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EXERCISING OF INTEGRATED APPROACH FOR THE SPECIALISED MEAT PRODUCTS DEVELOPMENT

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Abstract
The principles of the specialized food products development differ from the traditional technologies, which require the integrated approach to their creation, taking into consideration the specified properties, purpose and type of the food product. This article describes the general algorithm for developing the specialized dietary therapeutic and prophylactic nutrition meat products, and demonstrates the implementation of the individual stages of the algorithm on the example of developing the food products for people who suffer from the most socially significant diseases like diabetes and CVD. The algorithm of methodology is a sequence of stages executed during the product development and a description of their content and practical implementation. The modern approaches to creation of healthy food products for people with socially significant diseases, the recommendations of the World Health Organization based on the analysis of scientific literature posted in open sources and publicly available databases were used as the material of the research, as well as the results of our own studies in the field of technologies for dietary therapeutic and prophylactic nutrition meat products. The specialized meat products for therapeutic and prophylactic nutrition, information about their ingredient composition, nutritional value, results of preclinical and clinical trials were used as the objects of the study. The stages of product creation include medical and biological substantiation of the composition, designing of a virtual model of the food product, technology development, evaluation of the safety and efficiency of the resulting product taking into consideration the technological impact, preclinical and clinical evaluation. The study showed the difference in the approaches to the dietary meat products development depending on the purpose — whether its therapeutic nutrition or prophylactic nutrition. The developed methodology can be used as a tool that provides for scientifically justified development of the specialized meat products and substantiation of their efficiency.

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Introduction

According to data of WHO the healthy nutrition is one of the factors that helps reducing the risk of spreading of non-communicable diseases.

Recently an obvious trend has appeared towards the vigorous development of food technologies in various countries, which technologies can be used for prevention of chronic non-communicable diseases. This has also led to an increase of the society's demand for healthy food products [1].

The researches of many foreign authors have shown the approaches to creation of healthy food products for people who suffer from the socially significant diseases (diabetes, cardiovascular diseases (CVD)).

The researchers Villaño et al. [2] consider that the methodology for specialized food development (SFD) must differ from the principles of the traditional products developing. This is necessary to ensure the stability of functional ingredients in the food matrix and the preservation of bioactive components through the food processing, storage, digestion and absorption [2].

The literature analysis showed that the researches of many authors are focused on using the methods to reduce the risk of disease only per the one critically significant parameter, characteristic for this particular pathology.

Bolger and al [3] used the various methods of adding flaxseed oil for increasing the content and bioavailability of alpha-linolenic acid in the chicken sausages. The results of their studies showed that alpha-linolenic acid in lyophilized encapsulated forms turned to be the most bioavailable, and can be used to fortify the food products of targeted action [3].

Many studies have noted the efficiency of various bioactive compounds in the treatment of cardiovascular diseases (CVD) and diabetes. Jeevarathinam G. in his work has presented the modern methods of food processing: macromolecular method (by adding fiber and fortifying with protein), thermal (temperature nodes selection), non-

thermal (ultrasound, high pressure, pulsed electric field, microwaves, irradiation, microencapsulation, extrusion and fermentation methods) to reduce the glycemic index (GI), which contributes to increasing the blood sugar level. The used approaches are aimed to changing the macromolecular structure of carbohydrates by influencing their digestion and absorption rate, and subsequently changing the GI of the resulting food product [4].

In the works of Hernandez et al [5] and Zhu et al [6] the authors found that bioactive peptides obtained from legumes can be used to fortify food products for cardiovascular diseases prevention.

Flores-Medellín et al [7] studied the effects of fermented phenolic compounds and protein hydrolysates of black kidney beans (*Phaseolus vulgaris* L.) obtained by solid-state fermentation (SSF) on the markers associated with obesity and diabetes of the 2nd type. The results showed that this method of processing significantly improves the yield of bioactive compounds from the food matrix, increases the antioxidant and biological potential of plain kidney beans, and is very promising for obtaining the functional ingredients rich in bioactive compounds that can be used in specialized food products for diabetes prevention [7].

Yakubu [8] has run *in vivo studies* and has proven the antidiabetic properties of bitter gourd (colocynth) seed protein hydrolysate. Zhou et al. [9] discovered an α-amylase inhibitory peptide extracted from quinoa protein hydrolysate, which property proves its potential as diabetes curative substance. In the article [10], the authors analyzed the role of glucuronic acid metabolites of phenolic acids in the glucose metabolism, providing the concepts of the new therapeutic targets. Tang et al. [11] drew attention to using of marine fucosyl polysaccharides to keep blood glucose levels under control and mitigate the complications caused by hyperglycemia. Various cereals, legumes and tuber crops also contribute to reducing the GI of products. For example, adding mung beans, chickpeas, green peas and rajma beans into the recipes reduced starch digestion rate and reduced glycemic index of noodles [12,13,14,15].

In Russia food products developed for disease prevention and nutritional support of people in hospital settings are classified as specialized food products and are covered by the technical regulations TR CU027/2012[1]. All scientific researches in this area are aimed to creation of new types of food products that feature their distinctive physiological efficiency.

In the case of developing of food for nutritional support of people, special attention is focused on satisfying the physiological needs of the human body for nutrients and energy, taking into consideration the mechanisms of disease development, absence of allergic reactions among the patients, the effect of the food product on tolerance and biochemical parameters of the blood (metabolism of proteins, carbohydrates, fats, vitamin and mineral status), that prove the efficiency of disease treatment.

In the case of formulation of dietary prophylactic nutrition food assigned to reduce the risk of human diseases, the composition of the product being created should be targeted to the pathogenetic mechanisms of disease development. For example, for CVD prevention the obligatory condition of the food being composed is its cardioprotective and antiatherogenic nature. The indirect markers associated with CVD should be studied thoroughly to study the efficiency of the product [16]. They should also be aimed at increasing the protective and antioxidant functions of the human body, regulating the processes of biotransformation of foreign compounds and their removal from the body, thus reducing the risk of essential nutrients shortage and increasing the overall immune resistance of the body.

According to the leading Russian nutritionists, recently there has been certain growth in the assortment of specialized food products. At the same time those food products are developed spontaneously, often without medical and biological justification of the product composition, without taking into consideration the directional properties and prophylactic purposes, without the availability of its proven properties. In addition, they note the necessity of the further development of the specialized food products assigned for dietary therapeutic nutrition in the Russian Federation [17].

Special approach is required to develop specialized meat-based food products for people with various non-infectious diseases, for whom food is one of the determining factors of health. Among food sources, meat is one of the most complicated and challenging matrices for creating dietary food products. The complexity of developing such products is caused by availability of a wide range of physiologically significant nutrients in meat on the one hand, and by availability of a range of anti-alimentary components (heme iron which serves as a possible reason of carcinogenicity, as well as saturated fats and cholesterol), on the other hand.

The strategies for healthy meat products development of reducing risk factors and enhancing the positive impact of meat on human health are being now actively studied around the globe via the approaches based on the inclusion of ingredients with proven therapeutic efficiency — prebiotics, dietary fiber, polyphenols, antioxidants, etc. It has been found that consumption of meat products fortified with dietary fiber prevents the diseases like coronary heart disease, diabetes, irritable bowel syndrome, obesity, etc. Dietary fiber, which has long story of being added to various minced meat products, is also associated with minimizing the carcinogenic effect of meat, reducing the period when feces remain in the colon and binding the minerals, thereby reducing heme activity. In addition, biologically active compounds such as polyphenols and antioxidants help prevent fat oxidation in meat [18].

[1] TR CU027/2012 Technical Regulations of the Customs Union "On safety of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition" (Adopted by the decision of the Council of the Eurasian Economic Commission of June 15, 2012 No. 34). Moscow, 2012. Retrieved from https://docs.cntd.ru/document/902352823. Accessed August 15, 2024 (In English)

Based on a number of scientific and practical works implemented by the authors of this article in the field of technologies of dietary therapeutic and prophylactic nutrition meat products, the prerequisites arose for systematization of requirements and using the principles of formulation of these food products. This contributed to the development of a unified methodology, which can be used as a comprehensive approach that combines various methods and integral indicators.

The aim of this work is formalization of the researches results related to the development of dietary therapeutic and prophylactic meat-based food products in the form of a methodology.

Objects and methods

The article describes the general algorithm for developing the specialized dietary therapeutic and prophylactic nutrition meat products, and demonstrates the implementation of its individual stages using the example of products for people with the most socially significant diseases like diabetes and cardiovascular disease.

The methodology algorithm is a sequence of the stages implemented during the food product development and a description of their content and practical implementation.

The research material was based on the modern approaches to the formulation of healthy food products for people with socially significant diseases, recommendations of the World Health Organization based on the analysis of scientific literature published in open and publicly available databases: ScienceDirect, eLIBRARY.RU, as well as on the results of our own research in the field of technologies for dietary therapeutic and prophylactic meat products.

As the objects of the research the authors used the specialized meat and meat-containing food products intended for therapeutic and prophylactic nutrition, developed by the authors: semi-finished beef products intended for people with diabetes; minced meat products for the correction of diets for people who suffer from cardiovascular diseases; products based on meat raw materials, for therapeutic (enteral) nutrition. Data on their ingredients composition, nutritional value, the results of their preclinical and clinical trials was used.

To select the criteria for the food composition parameters and to define their values, the main characteristics (properties) of specialized food products were formalized. Numerous parameters (nutritional value, content of critically important substances, criteria of nutrient adequacy) were analyzed. Nutrient adequacy was assessed with the software "System for designing and assessing the quality of multicomponent food compositions" by Lipatov's method [19].

Results and discussion

The sequence and content of the stages of meat and meat-containing food products development for dietary therapeutic and dietary prophylactic nutrition are presented below in the Figure 1.

Depending on the purpose, a specialized meat product can be either therapeutic or prophylactic. This property is determined taking into account the clinical condition of the consumer. The dietary therapeutic product is intended for nutritional support of people with nutritional deficiency developing against the disease background, used as the only source of nutrition. A dietary prophylactic food product is intended for its inclusion in the diet in order to prevent exacerbation of diseases and mobilize the body's immune defense.

Nutritional support is a therapeutic nutrition in the form of nutritional mixtures, the purpose of which is to provide the body with all the necessary nutrients using special nutritional methods that differ from the conventional food intake, which support is prescribed in various diseases. The enteral product based on meat can be used as a sole source of nutrition or used in combination with specialized enteral nutrition mixtures. It is assigned for consuming in accordance with the recommendation and under the supervision of a physician. The composition of the food product must fully satisfy the daily demand for essential nutrients, energy, vitamins, macro- and microelements. The volume of the product and the number of food intakes are determined by the physician depending on the age, body weight and clinical condition of the patient.

The formulation of specialized meat products for disease prophylactic nutrition is based on the application of traditional technologies of conventional meat food, modified as per the characteristics of the properties and chemical composition of meat and innovative ingredients that form the food matrix, their technological compatibility, and the assignment of the food product.

Special role belongs to medical and biological requirements (MBR), which have the most important role in the formation of the nutrient profile of a specialized meat product for both purposes: therapeutic and prophylactic. MBR are developed jointly by medical and technological process specialists and include requirements for the safety and physiological properties of the food product, taking into consideration the physiological and metabolic characteristics of the category of people whom this food is intended for. General MBR criteria for meat products have been established. The criteria are shown below in the Figure 2.

Medical and biological requirements determine the values and proportions of nutritional value parameters, calories content, functional ingredients content, as well as limitations on the content of critically important nutrients. Depending on the type of disease, the specialized food products may additionally contain protective food components or, in opposite, lack the nutrients that contribute to the disease progress. For example, diabetes and obesity require cutting down the consuming of easily digestible sugars in food; food recommended for cardiovascular pathology should contain less table salt, saturated fats and be rich in polyunsaturated fatty acids (PUFA), which

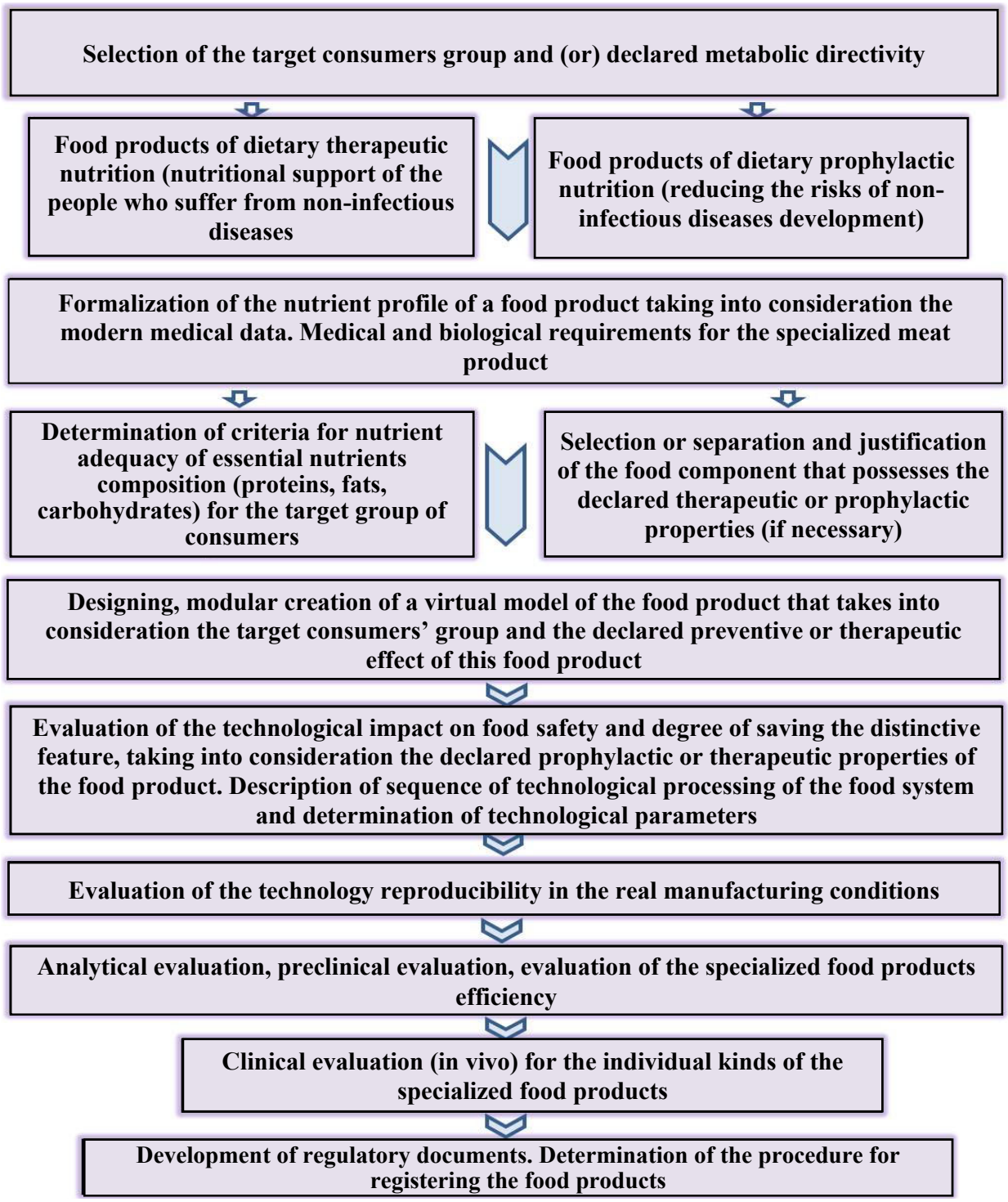

Figure 1. Scheme of specialized meat products development

provide an anti-inflammatory effect. Michalina Banaszak and colleagues presume the importance of not only the anti-inflammatory but also the modulating effect of polyunsaturated fatty acids EPA and DHA [20]. The available researches demonstrate that EPA and DHA supplements provide a beneficial effect on regulation of triglycerides, total cholesterol, insulin resistance, blood pressure, liver enzymes, inflammatory markers and oxidative stress. In addition, there are data of their potential benefit in terms of mitochondrial function, regulation of plasma lipoproteins and reduction in the risk of sudden cardiovascular events related to atherosclerotic plaque rupture [20].

To implement the above specified requirements, first of all it is necessary to select the relevant raw materials of animal and plant origin as the source of the main macronutrients (protein, fats and carbohydrates) that form the product matrix, then select the fortifying ingredients — the micronutrients and biologically active components with proven health benefits in case of certain diseases. Ingredients included into the composition of specialized meat products assigned for the patients with cardiovascular disease and with diabetes of the 2nd type shall be organoleptically and technologically compatible both with each other and with the product matrix, have no

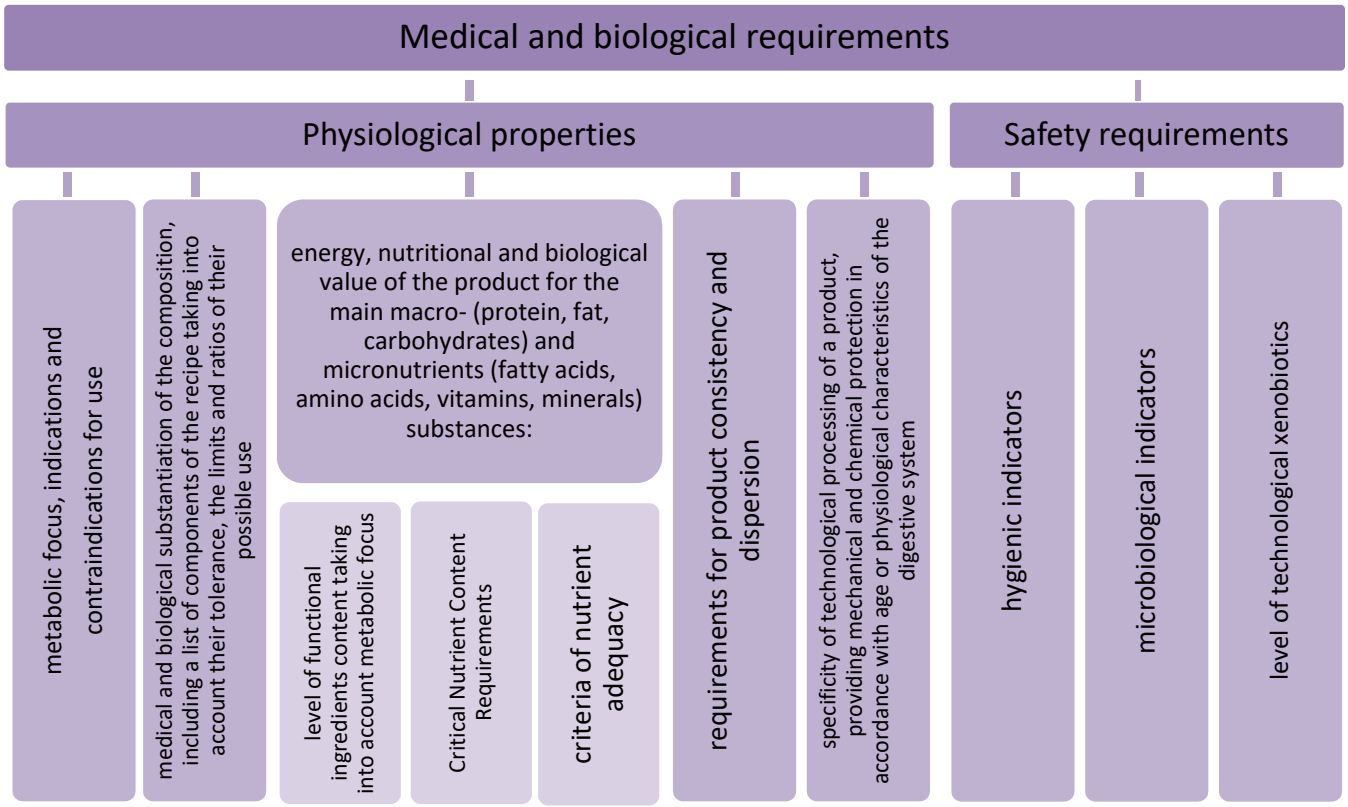

Figure 2. MBR structure and main criteria

hyperglycemic effect, help reduce cholesterol and regulate fat metabolism.

When forming the nutrient profile of products for both dietary therapeutic and dietary prophylactic nutrition, one of the main macronutrients is protein, which is involved into maintaining nitrogen balance, thus ensuring normal metabolism and preserving muscle tissue. Protein included in specialized food products should be complete, balanced in amino acids composition, and have high digestibility. When developing meat products, meat raw materials with high content of muscle tissue are selected as a basis, which ensures a high level of animal protein content in the finished food product. As an additional source of protein, it is possible to use milk protein (casein), or highly hydrolyzed milk protein, or whey protein, or vegetable protein to achieve optimal amino acid balance in reference to the standard of FAO/WHO [21].

Fat is also a significant macronutrient in food. Given the fact that meat fat has a specific fatty acid composition with saturated fats predominance, it is necessary to adjust the fat component of the product by creating a combination of fat obtained from meat raw materials and vegetable oils mixtures. The purpose of this correction is to ensure the required content of mono- and polyunsaturated fatty acids in the product, including the omega-3 family, which improve the lipid spectrum of the blood, help reduce the level of total cholesterol, provide the positive effect on the immune system and improve the inflammatory response.

To develop the high-quality composition of therapeutic enteral nutrition food, together with the need for protein and fat it is also necessary to provide a certain amount of non-protein calories due to carbohydrates for the adequate protein absorption by the body. For meat products of therapeutic nutrition, the carbohydrate profile is formed by inclusion into the recipe the slowly digestible and slowly absorbable carbohydrates, which do not increase the level of postprandial glycemia compared to the consumption of mono- and disaccharides.

Micronutrient deficiency is one of the risk factors for many diseases, including cardiovascular disease and diabetes. Taking this into account, it is recommended to include vitamins, minerals and other nutritionally significant ingredients, including those with antioxidant properties, into the composition of specialized food products in relevant quantities that ensure the correction of their insufficient consumption [22,23].

The content of each nutritionally significant component (biologically active substance) introduced into the food product must correspond to the daily norm and obey the following rule: in 100 g of the specialized prophylactic food products, or in a single portion of the formulated food product, the minimum content of the introduced nutritional component should be kept at the level of 15% from the recommended daily consumption of this component, and in case of a product for nutritional support the dose of introduced vitamins and minerals should cover 100% of the daily demand when consuming the established daily dose of this product.

When introducing a nutritionally significant component into food, it is necessary to ensure its safety, heat resistance and stability during storage. This fact is particularly important for the food products subjected to sterilization.

Moreover, for each nutrient-significant component the research methods with the sufficient detection limit must be known, which method is able to define the quantitative content of the introduced component to be detected even in small concentrations.

There is one more important condition for introduction of nutritionally significant components — this is the preservation of the nutritional value and consumer properties peculiar for this type of food product. The product based on meat proteins, intended for dietary therapeutic nutrition in the form of enteral nutrition, should be produced ready-to-consume and should be a sterilized homogenized mixture with a texture that allows it to be freely introduced through a gastrostomy tube ≥14 Fr (the outer diameter of the tube is 4.62 mm) via syringe as bolus or with the help of "natural gravity" (gravity). The food product should be a thick viscous-flowing homogenized mass made up of finely dispersed particles. For enteral nutrition products, the particle size is an important quality parameter, especially for the food products fed to the patient through probe tubes. The maximum possible decreasing of particles size of a meat product is necessary to increase the efficiency of gastrointestinal enzymes, which provide positive effect on the digestibility of the most important micro- and macronutrients. Increasing of dispersion degree is achieved by using technological methods aimed at reducing the particle size (high-pressure homogenization) in the technology of specialized meat products manufacture.

The appearance of the food product intended for dietary prophylactic nutrition should not differ from the relevant traditional food product, the color and taste peculiar to the product should correspond to the raw materials and the used components.

The next stage of the methodology implementation involves computer designing of a model recipe for the specialized meat product, taking into consideration the distinctive features of the meat raw material and the degree of nutritionally significant components introduction.

Depending on the species kind of the meat, and its anatomical and morphological origin, the meat may possess certain distinctive features that can be used to select the preferred meat raw material for the specific specialized food product, such as a source of the meat, or due to high content of protein, vitamins (B2, B9, B6, B12, PP), minerals (iron, zinc, selenium), low fat content, saturated fatty acids, as a source of omega-3 fatty acids.

To characterize the content and mutual balance of macro- and micronutrients and their components in the meat products of the specialized nutrition, the indicators of nutrient adequacy are used, like the amino acid composition of protein, fatty acid composition of the fat component, the content of metabolically dominant macro- and microelements, water- and fat-soluble vitamins. To assess the balance of fatty acids, fatty acid balance coefficients — R1…3 are used, taking into account the proportions of SFA, MUFA, PUFA sums in comparison to the similar criteria of the standard proportions. To assess the quality of protein in therapeutic nutrition products, the protein digestibility-corrected amino acid score (PDCAAS) is also used [24].

The criteria which the model recipe is assessed by are the nutritional value indicators and the values of the nutrient adequacy coefficients specified for specialized meat products, specified below in the Table 1. The adequacy indicators were defined empirically based on the results of numerous studies in the field of developing meat products for therapeutic and prophylactic nutrition purposes, taking into consideration the consumer characteristics and properties of the specialized meat products, the content of critically important nutrients, and the norms of physiological needs for energy and nutrients for the various groups of the population of the Russian Federation[2].

The above specified limit values are generalized, and for each specialized meat product it is necessary to establish individual quality and safety indicators, which should be included into the regulatory documentation for specific types and names of products.

Taking into consideration the range of recommendations for reducing the cardiology risk while developing minced meat products intended for the diet to prevent cardiovascular diseases, saturated fatty acids in the fat were partially replaced with polyunsaturated ones. Also, the level of table salt in the recipe was reduced by 50%, the vitamins with cardioprotective properties, vitamins and minor biologically active substances with profound antioxidant action that fight free radicals were added [25,26]. Modification of the fat composition allowed significant reducing the content of saturated fatty acids and increase the quota of unsaturated ones, ensuring a given PUFA/SFA ratio in the range of 1.6–2.3 and increase the total antioxidant capacity by 9 times in comparison with the similar traditional product. The introduction of an antioxidant complex contributed to the preservation of high antioxidant activity of the food product during its storage [27].

When developing a meat semi-finished food product for nutrition of the diabetic patients, it was taken into account that the main risk factor for carbohydrate metabolism disorders development is obesity. This requires cutting down the caloric content of the food product. In addition to carbohydrate metabolism disorders, the increased content of fats in the blood plays a major role in the progression of *diabetes mellitus*. Because of that it is necessary to significantly cut down the level of saturated animal fats in the diet, yet ensuring the intake of monounsaturated and polyunsaturated fatty acids (the oils with omega-3, omega-6, phospholipids). Another important factor is the inclusion of dietary fiber and hypoglycemic substances into the food product. The plants like amaranth, green beans, oregano,

[2] Methodological recommendations MP 2.3.1.0253-21 "Norms of physiological needs for energy and nutrients for various groups of the population of the Russian Federation". Moscow: Garant, 2021. Retrieved from https://www.garant.ru/products/ipo/prime/doc/402716140. Accessed July 29, 2024. (In Russian)

Table 1. Limit values of nutritional value indicators, coefficients adequacy of amino acid and fatty acid compositions of products, content of critically important substances

Indicator	Nutrient content and amino acid and fatty acid balance indicators	
	Meat-based product for dietary therapeutic nutrition	Meat product for dietary prophylactic nutrition
Protein, not less than	15% of calories	10 g/100 g of product or 12% of calories
Fat, no more	35% of calories	12 g/100 g of product
Table salt, g/100 g	—	no more than 1.8
ΣNFA	no more than 20 g/100 g of lipids	no more than 10% of calories
ΣMUFA	50–60 g/100 g of lipids	not less than 10% of calories
ΣPUFA	27–31 g/100 g of lipids	6–10% of calories
Minimum score, fractional unit (C_{min})	0.85–1.0	
Utility score, fractional units (σ)	0.85–1.0	
Comparable excess score, g/100 g protein (U), no more than	7	10
Protein digestibility corrected amino acid score (PDCAAS)	1	—
Fatty acid balance score, fractional units R_{Li}, I=1…3	0.85–1.0	
ω-6/ω-3 fatty acid ratio	3–4,4:1	3–5:1

chicory, garlic, celery, as well as vegetables that contain no starch, feature the effect similar to insulin.

The next stage related to the evaluation of the technological impact on the food product safety, consists of establishing the impact of technological processes on the formation of "thermal" carcinogens (melaidins, peroxides, heterocyclic amines, acrylamide, etc.), which is especially peculiar for the meat products exposed to high-temperature processing sterilization). The influence of temperature-time factors on the indicators and biological value of the food product, organoleptic parameters and the safety of the introduced fortifying components is also evaluated.

It is necessary to note that the type of heat treatment plays a key role in influencing the oxidation processes direction. If the development of meat products for specialized nutrition requires changing the fat composition of the product by introducing PUFA sources, it is necessary to focus on researches of the heat treatment effect on their preservation. PUFAs are most susceptible to the high temperatures exposure as they form the various radicals, which subsequently are able to form malonic dialdehyde [28]. Fats oxidation is accompanied by deterioration of their organoleptic properties and the formation of various oxidation products — first peroxides, and then polymeric compounds with a toxic action. The oxidation resistance of the fat component of the food products with various types of vegetable oils is evaluated by changes in acid and peroxide numbers. It is also known that some methods of thermal processing of high-protein foods of animal origin produce the potentially carcinogenic compounds, including heterocyclic aromatic amines — chemical compounds that have in their structure at least one aromatic ring and one amino group [29].

One of the purposes of the methodology stage is to cutting down to minimum the risks related to the formation in specialized meat products of chemical compounds xenogeneic to the human body. This can be achieved by refusing from the aggressive methods of technological processing (high temperature, smoking, etc.), by standardizing the content of xenobiotics in the finished food product, by refusing from the process food additives or significantly reducing their content, and by using modern control methods that guarantee food safety.

At this stage, pilot production of the full-scale food product samples is run in order to analytically evaluate their compliance with the model samples and to study the effect of introduced biologically active components on the organoleptic properties of the finished food product. The stage involves the development of technological modes for the preparation of biologically active substances for their further introduction, selection of the stage and effective method of their introduction, and the analysis of consumer properties of the developed product. If the full-scale samples is relevant to the model sample in terms of its quality, safety, and organoleptic characteristics, they proceed to the next stage which consists of assessment of possibility to reproduce the developed technology in the real conditions of an operating enterprise, taking into consideration its raw material sources and technological base.

An important stage of the specialized meat products development algorithm is a comprehensive evaluation of efficiency and safety, including three areas: analytical assessment, evaluation *in vitro, in vivo, ex vivo experiments,* and clinical tests.

The food product is analytically evaluated for its compliance with the quality and safety indicators specified at the initial stage of development of the specialized food product, including the actual content of the introduced nutritionally significant components and biologically active substances. Safety standards are formed depending on the type of meat products, and are adopted in accordance with

the requirements of technical regulations TR CU021/2011[3], TR CU034/20134, TR CU027/2012[5].

Preclinical efficiency of specialized food products consists of studying biological properties (antioxidant, immunomodulatory, cytoprotective, hypolipidemic, hypoglycemic, neuroprotective, etc.) and identifying the specific activity of functional ingredients introduced into the food product in *in vitro, in vivo,* and *ex vivo* experiments.

To define the therapeutic and prophylactic nutrition effects of the food product in *in vivo* experiments on the laboratory animals, the methods of experimental modeling of human diseases are used. Experimental modeling of functional states on animals is carried out by varying diet components, introducing chemical agents — damage inducers, surgical intervention. The main markers that indicate the condition of animals are the parameters of blood serum, urine, liver-aspartate aminotransferase (AST), alanine aminotransferase (ALT), total cholesterol (TC), low-density lipoprotein cholesterol (LDL–C), high-density lipoprotein cholesterol (HDL–C), triglycerides TG, histological studies of tissues, etc.

Preclinical evaluation of the specialized meat product assigned for the patients with cardiovascular diseases was conducted on sexually mature female laboratory rats of the NISAG line, which rats were obtained at the Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences from a population of Wistar rats by selection for hypertensive increase response when exposed to mild emotional stress [30]. The rats of this line represented a model of hypertensive disease similar to that in humans. Aging rats showed a well-pronounced increase in blood pressure, which makes them a worthy model for research. The results of noninvasive measurement of blood pressure using a tail cuff, immunoenzyme indices associated with damage to the heart muscle, vasoconstriction and increased blood pressure, and histological studies of rat heart samples were used as markers of their health condition [31].

To model *diabetes mellitus* in laboratory animals, a drug was administered into their bodies that caused the development of disease symptoms: glucosuria, hyperglycemia, polydipsia, polyphagia and polyuria, hematocrit increase, decrease in blood clotting time and an increase in its viscosity, activation of cytolytic processes in liver and pancreas of the animals. To assess the health condition of the animals, blood parameters were studied, including changes in blood glucose levels, the content of ketones and glucose in the urine, and activity of AST and ALT enzymes [32].

When positive results are obtained in animals, the desired procedure of confirmation the prophylactic dietary meat products efficiency is their evaluation in clinical conditions.

The clinical trials are mandatory for dietary therapeutic food products.

The purpose of clinical studies is to evaluate in a clinical setting the effect of the food product on the patients' clinical status and biochemical parameters, including parameters of carbohydrate and lipid metabolism in the blood serum of the patients with type 2 *diabetes mellitus*, their medical examination, anthropometric measurements, physical and instrumental evaluation of the functional state of their internal organs and body systems, biochemical studies of blood serum, general blood test and urine test, the level of daily glucosuria, hypolipidemic effect (level of total cholesterol, triglycerides, VLDL–C, LDL–C and the value of the atherogenicity coefficient) [33].

During clinical trials of enteral therapeutic nutrition products, during the patient's stay in the clinic, the tolerance is assessed using a specially designed chart, where patients every day mark the dynamics of their complaints and disease symptoms severity (dryness, bitterness in the mouth, heaviness in the stomach after intake of the food product, presence and severity of abdominal pain, flatulence, heartburn, nausea, feeling of heaviness after eating, incomplete bowel movement), an evaluation of the stool parameters dynamics. The results of laboratory tests and evaluation of the quality of life, body composition indicators are compared before and after the relevant modification of the diet [34].

The final stage of the food product development is its state registration, which is a mandatory procedure of compliance confirmation for the specialized food products.

Conclusion

The principles of developing the specialized food products differ from the traditional technologies, and that circumstance requires the comprehensive approach to their creation, taking into consideration the specified properties, purpose and type of the food product. For meat products the comprehensive approach provides for taking into consideration many factors, including the characteristics of the properties and chemical composition of meat and traditional technological methods of the ready food products manufacturing.

Using the theoretical and experimental approaches, a methodology for creating specialized meat products for dietary nutrition has been developed, which methodology exercises a comprehensive approach starting from the development of the food product till its manufacturing. The developed methodology can be used as a tool for scientifically justified development of specialized meat products and justification of their efficiency.

[3] TR CU021/2011 Technical Regulations of the Customs Union "On food safety". (Adopted by the decision of the Council of the Eurasian Economic Commission of December 9, 2011 No. 880). Moscow, 2011. Retrieved from https://docs.cntd.ru/document/902320560. Accessed August 15, 2024. (In English)

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