REVIEW ARTICLE

CONTENTS

# Foodstuffs for particular nutritional purposes and dietary supplements in the legal-medical context

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## ABSTRACT

Foodstuffs for special dietary purposes are products that, due to their special method of preparation or composition, differ from common foodstuffs and are intended to meet the nutritional needs of specific groups of consumers, such as oncology patients. The indication for the use of these products is to provide the body with essential nutrients in the right proportions, thereby improving or maintaining the current state of health. Dietary supplements are also food products that contain vitamins and other substances, and their intake is aimed at helping to maintain specific nutrients in the human body at the appropriate level.Dietary supplements should be used under medical supervision and at a dosage determined by the body's needs. Both of the above-mentioned groups of nutritional products are gaining increasing popularity among consumers. Many of them, encouraged by the described health benefits, use and dose these products without consulting a doctor or pharmacist, often exceeding the recommended intake and even replacing a well-balanced diet, which can pose a serious health risk.These products, in combination with certain medications, can also pose a serious risk of adverse effects, especially in the elderly population taking multiple medications.Therefore, their use should be cautious, and in case of any doubts, it should be preceded by consultation with a doctor or pharmacist.

**KEY WORDS:** dietary supplements, foodstuffs for special dietary purposes, food law, medical practice.

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## INTRODUCTION

The Act on Food and Nutrition Safety includes regulations concerning foodstuffs for special dietary purposes and dietary supplements [1]. This law is supported by numerous directives and regulations of European Union bodies related to nutritional products [2-7]. The discussed products are available for general sale or by prescription in pharmacies, pharmaceutical outlets, and some of them are also available in grocery stores and other non-pharmaceutical entities. The Act defines and categorizes foodstuffs for special dietary purposes and dietary supplements as food products governed by specific conditions of use and availability [1]. This pertains to modifications, fortification, or recommendations for a special diet, which fall under the expertise of a physician, dietitian, or may be a decision made by the consumer themselves (in the case of dietary supplements).

## AIM

The aim of this paper is to present the legal regulations in force in Poland regarding dietary supplements and foodstuffs for special dietary purposes, as well as to provide medical professionals and other interested parties with a characterization of these nutritional products, the differences between them and medicinal products, and to highlight the difficulties in their clear classification. Additionally, attention should be drawn to their wide availability and the related safety of their use.

## MATERIALS AND METHODS

A review and analysis of legal regulations concerning foodstuffs for special dietary purposes and dietary supplements was conducted, with particular emphasis on the *Act of August 25, 2006, on Food and Nutrition Safety*. Additionally, a review and analysis of available statistical

data prepared by Polish and foreign research entities, as well as data from the medical literature, were carried out using PubMed and Google Scholar databases. Publications in both Polish and English were analyzed, using the following keywords for the review: *dietary supplements, foodstuffs for special dietary purposes, food law.*

## REVIEW AND DISCUSSION

### FOODSTUFFS FOR SPECIAL DIETARY PURPOSES

A foodstuff for special dietary purposes, according to the definition contained in the Act (Chapter 6), is a *product that, due to its special composition or method of preparation, significantly differs from traditional food and, according to the information provided on the packaging, is marketed to meet the specific nutritional needs of particular groups of consumers (e.g., patients)* [1].Foodstuffs for special dietary purposes are products that must meet both the requirements applied to commonly used foodstuffs, as well as specific requirements regarding their composition and method of production [1].

This arises from the fact that the rationale for introducing and using foodstuffs for special dietary purposes in a specific patient often stems from medical considerations. Therefore, this category of food is of significant importance for certain groups of consumers and is used in some health conditions and diseases as a partial or exclusive source of nutrition [8].

Foodstuffs for special dietary purposes include: food products intended for infants, food products intended for young children, foodstuffs for people on a diet, foodstuffs for physically active individuals (athletes), as well as foodstuffs used in specific diseases or health conditions [9].

The foodstuffs for special dietary purposes described in the Act specifically include:

1) preparations for initial infant feeding (infant formula), and preparations for continued infant feeding (follow-on formula)
2) complementary foodstuffs, including processed cereal-based products and other foodstuffs for infants and young children aged 1 to 3 years.
3) foodstuffs used in energy-restricted diets for the purpose of weight reduction.
4) dietary foodstuffs for special medical purposes.
5) foodstuffs that meet the body's needs during intense physical exertion, especially for athletes
6) foodstuffs for individuals with carbohydrate metabolism disorders (diabetes)
7) low-sodium foodstuffs, including low-sodium or sodium-free dietary salts
8) gluten-free foodstuffs [1].

Unlike dietary supplements, which are intended to complement a balanced diet rather than replace it, foodstuffs for special dietary purposes can be used as the sole source of nutrition under the supervision and prescription of a doctor (they are often available only by prescription). The issue of correctly classifying a product as food for special dietary purposes was addressed by the Court of Justice of the European Union (CJEU) in a ruling published on October 27, 2022, in which it stated that: "for the purposes of such classification, it is not sufficient that the patient derives a general benefit from consuming this food because the substances it contains counteract or alleviate the symptoms of the disorder"[10]. Therefore, in accordance with the *Act*, foodstuffs for special dietary purposes must meet the general requirements set for foodstuffs, as well as certain specific regulations, including those regarding their composition and method of production [11]. For example, a foodstuff for special dietary purposes intended for infants must meet very strict safety standards and also cater to the specific and dynamically changing nutritional needs of a developing child's body, which differ from those of the general population. Its composition should be tailored to the age and health condition of the developing child, ensuring proper physical growth and psychosocial development, especially since this product may serve as the sole source of nutrition for the child for a certain period. The amount of specific nutrients must be precisely determined, and the presence of substances in quantities that pose a threat to the health and life of an infant is unacceptable. Therefore, the labeling on the product must be accurate and clearly inform consumers about the product's composition and purpose, with the label being clear, reliable, and not misleading [12]. Similarly, products intended for individuals with health problems, whose metabolism is impaired or whose body is severely weakened by a progressing illness, must have a precisely defined composition, and their nutritional properties should be tailored to the health needs of these individuals [10].

*The Act* permits advertising of these products in a very limited scope, and it prohibits:1) the advertisement of preparations for initial infant feeding in places where they are sold (e.g., in pharmacies)

2) the conducting of promotional activities (such as the distribution of samples, special promotional displays, discount coupons, premiums, special sales, or bundled sales) that encourage the purchase of preparations for initial infant feeding and items used for infant feeding

3) the offering or providing by manufacturers or distributors of preparations for initial infant feeding and items used for infant feeding, as well as their samples (or

other promotional items), to consumers—particularly to pregnant women, parents of infants, or members of their families—either directly or through healthcare providers, free of charge or at a reduced price [1].

Correct and clear labeling of food products, including foodstuffs for special dietary purposes, is of great importance. The product label should primarily serve an informational function, with a promotional function being secondary. This is because the label serves as a crucial source of information for consumers about the food product and can also play an educational and warning role [13-14]. The product label must clearly indicate the product's characteristics and must not mislead the consumer regarding its properties or intended use. Food certification systems are applied in the EU market [15].

Sometimes, the clear classification of food products into the correct group is very challenging, not only for consumers but also for dietitians, pharmacists, and doctors. Often, the only source of information about a product is the leaflet and label. The form of the food product, its packaging, or the product information can be misleading for consumers. As a result, consumers may not be aware of what type of product they are using—whether it is a medication, dietary supplement, or foodstuff for special dietary purposes—and the differences between these product categories [11]. The solution lies in precise and understandable definitions and descriptions of food products, which should ensure their transparency and safe use [16].

Information and recommendations regarding foodstuffs for special dietary purposes may be directed exclusively to individuals qualified in the fields of medicine, pharmacy, or nutrition. This requirement is particularly important for those offering such products, namely doctors and pharmacists. As a qualified and competent individual, the pharmacist informs interested consumers about the effects, specifics, intended use, and safety of a given product. Additionally, since some of these products are subject to reimbursement, the pharmacist is responsible for checking and verifying the details related to dispensing products eligible for such reimbursement.

## DIETARY SUPPLEMENTS

Dietary supplements are classified as food products and can be offered in pharmacies, pharmacy outlets, grocery stores, or sold online commercially. Unlike medicinal products, they are not subjected to detailed testing in terms of stability, interactions, or pharmacotherapy safety supervision, and their composition is determined by the product manufacturer [11]. In the European Union and in Poland, dietary supplements are treated as food products, and their use is not intended for treating or preventing diseases in humans or for modifying physiological functions. Instead, their purpose is solely to supplement the daily diet, which should be the foundation of a healthy lifestyle [4].

In the United States, a dietary supplement is defined as a product intended to supplement the diet. A dietary supplement contains one or more dietary ingredients, including vitamins, minerals, herbs or other botanical ingredients, amino acids, and other substances or their components. It is intended for oral intake in the form of a pill, capsule, tablet, or liquid and is labeled on the front of the product packaging as a dietary supplement [17]. The definition of a dietary supplement explicitly highlights its complementary (dietary) nature, which should also be reflected in the corresponding description on the product label. Supplements are considered food products, not medicinal products. As a result, they do not carry information about potential risks to consumer health or life [18]. However, it is important to pay attention to their safety and the possible interactions with other medications, foods, and herbal products [19]. For example, St. John's wort can reduce the effectiveness of certain cancer and antiviral drugs by increasing glycoprotein activity [20, 21].

Dietary supplements are designed to meet the specific needs and requirements of various consumer groups [22]. According to the "Poland and Supplements" report prepared by the Polish Economic Institute, the value of the dietary supplement market in 2024 exceeded 7 billion PLN, marking continued growth compared to previous years [23]. For comparison, the market was valued at 4.4 billion PLN in 2017 [24]. Furthermore, according to the "Poles and Dietary Supplements" report from 2022, two-thirds of Poles take dietary supplements, with over 20% consuming as many as three different types of such products. However, only about 15% of supplement users consult a doctor before purchasing a specific product [25]. The appearance, presentation, availability of supplements in pharmacies, and their intended use often make them closely resemble medications, potentially misleading consumers into thinking these products are as safe as medicines [26, 27].

Unfortunately, the safety of dietary supplements is not confirmed by appropriate studies before they are placed on the market, leading to risks associated with irresponsible use, overconsumption, and potential dangerous interactions with medications, herbs, or other supplements. A separate risk category is related to their composition, which may be contaminated with substances like heavy metals or microorganisms. The potential presence of hazardous substances, contro-

versial compounds, or those subject to regulation can pose serious health risks [28]. Additionally, counterfeit supplements may also be on the market, where the actual composition differs from what is stated on the packaging, especially when sourced from unreliable places, such as suspicious websites.

A review conducted in Poland by the Supreme Audit Office (Najwyższa Izba Kontroli) revealed that the system for monitoring the introduction of dietary supplements into the market did not adequately protect consumers [29]. The audit identified dietary supplements sold online that contained ingredients prohibited for use in food products and potentially dangerous to health. Furthermore, many of the tested products were found to contain unauthorized ingredients, whose use is not permitted [29].

The dietary supplement market continues to grow rapidly, driven by widespread promotion in the mass media, an easy process for introducing products to the Polish market, and their wide availability [30]. Besides the issue of supplement composition, which remains questionable without proper quality testing, another significant risk lies in the conditions of sale and storage. For example, dietary supplements sold in drugstores, grocery stores, or at gas stations could be subject to improper storage conditions that may affect their quality and efficacy.

## CONCLUSIONS

In Polish law, the Food Safety and Nutrition Act defines foodstuffs for special nutritional purposes and dietary supplements. Both are categorized as food products, not medicinal products, which aligns with their categorization in European law. Due to their potential harmful effects when misused or overused, it is essential to continuously raise consumer awareness. Consumers should pay close attention to the information provided on product labels and leaflets, and avoid purchasing products with unclear details about their composition or purpose, especially from questionable sources.

These products are widely available to consumers in pharmacies, stores, and other outlets, mostly without a prescription. Therefore, medical professionals such as doctors, pharmacists, and dietitians play a crucial advisory and supervisory role in ensuring consumer safety. Additionally, legislative changes are necessary to introduce stronger oversight and regulation, particularly concerning the dietary supplement market.

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## CONFLICT OF INTEREST

The Authors declare no conflict of interest.

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