REVIEW ARTICLE

CONTENTS

Legal regulation of the circulation of dietary food and dietary supplements in eu countries: the experience of Germany

Vitalii M. Pashkov[1], Oleksii S. Soloviov[2], Olga A. Khmelnytska[3]

[1]ACADEMICIAN STASHIS SCIENTIFIC RESEARCH INSTITUTE FOR THE STUDY OF CRIME PROBLEMS; YAROSLAV MUDRIY NATIONAL LAW UNIVERSITY, KHARKIV, UKRAINE

[2]INTERNATIONAL ACADEMY OF PERSONAL MANAGEMENT, KYIV, UKRAINE

[3]PROFESSIONAL COLLEGE OF MEDICINE AND PHARMACY OF POLTAVA STATE MEDICAL UNIVERSITY, POLTAVA, UKRAINE

ABSTRACT

Despite the EU legislation regulating the circulation of dietary and food supplements within the internal market, the system of state control requires improvement. For instance, due to existing regulatory gaps, certain pharmaceutical entities commit violations of regulatory requirements, such as failing to register medicinal products and selling them under the guise of dietary and/or food supplements. Conversely, physicians may recommend ordinary dietary and food supplements to patients as if they were medicinal products.

Additionally, violations posing health risks may include the presence of active pharmaceutical ingredients, including prescription-only substances that should be used exclusively for production of medical product ; the absence of declared nutrients (proteins, fats, carbohydrates, vitamins, minerals) or other substances with nutritional or physiological effects; and labeling that fails to meet established requirements, such as claims of therapeutic effects.

In other words, there is a lack of clear mechanisms in legislation for introducing dietary and/or food supplements to the market and defining requirements for substances used in their production, such as vitamins, minerals, and other substances with nutritional or physiological effects.

KEY WORDS: dietary food for special medical purposes, dietary supplements, food supplements, food products for specific consumer groups, legal regulation

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INTRODUCTION

Over the past few decades, there has been a rapid increase in knowledge about the biochemical and physiological cellular functions of human nutrients. Moreover, recommendations for the consumption of macroelements, microelements, and essential nutrients for maintaining health have grown. Additionally, the social perception of dietary habits and physical activity, along with their impact on current and future health, has evolved rapidly [1]. Clinical trials have not demonstrated the efficacy of certain dietary and food supplements in disease prevention. However, concerns about the safety of increased daily doses of such products necessitate legislative regulation of new aspects of their circulation. This issue is common across all countries, as the dietary and/or food supplement market is becoming increasingly global. Nutrition is one of the factors linking humans to the external environment and significantly influences national health. Modern humans require fewer calories and smaller food quantities than in the past. However, the need for essential nutrients and biologically active substances remains unchanged, resulting in a deficit. Insufficient quantities of these substances lower the body's resistance to adverse environmental impacts, contribute to immune deficiency and chronic diseases, or increase the risk of developing illnesses. Consequently, this leads to reduced quality of life and effectiveness of medical treatments.

In response to these regulatory challenges, the following three-tier regulatory framework has been established at the international level:

1. Diet modification**:** Promoting healthy and balanced nutrition through state policies in the field of healthy eating.
2. Fortification of staple foods**:** Enriching foods like salt (with iodine), flour (with vitamins and minerals), vegetable oils, and margarine (with vitamins A and D). The mandatory fortification of foods is typically stipulated by regulatory acts.
3. Use of food supplements**:** Addressing the problem of high-quality and balanced nutrition as a basis for optimal human health.

This mechanism has led to the emergence of one of the most pressing global healthcare issues today: the quality, efficacy, and safety of medicinal products and food for special medical purposes.

AIM

The purpose of this article is to determine the legal status of food products for special medical purposes, dietary and food supplements, and food products intended for specific consumer groups, including herbal and fruit teas for infants or young children. For instance, Directive 2002/46 (Article 2) and Regulation No. 609/2013 (Article 2) should be interpreted to mean that the terms "food supplements" and "food products for special medical purposes," as defined in these provisions, are mutually exclusive. Each case requires individual analysis based on the characteristics and conditions of use to determine whether a product falls under one category or the other.

MATERIALS AND METHODS

This study primarily relies on the analysis of EU Directives and Regulations, using Germany's legal framework as an example, including content analysis and case law. It also employs the dialectical method and incorporates perspectives from scientific literature.

REVIEW AND DISCUSSION

For example, the German Dietary Supplement Regulation (NemV) of May 24, 2004, as amended [2], regulates the circulation of dietary supplements, which, under this Regulation, are classified as food products (§ 1). These products:

1. Are intended to complement the general diet;
2. Consist of concentrates of nutrients or other substances with nutritional or physiological effects, either individually or in combination;
3. Are marketed in dosed forms, such as capsules, lozenges, tablets, pills, and similar pharmaceutical forms, as well as powder sachets, liquid ampoules, dropper bottles, and similar forms for consumption in small measured quantities.

Nutrients, under this Regulation, include vitamins and minerals, including trace elements.

Thus, the term "dietary supplement" (§ 4 NemV) refers to food products as defined by Regulation (EU) No. 1169/2011. A dietary supplement (§ 2 NemV), intended for consumer supply, may only be sold as a pre-packaged food product under Article 2(2)(e) of Regulation (EU) No. 1169/2011 of the European Parliament and Council, dated October 25, 2011, regarding the provision of food information to consumers, amending Regulations (EU) No. 1924/2006 and (EU) No. 1925/2006, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, European Parliament and Council Directive 2000/13/EC, Commission Directive 2002/67/EC, Commission Directive 2008/5/EC, and Regulation (EU) No. 608/2004 [3].

The production of dietary supplements is limited to substances (§ 3 NemV) listed in Annex I of Directive 2002/46/EC of the European Parliament and Council, dated June 10, 2002, concerning the approximation of member states' laws regarding dietary supplements (OJ L 183, July 12, 2002, p. 51). The nutrients listed under § 1, paragraph 2, are used in forms outlined in Annex II of Directive 2002/46/EC. Annexes I and II to Directive 2002/46/EC are applied in the version of December 5, 2011 (OJ L 296, November 15, 2011, p. 29).

Food products are defined as "specific substances suitable for human consumption." They consist of basic food items (e.g., meat, fish, eggs, dairy products, fruits, vegetables, and grains containing proteins, carbohydrates, fats, vitamins, and minerals) and additives (herbs and spices, sweeteners, colorants, preservatives, antioxidants, emulsifiers, thickeners, stabilizers, and solvent carriers) [4].

Substances listed in Annex II of Directive 2002/46/EC, as amended on December 5, 2011 (OJ L 296, November 15, 2011, p. 29), must conform to the specifications set forth in Regulation (EU) No. 231/2012 of the Commission, dated March 9, 2012, which establishes specifications for food additives listed in Annexes II and III to Regulation (EU) No. 1333/2008 of the European Parliament and Council (OJ L 83, March 22, 2012, p. 1), in its current version, and meet the prescribed purity requirements. Simultaneously, substances listed in Annex II of Directive 2002/46/EC, as amended on December 5, 2011, (OJ L 296, November 15, 2011, p. 29), but not listed in Regulation (EU) No. 231/2012, must meet purity requirements achievable under generally recognized standards.

According to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, and Article 2 of Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC, and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council, and Regulations (EC) No. 41/2009 and (EC) No. 953/2009 of the Council and the Commission, it should

be interpreted that, to distinguish between the terms "medicinal products" and "food for special medical purposes" as defined in these provisions, it is necessary to assess whether the product is a food in light of the nature and characteristics of the relevant product designed to meet specific dietary needs, or whether it is a product intended to prevent or treat human disease, restore, correct, or influence human physiological functions through pharmacological, immunological, or metabolic action, or to establish a medical diagnosis.

Regulation No. 609/2013 should be interpreted, firstly, that the term "dietary compliance" encompasses the need caused by a disease, disorder, or health complaint, and the satisfaction of such a need is critically important for the patient in terms of nutrition. Secondly, the qualification as a "food for special medical purposes" cannot depend on the success of "dietary management" caused by a disease, disorder, or complaint and, thus, the product's effect that necessarily arises due to or as a result of digestion. Thirdly, the phrase "diet modification for the patient only" includes situations where diet modification is impossible or dangerous for the patient, as well as situations where it is very difficult for the patient to meet their nutritional needs using regular food.

In Article 2 of Regulation No. 609/2013, this sentence should be interpreted, firstly, that the product must be used under medical supervision if a recommendation and subsequent evaluation by a medical professional regarding a disease caused by a specific condition or dietary needs related to a disorder or specific complaints is necessary due to the impact of the product on the patient's nutritional requirements. On the other hand, the requirement that food for special medical purposes "must be used under medical supervision" does not exist as a mandatory condition for classifying the product as food for special medical purposes.

Directive 2002/46 (Article 2) and Regulation No. 609/2013 (Article 2) should be interpreted to mean that the concepts of "food supplements" and "food for special medical purposes," as defined in these provisions, are mutually exclusive. In each case, it is necessary to decide based on the characteristics and conditions of use whether the product falls under one or the other of these definitions.

Thus, among regular food and/or dietary supplements and food products, it is essential to distinguish food for specific consumer groups, including herbal and fruit teas for infants or young children.

According to the Regulation on Food for Specific Consumer Groups (LMBVV) of 26 April 2023 [5], herbal and fruit teas for infants or young children are defined as: 1) herbal or fruit tea, extracts of herbal or fruit tea, or food products containing extracts of herbal or fruit tea, which must be prepared with water to be suitable for consumption, and which, according to their name, other information, or symbols on the packaging or label attached to the packaging, based on their presentation, appearance, or advertising claims, are exclusively or partly intended for consumption by infants and young children; and 2) beverages prepared from herbal or fruit tea extracts and intended for immediate consumption, their extracts, or preparations, as determined by the name, other information, or symbols on the packaging or label attached to the packaging, product appearance, or advertising claims, which are exclusively or partly intended for consumption by infants and young children.

When preparing these specific types of food for infants and young children, certain groups of ingredients listed in § 4 LMBVV must not be used. Herbal and fruit teas for infants and young children may only be sold in retail stores as pre-packaged food products, provided that the labeling on the packaging or a label attached to it contains information:

1. indicating that sugar and other sweeteners should be avoided when preparing and serving the tea;
2. specifying the age from which infants or young children can consume the tea.

This information must be clearly visible, legible, and understandable on the packaging and must not be hidden or obscured by other information, symbols, or inserted materials.

The marketing of infant formula or follow-up formula with statements that may mislead consumers is prohibited pursuant to § 7 LMBVV, such as "contains only lactose" or "lactose-free," "very low-calorie diet," or "low-calorie diet."

Advertising for infant formula or follow-up formula is not allowed. Specifically, promotional activities in retail settings are prohibited, including distributing samples or using other promotional materials like special displays, discount coupons, bonuses, special offers, incentives, etc., as part of marketing agreements.

It shall be prohibited for manufacturers and distributors to engage in the distribution of products at no cost or at reduced prices, including but not limited to promotional samples to the general public, pregnant women, mothers, or their families, either directly or indirectly through healthcare services or medical professionals.

The use of phrases such as "for special medical purposes" is prohibited if it may mislead specific categories of consumers. Often even professionals fail to distinguish between foods for special medical purposes, dietary supplements, and medicinal products.

The Court of Justice of the European Union has issued a preliminary ruling on this matter [6] in response to a request for a preliminary ruling concerning the

interpretation of Article 2(2)(g) of Regulation (EU) No 609/2013 of the European Parliament and Council of June 12, 2013, on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC, and 2006/141/EC, Directive 2009/39/EC of the European Parliament and Council, and Regulations (EC) No 41/2009 and (EC) No 953/2009 of the Council and Commission (OJ 2013, L 181, p. 35), and the interpretation of Directive 2002/46/EC of the European Parliament and Council of June 10, 2002, on the approximation of laws of the Member States relating to food supplements (OJ 2002, L 183, p. 51).

The European Court emphasizes that the characteristics and functions of foods for special medical purposes differ from those of medicinal products. Foods for special medical purposes are intended to support the dietary management of patients and are not meant to prevent or treat human diseases that affect physiological functions through pharmacological, immunological, or metabolic processes, nor to restore or correct physical conditions or provide medical diagnoses.

Therefore, foods for special medical purposes do not inherently combat diseases or bodily disorders. The patient benefits from consuming the product insofar as its ingredients contribute to preventing, alleviating, or treating the disease. However, the product is not intended to provide nutritional benefits to the patient but rather to address, prevent, or restore human physiological functions through pharmacological, immunological, or metabolic effects. This suggests that the product should be classified as something other than "food for special medical purposes".

Foods for special medical purposes are designed for patients with specific nutritional needs that cannot be met by modifying a regular diet as defined in Article 2 of Regulation No 609/2013. These needs cannot be satisfied by consuming ordinary foods alone.

The requirement of 'under medical supervision' as set forth in Article 2 of Regulation No 609/2013 shall be interpreted to mean that qualified medical oversight must be established prior to the product's placement on the market.

Thus, the use of foods for special medical purposes, which are tailored to the patient's nutritional needs, should be recommended by a healthcare professional based on the patient's dietary requirements, without necessarily requiring a prescription. In this context, "medical supervision" necessitates that a healthcare professional, as defined in Regulation 2016/128, ensures that the use of foods for special medical purposes aligns with the patient's specific nutritional needs.

Additionally, the legislator, based on Article 9 of Regulation No 609/2013, allows for the provision of useful information or recommendations exclusively for medical, dietary, or pharmaceutical professionals or other healthcare workers responsible for maternal and child care, recognizing their unique responsibilities when dealing with foods for special medical purposes.

Moreover, a healthcare professional's recommendation for foods for specific medical purposes is even more critical, as indicated in the fourth preamble of Regulation No 2016/128. The composition of these foods may significantly differ depending on the disease, disorder, or condition they are intended to manage, as well as the patient's age, the location of medical care, and the intended use of the product.

Such a recommendation ensures that food products for special medical purposes, as specified in Article 2 of the Regulation, can be used effectively in accordance with the manufacturer's instructions and fulfill the specific dietary needs of the individuals for whom they are intended. Specifically, since food products for special medical purposes are designed to address nutritional needs arising from specific diseases, disorders, or medical conditions, using an unsuitable product may not only fail to meet the patient's needs but could also lead to negative consequences.

This risk must also be communicated to the patient, and according to Article 5 of Regulation 2016/128, it must be indicated on the packaging of foods for special medical purposes. In view of this, Article 2 of Regulation No. 609/2013 should be interpreted to mean, on the one hand, that a product must be used under medical supervision if special dietary management is required due to a disorder or specific complaints affecting the patient's nutritional needs. On the other hand, the requirement that a food product for special medical purposes "must be used under medical supervision" is not an absolute condition for classifying a product as food for special medical purposes.

There is also a question about the criteria for distinguishing the terms "food for special medical purposes" under Regulation No. 609/2013 and "dietary supplements" as defined in Article 2 of Directive 2002/46, and whether these terms are mutually exclusive.

In this regard, it should be noted that considering the respective characteristics of foods for special medical purposes and dietary supplements, their uses may overlap. However, the two terms and the legal classifications they imply are necessarily mutually exclusive. Thus, in each specific case, it must be determined whether the product should be classified as "food for special medical purposes" or as a "dietary supplement".

Although dietary supplements under Article 2 of Directive 2002/46 merely supplement a "normal diet,"

Article 2 of Regulation No. 609/2013 and Article 2 of Regulation 2016/128 establish the concept of "foods for special medical purposes." For purposes that wholly or partially replace regular nutrition, dietary supplements are concentrates of nutrients or other substances with specific nutritional or physiological effects that, like certain foods, may meet some nutritional needs for specific medical purposes. However, foods for special medical purposes are characterized by their medical intent, which dictates that they are intended for patients and must be used under medical supervision.

For these reasons, the Court (Second Chamber) has ruled that the requirements of Directive 2001/83/EC of the European Parliament and Council of November 6, 2001, on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of March 31, 2004, and Article 2 of Regulation (EU) No. 609/2013 on foodstuffs intended for infants and young children, foods for special medical purposes, and total diet replacement for weight control must be interpreted as follows: "To distinguish between the terms 'medicinal products' and 'foods for special medical purposes,' as defined in these provisions, it is necessary to assess, based on the nature and characteristics of the relevant product, whether it is a food intended to meet specific dietary needs or a product designed for the prevention, treatment, restoration, correction, or modification of human physiological functions through pharmacological, immunological, or metabolic action, or for making a medical diagnosis".

Article 2 of Regulation No. 609/2013 should be interpreted as follows: firstly, the term "dietary management" includes needs caused by disease, disorder, or condition that are nutritionally significant for the patient. Secondly, the classification as "food for special medical purposes" should not depend on the success of "dietary management" resulting from disease, disorder, or condition or necessarily depend on digestion as the product's mode of effect. Thirdly, the subcategory "modification of the patient's diet alone" includes situations where dietary change is impossible, dangerous, or very challenging to meet nutritional needs with regular food consumption.

In this context, it should be noted that food for special medical purposes and dietary supplements are foodstuffs intended for different target groups. Specifically, Article 3 of Directive 2002/46 does not imply that dietary supplements, like foods for special medical purposes, are intended only for patients.

It is important to emphasize that, according to Article 2 of Regulation No. 609/2013, foods for special medical purposes must meet specific dietary requirements. This classification depends on the fact that modifications to the normal diet are insufficient to meet these needs, while dietary supplements are intended to complement a regular diet as an integral part of it.

The rules regarding the composition of these two categories of food products reflect these differences and particularities. For example, Directive 2002/46 establishes maximum levels for vitamins and minerals in dietary supplements, taking into account safe upper levels based on risk assessments from scientific data, consumer sensitivity variations, dietary intake from other sources, and reference population levels for vitamins and minerals.

However, such reference values are established for the general population pursuant to the provisions of Directive 2002/46/EC, not patients with dietary needs arising from diseases, disorders, or medical conditions.

Dietary supplements may only be marketed if, in addition to the information required by Regulation (EU) No. 1169/2011, the packaging indicates: (1) the names of categories of nutrients or substances characterizing the product or their characteristics, (2) the recommended daily portion, (3) a warning not to exceed the recommended daily intake, (4) a statement that supplements should not substitute a balanced diet, and (5) a directive to store the product out of children's reach.

Dietary supplements may not be marketed under names, claims, or presentations, nor advertised in a way that implies a balanced and varied diet does not generally provide sufficient nutrients.

Products that contain, exclusively as an addition to vitamins or minerals, other substances with nutritional or physiological effects may also be labeled as "food supplements" provided this does not mislead consumers. This is because food supplements are not defined solely by their nutrient content. Instead, what determines the product's classification as a food supplement is the presence of ingredients intended to complement the general diet and the fact that the product is marketed in a dosed form. In such cases, other specific labeling elements in accordance with NemV [8] must be taken into account. In this context, misleading consumers is prevented by the obligation to specify the category of the characteristic substance, meaning the necessary trade name is supplemented with descriptive elements. If a product is suitable both as a standard food supplement and for dietary purposes, the manufacturer must decide and develop the product according to its designation. A product either serves as a supplement to the general diet, thereby qualifying as a "food supplement," or it is intended for a special diet and, depending on the product type, is given a trade name.

Moreover, according to the Regulation implementing Union law provisions related to consumer information

about food products, dated July 5, 2017 [9], if the country or place of origin of the food product does not match the country or place of origin of its primary ingredient, the food product must also indicate the origin of the main ingredient or specify that the primary ingredient comes from a different country or place of origin than the food product itself.

Regarding the incorrect labeling of dietary supplements in terms of health benefits or effects on health, there is relevant case law in Germany. For instance, the Higher Regional Court of Munich considered a case of misleading labeling of a dietary supplement for weight loss. The product was labeled in a way that gave the impression it was a medicinal product. The Court issued an injunction prohibiting the distribution and sale of said product pursuant to the applicable provisions of pharmaceutical law [10].

Given the closely related functions of medicinal products and dietary supplements, as well as the complex interplay of European and national standards in pharmaceutical and food law, numerous issues traditionally arise in distinguishing between these two product categories. This has been one of the most interesting areas of administrative and competition law over the past 30 years. "The issue of differentiation is further complicated by the external appearance of dietary supplements, the economic significance of the differentiation outcome for sales, and the rapid Europeanization of the market", says German expert Marc Dilewski [11]. First and foremost, the researcher notes, the relevant terms for differentiating medicinal products from food/food supplements have fundamentally changed in recent years.

With the entry into force of Directive 2002/46/EC of the European Parliament and Council of June 10, 2002, on the approximation of the laws of the Member States relating to food supplements as of July 12, 2002 [12], and its implementation at the national level through the Dietary Supplement Ordinance (NemV) of May 24, 2004 [13], the term "dietary supplement" was legally defined at the Community level for the first time. It was also clearly stated that dietary supplements are not medicinal products within the meaning of Directive 2001/83/EC of the European Parliament and Council of November 6, 2001, on the Community Code for Medicinal Products for Human Use [14]. Furthermore, existing case law has shown that the legal definition of dietary supplements is becoming increasingly important for distinguishing them from medicines [15]. By the decision of the First Civil Senate of the Federal Court dated May 6, 2004 [16], specific distinctions between medicines and food supplements were clarified.

The matter had previously been subject to judicial review by the Fifth Civil Senate of the Supreme Court, specifically, the decision of the Fifth Civil Senate of the Supreme Court dated May 11, 2001, which was overturned upon appeal by the defendant, and the case was returned to the appellate court for rehearing and decision, including appeal costs.

For example, The defendant, a legal entity established under the laws of the Netherlands, engaged in the distribution within the territory of the Federal Republic of Germany of products not registered there as medicinal products but claimed to help build larger or stronger muscles. These products, including "Creatine Monohydrate,""HCA+," and "Liquid L-Carnitine," were positioned as aids for fat reduction and products for boosting the body's resistance.

CONCLUSIONS

For the purposes of this Regulation, food supplements shall be defined as food products that:

1. Are intended to complement the general diet;
2. Contain a concentrated source of nutrients or other substances with nutritional or physiological effects, individually or in combination;
3. Are marketed in a dosed form, such as capsules, lozenges, tablets, pills, and other similar pharmaceutical forms, sachets of powder, liquid ampoules, dropper bottles, and similar liquid and powdered forms for intake in measured doses.

Among regular food and/or dietary supplements and food products, food for specific consumer groups should be distinguished, such as herbal and fruit teas for infants or young children.

Food products for special medical purposes are those intended for the dietary management of patients and are not designed to prevent or treat human diseases, nor to restore, correct, or affect physiological functions through pharmacological, immunological, or metabolic processes, nor to make medical diagnoses.

Thus, food products for special medical purposes do not allow them to counteract diseases or disorders as such.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

CORRESPONDING AUTHOR

Vitalii M. Pashkov
Academician Stashis Scientific Research Institute
for the Study of Crime Problems of the
National Academy of the Law Sciences of Ukraine,
Yaroslav Mudriy National Law University , Kharkiv, Ukraine
e-mail: v.pashkov26.06@ukr.net

ORCID AND CONTRIBUTIONSHIP
Vitalii M. Pashkov: 0000-0001-9489-7768 A B D E F
Oleksii S. Soloviov: 0000-0002-6615-4868 A B D E F
Olga A. Khmelnytska: 0009-0009-1489-8062 A B D E F

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