaking independent study at the Department of Public Law Sciences, Faculty of Law, Paisii Hilendarski University of Plovdiv.

Prof. Dr Veselina Kanatova-Buchkova

22 September 2026