

LEGAL ASPECTS REGARDING THE REGULATION OF THE MARKETING OF FOOD SUPPLEMENTS

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RESEARCH ARTICLE

Abstract

This paper analyzes the main legal aspects concerning the regulation of food supplements, both from the perspective of national legislation and that of European Union law. The fundamental principles governing the food supplements market, the obligations of economic operators, and the competent authorities responsible for ensuring consumer protection are highlighted. The study emphasizes the importance of the coherent application of legal norms in the context of the free movement of goods within the European Union.

Keywords: food supplements, legislation, consumer protection, marketing, food safety

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INTRODUCTION

The regulation of the marketing of food supplements in Romania is based on a complex legal framework that transposes European Union legislation and involves national authorities such as the Ministry of Health and the National Sanitary Veterinary and Food Safety Authority. Food supplements are considered food products, not medicines, whose purpose is to supplement a balanced diet and which represent concentrated sources of nutrients with a nutritional or physiological effect, marketed in dose form.

Food supplements represent a distinct category of products situated at the boundary between food and products with an impact on public health, which justifies the existence of a complex legal framework regarding their production, labeling, and marketing.

In recent decades, food supplements have experienced significant development on both the European and national markets, being widely used to complement dietary intake. This expansion has been driven by changes in lifestyle, increased interest in health and prevention, as well as technological advances in the food industry. From a legal perspective, food supplements raise a number of specific issues, as they are not considered medicines, yet they may have significant physiological effects on the human body. This intermediate positioning requires the existence of clear and rigorous regulations in order to prevent risks to public

health and to ensure accurate consumer information.¹

The dual nature of supplements—positioned between food and medicines—has generated considerable regulatory complexity. Although they are predominantly regulated as foods, the health-related claims associated with them require strict control standards, similar to those applicable to pharmaceutical products with regard to communication. The main objective of legal regulation is to protect public health and to guarantee that the information provided to consumers is truthful, scientifically substantiated, and not misleading.

MATERIAL AND METHOD

The methodology used in preparing this paper is based on the analysis of the main normative acts relevant to the field of food supplements and their marketing, both at the national and at the EU level. The method employed was a comparative one, with the research focusing on:

1. normative analysis through the examination of the basic legislation defining food supplements, establishing their composition, and regulating communication (labeling, claims, marketing)
2. analysis through the identification of relevant normative acts

¹ Popescu, A., *European Food Law*. Universul Juridic Publishing House, Bucharest, 2019

3. the comparative method by comparing the regulatory standards established by general food law

RESULTS AND DISCUSSIONS

The nutrients that may be used in food supplements are the following: vitamins (Vitamin A, Vitamin D, Vitamin E, Vitamin K, Vitamin B1, Vitamin B2, Niacin, Pantothenic acid, Vitamin B6, Folic acid, Vitamin B12, Biotin, Vitamin C); minerals (Calcium, Magnesium, Iron, Copper, Iodine, Zinc, Manganese, Sodium, Potassium, Selenium, Chromium, Molybdenum, Fluoride, Chloride, Phosphorus); substances with nutritional or physiological effects (macronutrients, amino acids, enzymes, live microorganisms, dietary fibers, essential fatty acids, plants, algae, lichens, fungi and their essential oils, plant extracts and animal extracts), as well as mixtures of vitamins and minerals with substances having nutritional or physiological effects. In the manufacture of food supplements, only the vitamins and minerals included in Community legislation may be used.²

The placing on the market of food supplements in Romania by the manufacturer, importer, or the person responsible for marketing the product is carried out on the basis of a *notification certificate*, which is an administrative act issued by the National Institute of Public Health within 15 working days from the date of product notification. The notification form must include information about the notifier (name, address, telephone, fax, registration number with the Trade Register), the person responsible for placing the product on the market, the trade name of the product, details regarding the product composition, the country of origin, a declaration on own responsibility that the submitted data are correct, the first and last name of the director (the person who will sign the notification form), signature, stamp, date, and a statement confirming that the food supplement for which notification is requested has NOT been registered in any other country as a non-prescription medicinal product (OTC product). The notification issued by the Ministry of Public Health for a food supplement is valid until any qualitative or quantitative modification of its composition occurs. The Ministry of Health website displays the documents required for

the notification of food supplements, the list of plants permitted in food supplements, the list of substances with nutritional or physiological effects permitted in food supplements, and the list of food supplements already notified.³

Dietary supplements:

- those that contain vitamins, minerals, mixtures of vitamins and minerals; substances with a nutritional or physiological effect other than vitamins and minerals; mixtures of vitamins and minerals with substances having a nutritional or physiological effect other than vitamins and minerals; mixtures of substances with a nutritional or physiological effect with plants and plant/animal extracts and/or bee products; mixtures of substances with a nutritional or physiological effect, other than vitamins and minerals, with plants and plant/animal extracts and bee products; as well as mixtures of any of the above-mentioned ingredients, must be notified to the National Institute of Public Health by submitting a standardized notification application, accompanied by the product label mock-up, including the original label and the technical specification of the product, submitted in hard copy or electronic format. Following the analysis of the notification file, the National Institute of Public Health issues or refuses to issue the notification certificate

- dietary supplements that have been notified in another European Union Member State may be placed on the Romanian market for the first time by submitting a standardized notification application, accompanied by a Romanian-language label mock-up, including the original label and the declaration of mutual recognition (in accordance with Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State)

- dietary supplements originating from third countries require the manufacturer, importer, or the person responsible for placing them on the market to apply for a notification certificate from the competent authority.

The maximum amounts of vitamins and minerals present in dietary supplements in the daily portion recommended by the manufacturer are established by taking into account the tolerable upper intake levels of vitamins and minerals determined through scientific risk assessment based on generally

² Order No. 1069/2007 approving the Norms on food supplements; the 2007 Norm on food supplements

³ Law No. 56/2021 on food supplements

accepted scientific data. The minimum amounts must represent 15% of the nutrient reference values.

In labeling, presentation and commercial communications, it is prohibited to attribute properties of preventing, treating, or curing a human disease or to refer to such properties. It is also prohibited to use statements, whether direct or implied, suggesting that a varied and balanced diet cannot provide adequate amounts of nutrients.

The labeling of dietary supplements must include the following information:

- the name of the categories of nutrients or substances that characterize the product, or an indication of the nature of these nutrients or substances;
- the recommended daily portion;
- a warning against exceeding the recommended daily portion;
- a warning advising against using dietary supplements as a substitute for a varied diet;
- a warning indicating that the products must be kept out of the reach of young children.

⁴Order No. 244/2005 establishes the list of plants and mushrooms that are permitted for use in food supplements. This regulatory act also sets out a series of prohibitions regarding the marketing of food supplements containing various types of plants and mushrooms. Thus:

- the marketing, as processed, prepared, processed or partially processed products in the form of food supplements, of plants that are dangerous for human consumption is prohibited
- the use of mushrooms that are dried; cut (in such a way that their species cannot be identified, except for truffles and morels); whole; containing insects, insect parts or insect residues; that are not fresh; or that are not included in the list mentioned in the Order is prohibited
- the manufacture or marketing of products in the form of pre-dosed food supplements containing one or more plants not included in the lists mentioned in the Order is prohibited without prior notification to the ⁵Institute of

⁴ Order No. 244/2005 on the processing, handling, and marketing of medicinal and aromatic plants used as such, partially processed, or processed in the form of pre-dosed food supplements

⁵ It is a research institute in the food industry in Romania, operating under the authority of the Ministry of Research and Innovation. It is the only research institute in Romania that develops products for food intolerances; it hosts the country's only information and dissemination center on genetically modified organisms; it has an information and

Food Bioresources (IFB), within which there is a Notification Approval Service

• the processing, manufacture and marketing of such products in the form of food supplements without the approval of the IFB is prohibited; such approval is granted following prior notification of the product. The notification file for obtaining approval must include the following:

- the nature of the product
- the quantitative and qualitative list of ingredients contained in the product
- the nutritional analysis of the product, quantitative and qualitative data on known significant active substances or the indicator per unit and per daily dose, toxicity and stability
- product labeling – the scientific name and the common name, if any

Within 30 days from the date of receipt of the notification file, the Service shall send, in writing, to the person who submitted it, the receipt approval, and the notification file number shall be used in all documents related to the marketing of the product.

Law No. 491/2003 is the regulatory act that establishes the general legal framework regarding the production, processing and organization of the market for medicinal and aromatic plants and bee products, as well as the relationships between producers, processors and traders (professionals). The production of medicinal and aromatic plants consists of obtaining them through cultivation or harvesting from wild flora; through processing they become teas, natural spices and raw materials for further processing, being transformed into products marketed as medicines, cosmetics, nutritional supplements, dietary products and food flavoring additives. Finished products based on medicinal and aromatic plants and bee products that are notified by operators in this field as medicines and classified as such are authorized or approved for market placement by the National Agency for Medicines and Medical Devices. The institution responsible for the notification, supervision and control of food supplements

dissemination center for human nutrition; it evaluates the physico-chemical and microbiological qualities of plant agricultural resources and food products; it prepares studies and conducts tests on dietary, organic, and special-purpose food products; it provides consultancy and services in various fields of the food industry, and it also has a specialized technical body in the field of organic agriculture, called the Organic Products Certification Body

and products for external use obtained from medicinal and aromatic plants and bee products, except for cosmetic products, is the National Service for Medicinal and Aromatic Plants and Bee Products, which operates under the Ministry of Agriculture and Rural Development.⁶

Order No. 1228/2005 is the regulatory act that establishes the technical standards regarding the marketing of pre-dosed food supplements of animal and plant origin and their mixtures with vitamins, minerals and other nutrients. According to this Order, food supplements may be marketed only in the form of tablets, capsules, dragees, powders, edible liquids, jellies, pastes, candies or bars, juices, syrups, tinctures, soft capsules, powders or granules in cases or packages, or as liquids presented in drinkable ampoules or in dropper bottles, containing nutrients with a role in human nutrition and administered exclusively by oral route.

The marketing of these products must comply with certain principles, namely that they must be safe, must not endanger consumer health, and must be made from raw materials guaranteed by suppliers through a declaration of conformity or of origin and provenance, accompanied by analysis reports. In their manufacture, additives, technological aids, and packaging materials may be used only if they are permitted by the legal regulations in force, and good manufacturing practices and food quality standards must be observed. In order to eliminate risks, throughout the technological flow of each production batch, flow parameters are internally monitored, and their values are recorded in documentation that is kept for at least 2 years.

The marketing of these products is carried out on the basis of prior notification. For notification purposes, the product dossier is submitted to the Institute of Food Bioresources, the Iași Public Health Institute, the Cluj-Napoca Public Health Institute, or the Timișoara Public Health Institute, which issue the notification certificate. The Institute of Food Bioresources maintains the single register of notification certificates for products and assigns to the other notifying institutes the series of notification certificates and the corresponding numbers for each notifier. The notifying institutes transmit

monthly to the Institute of Food Bioresources a centralized report of the notification certificates issued. Within 10 calendar days from the date of submission of the notification dossier, the notifying institute sends the notification certificate in writing to the applicant, and the notification dossier number is used in all commercial documents, including the numbering of the product's notification certificate. By the 2nd day of the following month, the Institute of Food Bioresources prepares the list of notification certificates issued and the list of unresolved notification dossiers, both of which are sent in writing to the Interministerial Technical Committee for Medicinal and Aromatic Plants, which analyzes, evaluates, and decides, from a technical point of view, the measures regarding notification dossiers for which certificates have not been issued. A food supplement that has been notified once does not require another notification, and the list of notified products is published on the website of the Institute of Food Bioresources.⁷

Food supplements are marketed to the final consumer only in pre-packaged form. With regard to the labeling and advertising of food supplements, these must not overlap with the regulations governing the placing of medicinal products on the market. Directive 2002/46/EC establishes a harmonized legal framework at the level of the European Union for food supplements, focusing on their definition, labeling, and composition. Its main purpose is to ensure consumer safety and to facilitate the free movement of these products on the internal market, and it provides minimum labeling requirements to ensure that information is not misleading, is clear, and is easily understood by consumers. Labeling must include: the legal name "food supplement"; the names of the categories of nutrients or substances it contains; the recommended daily dose; a warning against exceeding the recommended daily dose; a statement that food supplements should not replace a varied and balanced diet, but only complement it; and it prohibits, through labeling and advertising, the attribution

⁶ Law 491/2003 on medicinal and aromatic plants, as well as beehive products - Republished

⁷ Technical Norms of 2005 regarding the marketing of pre-dosed food supplements of animal and vegetable origin and/or their mixtures with vitamins, minerals and other nutrients - Order 1228/2005

of properties related to the prevention, treatment, or cure of a disease.⁸

The rules on the marketing of food supplements are not limited only to those normative acts that directly regulate these products, but, in conjunction with other normative acts, establish the general legal framework that allows their placement on the market for safe consumption. Thus, the rules concern: combating unfair commercial practices, which aim at better market functioning and ensuring a high level of consumer protection by regulating commercial practices that may harm consumers' economic interests, including unfair, misleading, and aggressive practices⁹; the free movement of safe and wholesome food products, which is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as to their social and economic interests. In order to ensure a high level of consumer health protection and to guarantee their right to information, appropriate consumer information regarding the food products they consume should be ensured. Consumer choices may be influenced, among other things, by health, economic, environmental, social, or ethical considerations; the establishment of general principles and general requirements for food information, fair information practices, and the responsibilities of food business operators, including the mandatory particulars that must be included on labels¹⁰; the general principles and objectives of food law, risk analysis, protection of consumer interests, risk communication, transparency principles, general obligations in food trade, requirements regarding food safety¹¹, and the use of nutrition and health claims made on food products, with the main objective of ensuring a high level of consumer protection and facilitating the efficient functioning of the internal market by guaranteeing that such claims are based on scientific evidence. According to this normative act, nutrition and health claims may be used only if they are scientifically substantiated and are not

misleading to the consumer. It prohibits claims suggesting that a balanced diet cannot provide the necessary nutrients or that exploit consumers' fears, provides for the creation of positive lists of authorized health claims, and imposes specific conditions for the use of certain claims.¹²

CONCLUSIONS

Following the analysis of the legal framework applicable to food supplements, it can be observed that the regulation of this field is characterized by a high degree of complexity, resulting from the positioning of food supplements at the intersection between food products and products with an impact on public health. This particularity justifies the existence of a rigorous regulatory system designed to ensure consumer protection and the maintenance of a high level of food safety.

National legislation, harmonized with that of the European Union, establishes clear rules regarding the composition, notification, labeling, and marketing of food supplements. The notification procedure, carried out through specialized institutions such as the National Institute of Public Health or the Institute of Food Bioresources, represents an essential preventive control instrument, allowing the verification of product compliance before they are placed on the market.

A particularly important aspect highlighted in the paper is the role of labeling and commercial communication. The prohibition of attributing therapeutic properties to food supplements and the obligation to provide accurate, clear, and non-misleading information directly contribute to protecting consumers against unfair commercial practices and to ensuring fair market behavior.

The analysis also reveals the importance of correlating the specific rules on food supplements with the general legislation in the fields of food law, consumer protection, and commercial practices. This integrated approach allows for the coherent application of the principles of safety, transparency, and responsibility of economic operators, in line with the objectives of the European internal market.

⁸ Directive 2002/46/EC on the definition, labeling, and composition of food supplements

⁹ Law No. 363/2007 on combating unfair commercial practices

¹⁰ Regulation (EU) No. 1169/2011 on the provision of food information to consumers

¹¹ Regulation (EC) No. 178/2002 laying down the General Principles of Food Law

¹² Regulation (EC) No. 1924/2006 on nutrition and health claims

In conclusion, the legal regulation of the marketing of food supplements represents a dynamic field, continuously adapting to scientific and economic developments. The correct and uniform application of legal norms, together with effective supervision by the

competent authorities, are essential conditions for guaranteeing consumer safety and for the fair functioning of the food supplements market in Romania and in the European Union.

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