## MODERN HYGIENIC APPROACHES TO ASSESSING THE COMPLIANCE OF SPECIALIZED FOOD PRODUCTS

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One way to meet the body's physiological nutrient needs is to normalize the population's diet through specialized food products (SFP), including biologically active supplements (BAS). At the same time, the content of bioactive substances in these products requires confirmation of compliance with the mandatory requirements of the Eurasian Economic Union (EAEU) legislation. Sanitary and epidemiological examination is key to obtaining a positive or negative decision on the SFP's compliance with established requirements and declared properties. ased on the results of the sanitary and epidemiological examination, Rospotrebnadzor or another authorized body decides to issue a state registration certificate (SRC), which serves as a document allowing the manufacturer to produce and sell SFPs within the EAEU. This article presents an assessment of modern hygienic approaches to the sanitary and epidemiological examination of SFPs and provides explanations of the procedure for preparing the required documentation for examination. The provisions of the publication will be useful to specialists performing sanitary and epidemiological examination of SFPs, as well as to manufacturers and applicants planning to obtain a SRC.

**Keywords:** specialized food products, list of documents for examination of specialized food products, sanitary and epidemiological examination, quality and safety requirements

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## СОВРЕМЕННЫЕ ГИГИЕНИЧЕСКИЕ ПОДХОДЫ К ОЦЕНКЕ СООТВЕТСТВИЯ СПЕЦИАЛИЗИРОВАННОЙ ПИЩЕВОЙ ПРОДУКЦИИ

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Один из путей обеспечения физиологических потребностей организма в нутриентах лежит в нормализации рациона питания населения с помощью специализированной пищевой продукции (СПП), в том числе биологически активных добавок к пище (БАД). Вместе с этим, содержание биологически активных веществ в данном виде продукции требует подтверждения соответствия обязательным требованиям законодательства Евразийского экономического союза (ЕАЭС). При этом санитарно-эпидемиологическая экспертиза является ключевой для получения положительного или отрицательного решения о соответствии СПП установленным требованиям и заявленным свойствам. Именно по результатам санитарно-эпидемиологической экспертизы Роспотребнадзор или другой уполномоченный орган принимает решение о выдаче свидетельства о государственной регистрации (СГР), который служит документом, позволяющим производителю производить и реализовывать СПП на территории ЕАЭС. В статье представлена оценка современных гигиенических подходов к санитарно-эпидемиологической экспертизе СПП, даны пояснения к процедуре подготовки пакета документов, необходимого для предоставления на экспертизу. Рассматриваемые положения будут полезны специалистам, выполняющим санитарно-эпидемиологическую экспертизу СПП, а также производителям и заявителям, планирующим получить СГР.

**Ключевые слова:** специализированная пищевая продукция, перечень документов для проведения экспертизы специализированной пищевой продукции, санитарно-эпидемиологическая экспертиза, требования к качеству и безопасности

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Measures aimed at improving and optimizing the population's diet and combating the constant increase in the incidence of non-communicable diseases of a nutritional nature, such as obesity, type 2 diabetes mellitus, diseases of the digestive and cardiovascular systems, and cancer, are being taken throughout the world. The Russian Federation (RF) adheres to the same policy.

Monitoring the health status of the Russian population has shown that lifestyle factors have become the most significant factors influencing the health of citizens in 2023.

According to Rospotrebnadzor, in 50 regions of Russia, more than half of citizens (53.1%, which in absolute terms accounted for 77.7 million people) had significant health consequences from the exposure to factors such as smoking,

alcohol consumption, and the unbalanced diet [1]. Furthermore, more than half of deaths in the Russian Federation occur as a result of foodborne diseases associated with the consumption of low-quality food products and poor nutrition. Chronic non-communicable diseases are the leading cause of death all over the world. Thus, in 2019 these caused 71% of deaths registered worldwide [2].

One of the ways to normalize the population's diet involves the development and production of innovative products, which include fortified and specialized food products (SFPs), including biologically active supplements (BAS), the use of which allows for a balanced diet, leveling out macro- and micronutrient imbalances. The use of SFPs reduces labor losses, medical expenses, etc., associated with foodborne diseases фоне. As a result, a better quality of life is achieved and the life expectancy of the population increases in general [2]. Rospotrebnadzor is responsible for controlling the production and release of such products for sale to the population.

Modern diets of the population in developed economies are characterized by the increased consumption of processed foods. Furthermore, manufacturers are constantly developing new types of food products to adapt to consumer preferences and demand. Compared to traditional food products, SFPs with the modified macro- and micronutrient composition, the effectiveness of which has been proven during the conformity assessment, have a competitive advantage. The production of such products is associated with specific preparation of the main raw materials and/or further introduction of functional food ingredients, and the technological process involves the use of auxiliary techniques: mixing, grinding, refining, heat treatment, extending storage periods, using additives that improve the organoleptic properties and shelf life of products, etc. Meanwhile, when trying to reduce the cost of production, there is risk of the SFP counterfeiting. In this regard, control over the production and release of such products, including sanitary and epidemiological examination, is extremely important to ensure the safety and health of the population. At the same time, in the course of their professional activities, the authors have become convinced that at the present time, in order to confirm the SFP compliance with the established requirements, objective hygienic criteria are required for conducting the sanitary and epidemiological examination.

The SFP hygienic assessment is the subject of research by many authors, but there are not enough relevant papers at the moment. Thus, the researchers [3] describe some of the features of the state registration procedure, including the procedure for its implementation. There are papers describing the market for baby food in the RF and abroad; the procedure for state registration of food products for children over the age of 3 years is provided [4]. The experience of implementing technical regulations of the Customs Union into the activities of regional bodies and organizations of Rospotrebnadzor is reported [5]. A number of papers provide the data on the market of SFPs in other countries of the Eurasian Economic Union (EAEU) [6]. The paper [7] provides information about the implementation of the draft "Guidelines for Conducting Sanitary-Epidemiological and Hygienic Assessment (Expertise) of Biologically Active Food Supplements" at the Eurasian Economic Commission with the participation of representatives of authorized bodies of the EAEU member states in the field of sanitary and epidemiological welfare.

Based on the above, hygienic assessment of the SFP compliance with mandatory requirements is a pressing issue. The provisions of the paper will be useful to specialists performing sanitary and epidemiological examination of SFPs, as well as to manufacturers and applicants planning to obtain a state registration certificate.

The aim was to develop modern hygienic approaches to assessment of the SFP quality, safety, and efficacy.

## Methods

We performed the analysis, systematization, and synthesis of the legal, regulatory, and scientific information concerning the SFP hygienic standardization. The research objects were full-text documents of the legislative and regulatory acts of the Russian Federation, the EAEU and other countries, scientific publications from the electronic databases (eLIBRARY, PubMed, Scopus, Web of Science) on the issue of SFP manufacture and conformity assessment, as well as our own research data [8].

## Analysis of the current situation

The analysis of the data of food quality and safety monitoring conducted by Rospotrebnadzor since 2019 has revealed an increase in the number of products that do not meet mandatory requirements [1], including SFPs, which suggests either insufficient registration control, or product falsification by manufacturers. However, both require careful analysis and corrective measures.

An example is the detection of the substances not declared by the manufacturers in food products (Fig. 1). According to Rospotrebnadzor, in 2023, undeclared ingredients or potentially hazardous substances were found in most categories of food products widely consumed by both adults and children in all regions of the RF [1].

Of particular concern is the fact that all of these are mass-market products present in the diet of a wide range of consumers. The diagram clearly demonstrates that SFPs, including baby food and dietary supplements, constitute a large share of products, in which the undeclared substances were found, which suggests the relevance of the issue under consideration.

At the same time, the exceeding of permissible levels of contaminants in food products is a serious concern, which once again highlights the importance of the SFP quality and safety control (Fig. 2).

The sanitary and hygienic studies conducted by Rospotrebnadzor in 2023 revealed the presence of hazardous and unacceptable substances in food products. Preservatives were found in 17.66% of the tested food samples, toxic elements in 7.83%, glycidol and glycidyl esters in 3.41%, microbial transglutaminase in 3.03%, sweeteners in 2.78%, pesticides in 2.03%, antimicrobial agents in 1.36%, nitrosamines in 1.29%, GMO ingredients in 0.66%, mycotoxins in 0.31%, β-adrenergic agonists in 0.25%, colorants in 0.16% [1].

The presence of the above substances in food products indirectly affects the total number of disease cases in the population. It is estimated that the share of diseases caused by the presence of toxic and other hazardous substances in food products throughout the Russian Federation in 2023 in absolute terms was 958.4 cases per 100,000 population.

Improving the quality and life expectancy of the population of the RF is undoubtedly possible with the use of SFP, but this category of food products is not an exception in terms of the possible presence of contaminants. The SFP quality and safety are monitored by Rospotrebnadzor, and the state registration system has been functioning since 1997. Some food products in this category are sold through the Chestny Znak (Honest Sign) state labeling and tracking system

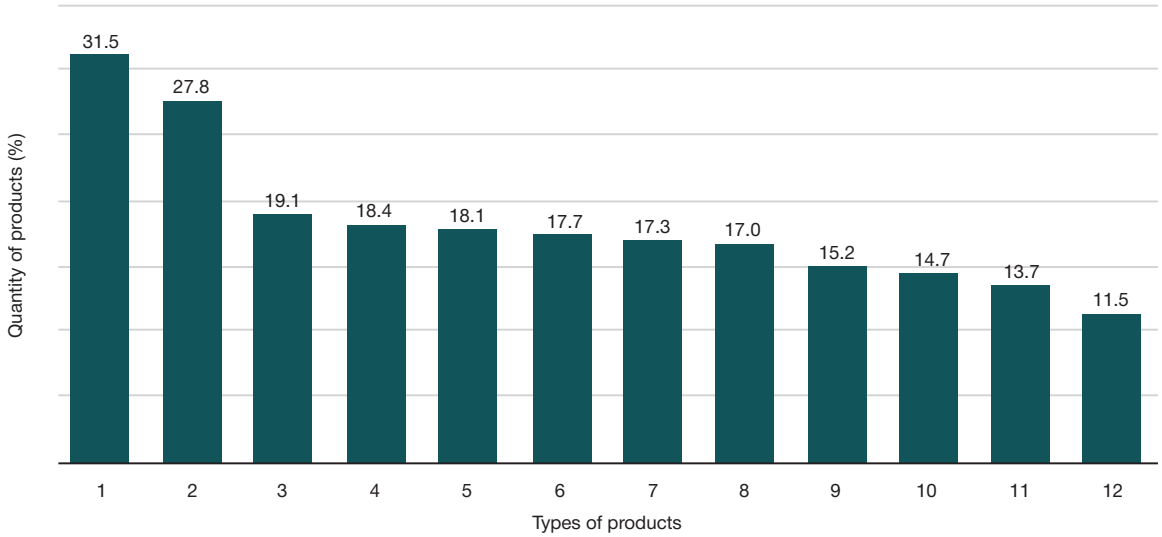


**Fig. 1.** The number of contaminated samples with the detection of undeclared substances by product group in the RF in 2023, % [1]: 1 — SFPs, including baby food and dietary supplements; 2 — fish, non-fish fisheries and products derived from them; 3 — meat and meat products; 4 — poultry, eggs and products of their processing; 5 — honey and bee products; 6 — sugar and confectionery; 7 — grain (seeds); 8 — fruit and vegetable products; 9 — packaged drinking water; 10 — fat and oil products; 11 — beverages; 12 — milk and dairy products

in the form of dietary supplements. Despite this fact, more than 30% of SFPs do not meet hygienic quality and safety standards, and the percentage of dietary supplements containing prohibited substances is high.

### Methodology for preparing a package of documents for examination

Information about the SFP state registration is contained in the Unified Registry of Registered Food Products "Unified Regulatory and Reference Information of the Eurasian Economic Union" [1]. In the RF, the national part of the Unified Registry of Specialized Food Products is in effect: the “Register of State Registration Certificates (within the Eurasian Economic Community Customs Union, Russian part)” [9]. The SFP state registration is indefinite, but it can be terminated or suspended by the authorized body for registration of SFPs. Such a forced measure is resorted to in cases of the SFP non-compliance with the requirements of technical regulations established as a result of state control (supervision) and/or by decision of the judicial authorities of a member state of the Customs Union, due to the fact that providing the population with high-quality and safe food products is one of the priority areas of the countries' development.

The procedure for implementing state registration [10] is based on the results of the sanitary and hygienic examination aimed primarily at assessing the compliance with the following hygienic criteria:

– production safety;
– quality and safety of raw materials and final products;
– SFP efficacy.

The SFP sanitary and hygienic examination represents a the process of reviewing documents, analyzing and evaluating the information contained therein, including information on the label (label layout) and information on the presence of food, biologically active and auxiliary substances, the results of laboratory testing, efficacy assessment, based on which the conclusions about the possibility of registering the product are drawn.

When analyzing the raw components used in SFP, it is necessary to evaluate not only the food components,

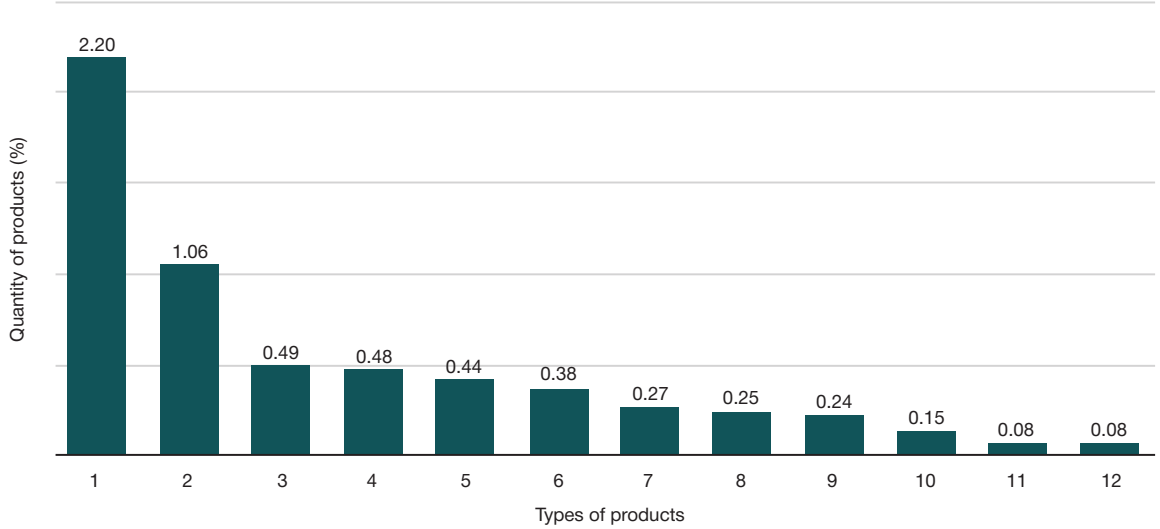


**Fig. 2.** The number of samples exceeding acceptable levels of contaminants by product group in the RF in 2023, % [1]: 1 — grain (seeds); 2 — SFPs, including baby food and dietary supplements; 3 — meat and meat products; 4 — fruit and vegetable products; 5 — fish, non-fish fisheries and products derived from them; 6 — packaged drinking water; 7 — milk and dairy products; 8 — poultry, eggs and products of their processing; 9 — honey and bee products; 10 — sugar and confectionery; 11 — fat and oil products; 12 — beverages

but also the biologically active substances characteristic of these types of raw materials. The documents, in accordance with which the products have been manufactured, are the sources of such information: technical conditions, technological instructions, specifications, recipes and/or information on the composition of products, and other documents. If the SFP contains components of animal origin, it is necessary to confirm their safety by providing documents, including veterinary certificates. If the SFP contains components of plant origin, the documents required must contain information on the part of the plant, as well as the binary name (genus and species of plant) in Latin and Russian. If the SFP contains auxiliary food components, including food additives and flavorings, a document containing information on the source and method of obtaining them has to be provided.

The documents provided for examination include the manufacturer's declaration indicating that the SFP manufactured is compliant with the requirements of the regulatory documentation according to which it is produced, such as copies of quality certificates or safety (quality) data sheets for products, or quality certificates certified by the manufacturer, or an information letter from the manufacturer.

Before starting selling the SFP, the manufacturer develops a draft label inscription (information indicated in the marking), including so that consumers are informed about the product features, and information about the product distinctive features is presented objectively and does not mislead the consumer. In this regard, copies of labels or their layouts must be submitted for expert evaluation, containing not only information on the product composition, nutritional and energy value, but also recommendations for use, restrictions on intake. The requirements for the labeling design are set out in TR CU 022/2011 "Food Products in Terms of Their Labeling" [11].

The SFP test samples are the object of conformity assessment [12]. The product samples selected must be identical to the products intended for sale to the consumer in all parameters, composition, and manufacturing technology образцы. The product samples selected must be isolated from other products, packed, sealed or stamped at the selection site., A selection report is produced in accordance with GOST R 58972—2020 based on the results of the SFP sample selection [13] .

Laboratory testing of the indicators characterizing the quality and safety of food products must be carried out in the testing laboratories (centers) accredited in the established manner and included in the "Unified Registry of Conformity Assessment Bodies of the Eurasian Economic Union" [14]. When establishing the SFP compliance with the safety and quality requirements, the test methods certified in accordance with the established procedure must be used. The product testing and measurement results are applicable to all the products, among which the specified product samples were selected [15].

The SFP production conditions are also the subject of expert evaluation. For substantiation the documents confirming the implementation of the management system and/or a copy of the certificate of production compliance with the principles of good manufacturing practice (GMP) are provided. Furthermore, a copy of the certificate of implementation of a food safety management system based on the ISO 22000 international standard and/or documents confirming that the manufacturer has developed, implemented and maintains procedures based on the principles of hazard analysis and critical control points (HACCP) can be provided [16].

When performing the SFP examination, the absence (presence) of psychotropic, narcotic, toxic, potent substances, doping substances as defined by the current WADA list, nanomaterials, hormones, pesticides, genetically modified (transgenic) organisms and microorganisms, as well as synthetic drugs in the products is determined [17, 18]. A declaration of absence of the listed substances and a declaration confirming the product compliance with the requirements of the applicable Customs Union technical regulations are provided [15, 17, 18].

To ensure objective assessment of the SFP quality and safety, as well as authenticity, the conformity assessment documents completed in accordance with the established procedure must be available for raw material ingredient. Such documents may include certificates of state registration, declarations of conformity, specifications, certificates of analysis, quality certificates and other documents that contain information on the SFP ingredients in accordance with the recipe, and research results. In addition, the documents confirming the product packaging material safety are provided.

If the SFP is manufactured in the country located outside the customs territory of the Customs Union of the Eurasian Economic Union, justification for the supplied product quality and safety is also required. The justification is documents issued by state authorized bodies of the country in which the SFP is manufactured. These may be health authorities, food regulatory authorities or other competent authorities that confirm the product safety and permit the SFP sale in the country of manufacture and other countries. The document is certified in accordance with the established procedure.

Furthermore, an agreement between the applicant and the foreign manufacturer, which provides for the product compliance with the requirements of technical regulations, must be submitted for examination. Such an agreement serves as a guarantee that in the case of the product non-compliance with the declared characteristics or harm to the environment and consumer health, the person authorized by the manufacturer is liable in accordance with the Customs Union legislation [12].

In addition to the above documents, the applicant may provide other information and materials of his/her choice, substantiating confirmation of the product conformity with mandatory requirements. In the SFP efficacy is declared, specifically the product therapeutic and/or prophylactic properties, it is necessary to provide evidence in the form of a report and conduct a clinical trial focused on the efficacy assessment in authorized medical institutions equipped with the essential equipment and qualified personnel, with the provision of a report completed in accordance with the established procedure. According to the Methodological Guidelines [19] the following guidelines represent the evidence of the SFP efficacy: the bioactive ingredient introduced into the product must be permitted for use in the food industry and registered in accordance with the established procedure; the inclusion of a bioactive ingredient in the SFP composition a must be justified; each bioactive component introduced into the SFP composition must have precise physical and chemical characteristics that can be reliably determined in accordance with the approved regulatory documentation in the laboratories accredited in the established manner. It should be noted that when developing a SFP, not only information on the effectiveness of bioactive ingredients and substances must be taken into account, but also possible interactions with other product ingredients, and the bioactive ingredient amount in the food product must be physiologically adequate and effective, but, in accordance with Appendix No. 5 "Daily Food Intake and Bioactive Substances for Adults in the Composition of Specialized Food Products (SFPs) and Dietary Supplements" [20], not exceeding the upper permissible consumption

level. Furthermore, the bioactive component introduction into a product should not worsen the product organoleptic characteristics and presentation. The effectiveness of a specialized dietary therapeutic and/or dietary preventive product means the presence of a significant positive result and the absence of a negative impact on the functions of human organs and systems in relation to the declared disease entities. The efficacy evaluation trial is conducted in accordance with the principles of good clinical practice in authorized medical institutions.

On September 1, 2025 the Federal Law No. 150-FZ of 07.06.2025 “On Amendments to Certain Legislative Acts of the Russian Federation” [21] came into force in the RF, in accordance with which the specifics of regulating the appointment and use of dietary supplements are provided. In August 2025, the Russian Government has submitted a draft Resolution "On the Approval of Quality Criteria for Bioactive Food Supplements and Their Effectiveness Depending on the Degree of Impact on Human Health" [22]. The Federal Law provides for the creation of a dietary supplement registry, from which medical professionals will prescribe dietary supplements to patients, if indicated. The registry will include dietary supplements that are registered and have been tested for quality and safety indicators in accordance with the established procedure in accredited testing laboratories of the RF, and also have evidence of effectiveness.

## CONCLUSION

Modern industrial production of food products, including specialized food products (SFP), is characterized by combining numerous different ingredients and many technological methods. In this context, the risk of contamination of final products with foreign compounds that have a negative effect on public health increases.

To reduce the risk of obtaining low-quality SFPs, manufacturers are advised to strictly comply with mandatory requirements for the manufacture, transportation, storage, and sale of products. The quality and safety of food products remain a pressing issue, the solution to which requires control at every stage of the food product's delivery to the consumer: from the beginning of manufacture to the "shelf". In this context, an important role is given to the SFP hygienic assessment with subsequent state registration.

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