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# FORTIFICATION OF FOOD WITH MICRONUTRIENTS: DEVELOPMENT OF METHODOLOGICAL AND Accepted for REGULATORY FRAMEWORK IN THE RUSSIAN FEDERATION

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### Abstract

The available scientific literature, domestic and international regulatory codes of normative documents concerning the fortification of various types of food products have been analyzed. The groups of food products of conventional and regular consumption included into the diets of all categories of consumers, recommended for fortification with essential micronutrients, have been determined: wheat and cereal flour (spelt wheat, buckwheat, oat, corn flour, etc.); pastry; milk and dairy products, including ice cream; non-alcoholic soft drinks; mineralized drinking water; fruit and vegetable juices; fat and oil products (vegetable oils, margarines, spreads, mayonnaise); confectionery and sweets (pastry, sugar, chocolate); cereals (breakfast cereals, muesli, ready-to-eat extruded cereals, instant pasta and cereals, mixtures for bakery, flour for sweet pastry); food concentrates (jelly, instant drinks, concentrates of sweet foods, instant food, instant cereal concentrates); table salt. The groups of food products assigned for certain categories of population are used as part of therapeutic diets for patients with various diseases (metabolic disorder syndrome, cardio-vascular system pathology with atherosclerotic vascular injury, type 2 diabetes mellitus, gastrointestinal tract diseases, non-alcoholic fatty liver disease, diabetic nephropathy, etc.), as well as assigned to reduce the risk of diseases developing, the nutrients are recommended for targeted fortification of certain types of food. Examples of micronutrients fortification of sausages and minced meat semifinished products are given below. Requirements for fortification of mass consumption food products and for fortification of foods for special dietary uses are formulated in this article, the amount of fortifying components in the various groups of food products are justified, ensuring their efficiency for improving the micronutrient status and safety of its consumption. Based on the analysis of the available scientific literature, domestic and international regulatory framework of normative documents on fortification of various types of food products, recommendations have been developed for fortification of food with micronutrients.

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### Introduction

In modern conditions the population of many countries, including Russia, suffers from multiple micronutrient deficiency, i. e. simultaneous deficiency of several vitamins (D, group B) and minerals (iodine, calcium, magnesium, iron, zinc, etc.) [1-4]. It is a cost-effective approach to increase micronutrient intake with the help of large-scale food fortification. In most economically developed countries (USA, Canada), as well as in some countries of the former USSR (Uzbekistan since 2005, Turkmenistan since 2006, Kazakhstan and Kyrgyzstan since 2009, Moldova since 2012), in many developing countries of Africa, Asia and Latin America, the problem of optimizing the vitamins supply of the population is solved by law-regulated fortification of food with vitamins B1, B2, B6, PP, folic acid and iron, added to the food of mass consumption: flour, pasta and bakery; vitamin D

in the dairy food [5,6]. The flour was obligatory fortified with vitamins B1, B2 and PP by the decision of the USSR Council of People's Commissars since 1939, but later this practice was stopped [7]. Currently, the food products are fortified with micronutrient only voluntarily at the initiative of product manufacturer. Essential micronutrients, which include vitamins, minerals and polyunsaturated fatty acids (PUFA), are most often used as food fortifiers. The basic requirements for the fortification of food with vitamins and minerals were formulated in Unified Sanitary Epidemiological and Hygienic Requirements (i. e. SanPiN) 2.3.2.2804-10 "Hygienic requirements for safety and nutritional value of food" [8], which were included in SanPiN2.3.2.1078-01 [9] as Addendum and Amendment No 22, but this practice is currently suspended. The regulations for fortification in general concerned the mass consumption food products [10,11].

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The practice of creating the foods for special dietary uses (SFP) and the information presented in the Unified Register of the Customs Union show that biologically active substances and compounds with certain physiological effect are used for fortification of such products, in addition to essential micronutrients. This gives rise to a number of problems, including the choice of food products to be fortified, the levels of fortification that ensure the safety and efficiency of the fortified types of food products, the interaction of the fortifying elements or ingredients within the food product and their interaction with the body, etc. In this regard, the structuring of recommendations for the fortification of various groups of mass consumption food products and certain categories of foods for special dietary uses with essential nutrients on the basis of an analysis of the available scientific literature, domestic and international regulatory code of normative documents for fortification of various types of food products is now of particular relevance.

The purpose of the research is to determine the groups of food products of conventional and regular consumption to be fortified with essential micronutrients, included into the diets of all categories of population; definition of food groups intended for certain categories of population, which food products are used in clinical practice as part of therapeutic diets or are intended to reduce the risk of developing diseases; determination of micronutrients for their targeted application to the food and its fortification; justification of amount of fortifying elements/components application in various groups of food products, ensuring their efficiency for improving their micronutrient status

and safety of consumption. The basic rules and principles of food fortification with essential nutrients are reduced to the following recommendations.

### List of food products to be fortified and micronutrients recommended for food fortification

The following food product categories are subject to fortification with food active substances and/or biologically active substances, and/or probiotic microorganisms:

- food products for general population except for food products that are not technologically processed (fresh fruits, vegetables, meat, poultry, fish), spices, fermented drinks, as well as drinks containing more than 1.2% alcohol (except for low-alcohol tonic drinks where vitamins and minerals are added with different purpose);
- foods for special dietary uses for healthy children;
- foods for special dietary uses for pregnant and breastfeeding women;
- foods for special dietary uses for athletes' nutrition;
- foods for special dietary uses for nutrition of workers who are exposed in their work to harmful and extremely harmful conditions [12,13];
- foods for special dietary uses for dietary medical and preventive dietary nutrition, including baby food.

The food products for general population is fortified in accordance with recommended list of foods product groups and recommendations on the nutrients used for fortification of the appropriate food groups (Table 1).

Table 1. List of groups of mass consumption food products, recommended for fortification

Food products groups	Recommended nutrients for fortification
Wheat flour of the highest grade and of the first grade	vitamins: B1, B2, B6, PP, folic acid, A, D, B12, pantothenic acid; minerals: iron, calcium
Bakery and pastry	vitamins: B1, B2, B6, PP, folic acid, beta-carotene, A, D, B12, pantothenic acid; minerals: iron, calcium, iodine
Dairy products (dairy product, dairy compound product, product of milk processing, milk-containing product)	vitamins: C, A, E, D, K, group B, beta-carotene; minerals: iron, calcium, iodine; dietary fiber; polyunsaturated fatty acids; phospholipids; prebiotics; probiotic microorganisms; dihydroquercetin
Meat products	vitamins C, group B, Fe, Ca, iodine
Non-alcoholic soft drinks	vitamins: C, A, E, D, K, group B, beta-carotene and other carotenoids; minerals: iodine, iron, calcium; dihydroquercetin
Fruit (including berries) and vegetable juice products (juices, fruit and / or vegetable nectars, fruit and / or vegetable juice drinks)	vitamins: C, A, E, B1, B2, B6, PP, folic acid, beta-carotene; minerals: iodine, iron, calcium; organic acids; dietary fiber; polyunsaturated fatty acids; polyphenolic acids; prebiotics; phytosterols; flavonoids; phospholipids; dihydroquercetin
Cereals (breakfast cereals, ready-to-eat extruded cereals, instant pasta and cereals)	vitamins: C, A, E, D, group B, beta-carotene; minerals: iron, calcium, iodine
Fat and oil products (vegetable oils, margarines, spreads, mayonnaises, sauces)	vitamins: A, E, D, beta-carotene; dihydroquercetin
Food concentrates (jelly, instant drinks, instant food)	vitamins: C, A, E, D, K, group B, beta-carotene; minerals: iodine, iron, calcium, magnesium, potassium; dihydroquercetin
Pastry and confectionery	vitamins: C, A, E, beta-carotene, B1, B2, B6, PP, folic acid; minerals: iodine, iron, calcium, magnesium; dihydroquercetin (for chocolate and confectionery products only)
Fruit and berry concentrates with added sugar or other sweetening substances (jam, jam, confiture, jelly, popsicles, etc.)	vitamins: C, A, E, B1, B2, B6, PP, folic acid, beta-carotene; minerals: iodine, iron, calcium
Table salt	minerals: iodine, fluorine*

Note: \*assigned for regions or areas with deficiency of this microelement

The criteria for classifying a food product as fortified with vitamins and/or minerals and/or other essential nutrients are given below in the Table 2.

Table 2. Criteria for classifying a food product as fortified with vitamins, minerals and/or other essential nutrients

Food group	Mass (volume) * of a food product, which must contain not less than 15% and not more than 50% of the normal physiological demand for this nutrient
Wheat flour of the highest grade and first grade	100 g
Bakery products from the highest grade and first grade of wheat flour and rye-wheat flour	150 g
Liquid dairy products, protein products made of grain, legumes, liquid grain food (soy milk)	200 ml
Dairy products and protein products from grain, leguminous crops (tofu), solid and pasty food	100 g
Minced meat products, cooked sausages	100 g
Fruit (including berries) and (or) vegetable juices, non-alcoholic soft drinks, incl. the drinks made from food concentrates	300 ml
Dry cereals (breakfast cereals, ready-to-eat extruded cereals, instant pasta and instant cereals)	50 g
Fat and oil products, sweet pastry, confectionery, hard rennet cheeses, canned food and vegetable, fruit and berry concentrates.	Per 100 kcal
Iodized edible table salt	1-2 g
<b>Edible salt</b>	5 g
Note: * average daily portion	

Note: \* average daily portion

The lists of food and biologically active substances used in the production of certain types of fortified food products are determined by the technical regulations of the Customs Union for food products of the corresponding homogeneous group.

### Recommendations for food fortification

The food is fortified by adding one or more nutrients i. e. additional food substance, biologically active substances or probiotic microorganisms — in accordance with the recommendations below:

- the food products for general population that do not contain nutrients or contain insufficient amount of nutrients, or which have lost those nutrients during the production (manufacturing) process, must be fortified with food substances (dietary fiber, prebiotics, etc.) and/or biologically active substances (vitamins, minerals, omega-3 PUFAs, etc.) and / or probiotic microorganisms;
- the added nutrients must be safe and stable during food
- each nutrient must possess accurate physical and chemical characteristics that can be reliably determined using appropriate analytical methods;

- the beneficial properties of the introduced nutrients must be scientifically proved and substantiated;
- the amount of fortifying nutrients additionally introduced into the products must be calculated taking into account their natural content in the original product or raw materials used for its manufacture, as well as their losses during production and storage, in order to ensure the content of these nutrients at a level not below the regulated value for the entire shelf life of the fortified food product;
- the choice of types, forms, methods and stages of the introduction of fortifying nutrients shall be carried out taking into account their possible chemical interaction with each other and with the components of the fortified product and ensure maximum safety during production and storage;
- fortification of food products shall not worsen the consumer properties of these food products, shall not reduce the content and assimilability of other food substances contained in the food product; shall not significantly change the organoleptic properties of products and shall not reduce their shelf life;
- food fortification shall not affect safety of the food;
- the guaranteed content of nutrients in the fortified food products at the end of shelf life shall be indicated on the individual package of this food product.

The amount of each food substance or biologically active substance, used for fortification and guaranteed by the food manufacturer, must be brought to a level that meets the criteria for this food product. The source of the food substance or other distinctive features, and the maximum level of food and (or) biologically active substances in such products shall not exceed the safe upper level of such substances consumption from all possible sources (if any).

The content of vitamins and minerals included in the fortified food product of mass consumption shall be brought to a consumption level corresponding to 15-50 percent of the average daily requirement of adult person for vitamins and minerals per 100 g or 100 ml, or per serving of the fortified food products. The weights (volumes) of the averaged daily portions of fortified foods are shown in the Table 2.

For fortified high-calorie foods (where energy value per 100 g is 350 kcal or more) the content of the fortifying nutrient shall range between 15% and 50% of the recommended daily intake per 100 kcal (1 serving of the product).

The content of probiotic microorganisms in the fortified food products shall ensure the level of their consumption in a daily portion of such products that meets the established requirements and be at least 106 (for bifidobacteria) and 10<sup>7</sup> (for lactobacilli) colony-forming units (microbial cells) in 1 gram or 1 ml of these kinds of food.

The vitamins and minerals shall be used in the production of fortified food products only in the forms which are approved in accordance with the established procedure. When fortifying salt with food iodine, the level of fortification element content shall be  $(0.04 \pm 0.015)$  mg/g. When fortifying salt with edible fluorine, the permissible level of its content shall not exceed 0.025%.

Foods for special dietary uses include:

- food products for baby nutrition incl. food products for children of early age, preschool and school age;
- food products for pregnant and breast-feeding women;
- food products for athletes' nutrition;
- food products for preventive dietary nutrition, incl. baby nutrition, as well as food for workers exposed in their jobs to harmful and extremely harmful working conditions;
- food products of dietary medical nutrition for children and adults.

Adequate and upper permissible values of daily consumption of basic food and biologically active substances as part of foods for special dietary uses for persons older than 18 years are established in the corresponding regulation in the Unified Sanitary and Epidemiological and Hygienic Requirements for Goods Subject to Sanitary and Epidemiological Surveillance (Control) (hereinafter referred to as USE & HT) [14].

To produce fortified foods for special dietary uses for adult population, the vitamins and minerals shall be used in the officially approved forms in accordance with the established procedure.

In addition to vitamins, macroelements and microelements, polyunsaturated fatty acids (PUFA), it is possible to add dietary fiber, prebiotics, probiotic microorganisms, ingredients with known physical and chemical characteristics and safe for human health. These elements shall be added in amount recommended for daily consumption. It is necessary to provide a scientifically grounded and confirmed effect on one or several physiological functions, metabolic processes in the human body. The criteria for the selection of fortifying nutrients, their types, forms and doses are safety and proven (in terms of evidence-based medicine) efficacy.

The amount of fortifying nutrients in a daily portion of recommended foods for special dietary uses shall be at least 15% of an adequate level of consumption and shall not exceed the upper permissible level of these elements consumption [14].

Regulations for fortification of mass consumption food products, of foods for special dietary uses, incl. baby nutrition, as well as a list of regulatory documents on the food fortification, are presented below in the Table 3.

Table 3. Regulations for fortification of food products

runcation of food products		
Regulatory document for food fortification	Amount of the fortifying nutrient	List and forms of vitaminand / or minerals
TR CU021/2011 [15], TR CU022/2011 [16], ESET [14] Appendix 5, TR CU023/2011 [17] (Article 5, clauses 14, 15)	not less than 15% and not more than 50% of the recommended daily intake of a particular food component in 100 ml or 100 g, or a single serving. For juice products, portion — 300 ml	In accordance with [14] Appendix 8
es		
TR CU027/2012 [18], TR CU022/2011 [16], Unified Sanitary Epidemiological and Hygienic Requirements [14], MP 2.3.1.2432–08 [19]	In accordance with [14] (Chapter 2, section 1, clause 11), for nutrients not specified in clause 11, at least 15% of the recommended daily intake of a specific component and not exceeding the upper permissible level of its intake in daily portion of the finished food product Appendix 5 [14].	In accordance with [14] Appendix 9
TR CU027/2012 [18], TR CU022/2011 [16], Unified Sanitary Epidemiological and Hygienic Requirements [14]	not less than 15% of the recommended daily intake of a specific component and not exceeding the upper permissible level of its intake in a daily portion of a finished food product Appendix 5 [14].	In accordance with [14] Appendix 11
TR CU021/2011 [15], TR CU033/2013 [20], TR CU023/2011 [17], Unified Sanitary Epidemiological and Hygienic Requirements [14], Sanitary Rules and Regulations 2.3.2.1078–01 [9]	In accordance with TR CU021/2011 [15], (Art. 7, item 12), TR CU033/2013 [19], (Appendix 13), TR CU023/2011 [17] (Art. 5, p. 14, 15, 28), Unified Sanitary Epidemiological and Hygienic Requirements [14] clause 13, [15] Appendix 20	In accordance with TR CU021/2011 [15], Appendix 9
TR CU021/2011 [15], TR CU027/2012 [18], TR CU033/2013 [19], TR CU023/2011 [17] Unified Sanitary Epidemiological and Hygienic Requirements [14]	Unified Sanitary Epidemiological and Hygienic Requirements [14] clause 16; TR CU027/2012 [18], (Appendix 3), TR CU033/2013 [19] (Appendix 14), TR CU023/2011 [17] (Article 5, paragraphs 14, 15, 28)	In accordance with TR CU021/2011 [15], Ap- pendix 9; Unified Sanitary Epidemiological and Hy- gienic Requirements [14] Appendix 9
TR CU021/2011 [15], TR CU027/2012 [18] Unified Sanitary Epidemiological and Hygienic Requirements [14]	Unified Sanitary Epidemiological and Hygienic Requirements [14] p. 14	In accordance with TR CU021/2011 [15], Appen- dix 9; [14] Appendix 11
TR CU021/2011 [15], TR CU027/2012 [18], Unified Sanitary Epidemiological and Hygienic Requirements [14]	Not less than 15% of the adequate level of daily consumption of a particular component and not exceeding the upper permissible level of its consumption in a daily portion of the finished food product Appendix 5 [14] (for saturated fatty acids with medium long chain (C8-C14), D-Ribose, sodium, caffeine, creatine — only separate items)	In accordance with [14] Appendix11, [21.22]
	Regulatory document for food fortification  TR CU021/2011 [15], TR CU022/2011 [16], ESET [14] Appendix 5, TR CU023/2011 [17] (Article 5, clauses 14, 15)  TR CU027/2012 [18], TR CU022/2011 [16], Unified Sanitary Epidemiological and Hygienic Requirements [14], MP 2.3.1.2432–08 [19]  TR CU027/2012 [18], TR CU022/2011 [16], Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17], Unified Sanitary Epidemiological and Hygienic Requirements [14], Sanitary Rules and Regulations 2.3.2.1078–01 [9]  TR CU021/2011 [15], TR CU027/2012 [18], TR CU023/2011 [17] Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17] Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU027/2012 [18] Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU027/2012 [18] Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU027/2012 [18] Unified Sanitary Epidemiological	Regulatory document for food fortification  TR CU021/2011 [15], ESET [14] Appendix 5, TR CU023/2011 [17] (Article 5, clauses 14, 15)  S  TR CU027/2012 [18], TR CU022/2011 [16], Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17], Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17], Unified Sanitary Epidemiological and Hygienic Requirements [14], Sanitary Repidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU021/2011 [15], TR CU023/2011 [17] (Art. 5, p. 14, 15, 28), Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17] (Art. 5, p. 14, 15, 28), Unified Sanitary Epidemiological and Hygienic Requirements [14] TR CU021/2011 [15], TR CU023/2011 [17] (Art. 5, p. 14, 15, 28) Unified Sanitary Epidemiological and Hygienic Requirements [14] Cuo33/2013 [19], (Appendix 14), TR CU023/2011 [17] (Art. 5, p. 14, 15, 28) Unified Sanitary Epidemiological and Hygienic Requirements [14] Cuo33/2013 [19], (Appendix 14), TR CU023/2011 [17] (Art. 5, p. 14, 15, 28) Unified Sanitary Epidemiological and Hygienic Requirements [14] Cuo33/2013 [19], (Appendix 14), TR CU023/2011 [17] (Article 5, paragraphs 14, 15, 28) Unified Sanitary Epidemiological and Hygienic Requirements [14] Cuo27/2012 [18], Unified Sanitary Epidemiological and Hygienic Requirements [14] Cuo27/2012 [18], Unified Sanitary Epidemiological and Hygienic Requirements [14] Chapter 2, section 1, clause ment in 100 ml rol 09 gor a single serving. For juice products, portion — 300 ml  In accordance with [14] (Chapter 2, section 1, clause 11, at least 15% of the recommended daily intake of a specific component and not exceeding the upper permissible level of its intake in clause 11, at least 15% of the recommended daily intake of a specific component and not exceeding the upper permissible level of dail

# Recommendations on food fortification for healthy children

Requirements for the quality and safety of food products for healthy children, processes of this food production, its labeling, storage, transportation and sale are regulated in the prescribed procedure [14, 15].

In accordance with the established procedure, the daily dose of vitamins and minerals included in the composition of foods for special dietary uses for children from 1.5 to 3 years shall not exceed 50% of the daily physiological need for these substances or elements [19].

The daily dose of vitamins and minerals in the composition of foods for special dietary uses for children from 3 to 18 years old shall not exceed (in % of the daily physiological need for these substances, established for children from 3 to 18 years old, determined in accordance with the established procedure: for vitamins A, D, minerals (selenium, copper, zinc, iodine, iron) — 100%, for water-soluble vitamins and other fat-soluble vitamins and other minerals — 200%.

The forms of vitamins and minerals in the production of food products for baby food are determined by the requirements of TR CU021/2011 (Appendix 9) [15]. The forms of vitamins and minerals in the production of foods for special dietary uses for children from 1.5 to 3 years old are regulated by the law established procedure [14, Appendix 9]. The forms of vitamins and minerals in the production of foods for special dietary uses for children over 3 years old are regulated by the established procedure [14, Appendix 7].

# Recommendations on food fortification for athletes' nutrition

In the production of foods for special dietary uses for the nutrition of athletes, it is allowed to use the forms of vitamins, vitamin-like and mineral substances determined by the relevant regulatory document [14, Appendix 11]. The types of foods for special dietary uses for the nutrition of athletes, recommended for fortification with essential nutrients, are shown in Table 4.

### Recommendations for fortification of food products assigned for dietary preventive nutrition and dietary medical nutrition

The foods for special dietary uses intended for dietary preventive nutrition, including for the nutrition of workers engaged in jobs where they are exposed to harmful and extremely harmful working conditions, as well as dietary medical food, including baby food, shall be fortified on the basis of medical and biological requirements for the chemical composition and properties of the finished food product, taking into account the physiological needs of the body, working conditions or alimentary pathologies.

Foods for special dietary uses for dietary therapeutic nutrition and preventive dietary nutrition, which can be also used as part of standard diets, shall have proven therapeutic and/or) preventive properties, confirmed by the results of studies of their clinical efficacy based on the principles of evidence-based medicine and in accordance with the current regulations of the Russian Federation.

The food products for the nutrition of workers, employed in jobs with harmful and extremely harmful conditions, shall be fortified in accordance with the relevant Orders of the Ministry of Health and Social Development of the Russian Federation [12,13].

The list of types of foods for special dietary uses of dietary (therapeutic and prophylactic) nutrition, recommended for fortification with micronutrients, is given below in the Table 5.

Groups of foods for special dietary uses, including fortified food products, assigned for nutrition of people engaged in enterprises and institutions with harmful and extremely harmful working conditions, are determined by the Order of the Ministry of Health of the Russian Federation [12]. The main fortifying ingredients include soluble dietary fiber (in particular: pectin), antioxidants and vitamins.

The food products are preferably to fortify not with individual vitamins only, but a complete set of B vitamins [23] in combination with other vitamins. When adding a set of micronutrients to fortified products, it is more convenient to use ready-made vitamin mixtures,

Table 4. Types of athletes' foods for special dietary uses, recommended for nutrient fortification

Types of foods for special dietary uses, purpose	Recommended nutrients for fortification
high-protein foods for athletes' nutrition control of muscle ratio, control of fat mass	vitamins: C, E, A, group B, beta-carotene; minerals: potassium, magnesium, chromium, zinc, copper, selenium, iodine; PUFAs of omega-3 family
protein-carbohydrate food products and carbohydrate- protein food products restoration of the body's energy resources and an increase in absolute and relative parameters of muscle body mass	vitamins C, E, A, D, group B, beta-carotene; minerals: calcium, phosphorus, magnesium, potassium, iron, chromium, zinc, selenium, copper, iodine, manganese, molybdenum; PUFA of the omega-3 family; soluble dietary fiber: pectin, carrageenan, gums, carboxymethyl cellulose
carbohydrate-mineral drinks maintaining the body's water- electrolyte balance, preventing dehydration, maintaining the balance of fluid and minerals in an athlete's body	vitamins of B group; minerals: calcium, potassium, magnesium, sodium in the form of electrolytes (water-soluble salts of organic and inorganic acids: calcium chloride, calcium phosphate, sodium citrate, potassium chloride, magnesium phosphate)

Table 5. Types of food products for dietary uses of dietary (therapeutic and prophylactic) nutrition, recommended for fortification with nutrients

***************************************	
Types of foods for special dietary uses, purpose	Recommended Nutrients for Fortification
foods for special dietary uses with hypolipidemic and hypoglycemic effect, assigned for patients with metabolic disorder syndrome	vitamins C, E, A, group B, beta-carotene; minerals: potassium, magnesium, calcium, chromium, zinc, selenium; PUFA of omega-3 family; soluble dietary fiber; biologically active substances with an antioxidant effect: flavonoids (flavonols and their glycosides — quercetin, kaempferol, rutin; flavones — luteolin, apigenin; flavonones — naringenin, hesperidin; dihydroflavonols, proanthocyanidins, catechins)
foods for special dietary uses for patients with cardiopathology caused by atherosclerotic vascular injury (ischemic heart disease and hypertension)	vitamins B1, B2, B6, B12, folic acid, C, E, A, D, beta-carotene; minerals: calcium, phosphorus, magnesium, potassium, iron, chromium, zinc, selenium, copper, iodine, manganese, molybdenum; PUFA of omega-3 family; soluble dietary fiber: pectin, carrageenan, gums, carboxymethyl cellulose; polyphenols; plant sterols; organic acids; rutin; coenzyme Q10 (ubiquinone)
foods for special dietary uses for patients with type 2 diabetes mellitus	vitamins D, A, E, C, beta-carotene; minerals: calcium, phosphorus, chromium, zinc, selenium, iodine, manganese, vanadium; PUFA of omega-3 family; soluble dietary fiber: pectin, beta-glucans, gums
foods for special dietary uses for patients with diseases of the gastrointestinal tract (syndrome irritable bowel with constipation)	vitamins: B6; PUFA of omega-3 family; inulin; curcumin
foods for special dietary uses for patients with non-alcoholic fatty liver disease	vitamins: D, C, E, group B minerals: potassium, magnesium, calcium, chromium, zinc, selenium; PUFA of the omega-3 family; phospholipids; soluble dietary fiber: pectin, gums; coenzyme Q10; alpha lipoic acid
foods for special dietary uses for osteoporosis prevention	vitamins: D, K2, C, E, group B minerals: calcium, magnesium, phosphorus, zinc
foods for special dietary uses for patients with diabetic nephropathy	vitamins: C, E, A, group B, beta-carotene; PUFA of omega-3 family; flavonoids; catechins; curcumin

mineral or vitamin-mineral mixtures (premixes) made on the basis of a carrier substance (often it is this very food product that is being fortified) in accordance with GOST R58040–2017 "Complexes of vitamin mineral. General technical conditions". The use of premixes increases the accuracy of dosage of micronutrients added to the food product, ensures their uniform distribution in the food product being fortified, and also allows production control of the micronutrient content through the determination of amount of several vitamins and / or minerals included in the premix [24].

### Deviation limits for fortifying nutrients in the fortified foods

The maximum permissible deviations of the nutritional value parameters (content of vitamins and minerals) of fortified food products, indicated on the food label on its packaging, from the actual nutritional value parameters shall be as follows: for vitamins C, B1, B2, B6, pantothenic acid, niacin and mineral substances (sodium, magnesium, calcium, phosphorus, iron, zinc)  $\pm$  20%, for vitamins A, B12, D, E, folic acid, biotin and iodine —  $\pm$  30%, iodine in iodized salt  $\pm$  38%. At the same time, the actual values of vitamins and minerals mass fractions shall comply with the requirements specified in the regulatory and technical

documents or standards of the organizations, which standards are used for production, analyzing and labelling of these products.

In the production of fortified food products for general population and fortified foods for special dietary uses, it is allowed to increase the content of vitamins in relation to the declared values, but not more than 70% for vitamin C and not more than 50% for other vitamins, due to a natural decrease of vitamins amount in fortified foods during their storage during the shelf life. Calculations show that excessive amount of micronutrients in fortified foods at the level of 25% still does not achieve the maximum permissible level of their consumption and remains safe [25].

### Labeling of the fortified food

The labeling of fortified food products for general population and fortified foods for special dietary uses must comply with the requirements of the technical regulations of the Customs Union TR CU022/2011 [16], TR CU021/2011 [15] and other technical regulations of the Customs Union for certain types of food products.

On the food packaging the word "fortified" must be written in the name of fortified food products or in the immediate vicinity. In addition the following shall be written:

- the names of the fortifying nutrients included in the composition of the food, their guaranteed content at the end of the shelf life of the food product in 100 g or 100 ml, or in one serving of the product, as well as the content expressed as a percentage of the average daily requirement for these nutrients;
- the content of a biologically active substance (mg, mcg, g), contained in the fortified food products for general population or fortified foods for special dietary uses and its percentage from the average daily (physiological) requirement for this element or substance in accordance with the established procedure [16,19]; if the daily requirement has not been established, it is necessary to write the amount of biologically active substance in the composition of fortified food products for general population or foods for special dietary uses and its ratio to the adequate level of consumption [14, Appendix 5];
- the number of probiotic microorganisms (CFU/g (ml)) included in the fortified food products for general population, or fortified foods for special dietary uses.

In the labeling of fortified food products for general population and fortified foods for special dietary uses, it is possible to use the principles of color indication, given in the relevant methodological recommendations [26].

The labeling of fortified food products for general population and fortified foods for special dietary uses may contain information on features and efficiency of the food product and (or) nutrient, characterizing its (their) nutritional and/or energy value, or information about the expected beneficial effect on the human body in case of this food systematic as part of food rations or as part of therapeutic diets in accordance with the regulatory documents [16, 27].

# Packaging, storage, transportation and sale of fortified food products

The packaging of fortified food products for general population and fortified foods for special dietary uses must comply with the requirements of the Technical Regulations of the Customs Union TR CU005/2011 [28] and TR CU021/2011 [15].

When storing products, the temperature and humidity conditions and the expiration date set by the manufacturer must be complied with. The fortified food products for general population and fortified foods for special dietary uses shall be transported in accordance with the requirements of TR CU021/2011 [15].

# Form of confirmation of compliance of fortified food products to the established requirements

Forms of confirmation of compliance of fortified mass consumption food products and fortified foods for special dietary uses are specified in TR CU021/2011 [15].

Verification of conformity of enriched food products for general population is carried out in the form of declaration, confirmation of conformity of fortified foods for special dietary uses is carried out in the form of state registration.

### Meat food fortification

Analysis of the available literature proved that dairy products, bakery and pastry, and various drinks are most often fortified with micronutrients. Much less often meat products are fortified, despite the fact that boiled sausages and minced meat semi-finished products get a significant share in the diet of the population in our country. Nevertheless, at present there is a certain range of these food products, including meat-based products, assigned to compensate for iodine deficiency, chopped culinary products fortified with vitamins and minerals [29].

It was shown that vitamins B1, B2, PP and C added to minced meat are well preserved during the preparation and heat treatment of minced meat products (cutlets, schnitzel, beef steaks). Preservation level achieved 66–70% for vitamin B1, 85% for B2, 76% for PP, 65–70% for C [30]. Studies and tests run on rats with vitamins B1, B2 and PP deficiency, showed that the vitamins introduced into cutlets are effectively digested by the body of animals, ensuring the normal functioning of the dependent enzymes. Long-term (for 2.5 months) inclusion of vitamins-fortified cutlets in the diet of vitamin-deficient rats as the only source of vitamins B1, B2 and PP fully ensured the growth of animals, the activity of biochemical processes dependent on these vitamins and a normal state of internal organs (according to histological and histochemical parameters) [30].

When fortifying cooked sausages, the main losses of thiamine and ascorbic acid occur at the stage of minced meat cooking and amount to 32 and 38%. Heat treatment of the food product has less effect on the stability of these vitamins (20 and 10%). The losses of riboflavin and niacin at these stages are practically the same, accounting for vitamin B2-18 and 14%, and for vitamin PP — 21 and 19%. To increase the stability of vitamins, it is advisable to use vacuum cutting [31]. As a result, to ensure the content of vitamins in the finished product from 30 to 50% of the daily requirement of the human body for the fortification of cooked sausages with vitamins shall be added to the recipe, g / 100 kg of raw material — thiamine — 1.5, riboflavin — 1.0, nicotinamide - 15, ascorbic acid - 75 [31]. The introduction of a vitamin premix into the recipe of cooked sausage not only increased the content of vitamins B1, B2, PP, C in 100 g to a level covering the phisiological need for them by 30-55%, but also reduced the amount of sodium nitrite [32].

The All-Russian Scientific Research Institute of the Meat Industry named after V. M. Gorbatov (currently the Federal Scientific Center for Food Systems named after V. M. Gorbatov) has developed vitamin-mineral mixtures for sausages for baby nutrition, as well as recipes that are used in the production of cooked sausages for kids. In accordance with GOST 31498–2012 "Cooked sausage products for baby nutrition" [33] sausages are produced fully

cooked and / or cooked pasteurized in the following assortment: sausages: "Kids sausages — Vita", "For diabetic kids", "Timka", "Lyubushka", "Gymnasium", sausages: "Zdorovye", "Skazka-vita", "For diabetic kids". In accordance with GOST R54753–2011 "Boiled ham in a casing for baby nutrition" [34], a ham fortified with vitamins B1, B2, PP, Fe, Ca, Zn and iodine is produced in the following assortment: "Kids sausages — Vita", "Klassnaya Vita", "Shkolnaya-vita", "Skazka-vita'. Canned sausages packed in cans or sterilized bags are fortified with vitamins B1, B2 and PP in an amount that provides 25–30% of the child's physiological needs [35].

Undoubtedly promising is the technology of canned beef products for enteral nutrition, fortified with biotin, vitamins B1, B2, B12, D, Ca: P = 1.5: 2, intended for people in the postoperative period with maxillofacial injury or burn injuries, who suffer from impaired swallowing and chewing [36].

In Belarus the special-purpose canned meat products have been developed for the nutrition of pregnant women and breast-feeding mothers "Vitaminized pate with pork and liver", "Fortified beef and pork puree", the recipe of which includes vitamins and minerals mixtures (vitamins A, D3, E, B1, B2, B6, B12, nicotinamide, folic acid, vitamin C, calcium, lactulose) and (iodine, selenium, folic acid, vitamin E) in a dose that covers the needs of a pregnant and breast-feeding woman by 20–25% [37]. Their clinical efficacy has been confirmed [37].

### Conclusion

It is known that the efficiency of food fortification depends on initial degree of the population's consuming the micronutrients, the correct choice of the fortified product, i. e. its share in the nutrition, dietary habits, coverage of the population with the fortified food supply, effective quality control and levels of fortification, regular monitoring and evaluation of consumption of fortified foods [38,39]. The

approaches presented in the article facilitate to a certain extent the choice of both the food product assigned for fortification, and the set of fortifying components.

Despite the heterogeneity of the analyzed studies (differences in fortified foods, composition of micronutrients, dosage, age of participants, duration of fortified foods consumption, differences in diet habits, initial consumption of micronutrients), it was found that consumption of foods in the diet fortified with several micronutrients led to an increase in serum concentration of these micronutrients; led to decrease in anemia occurrence by 34%, the development of bronchocele by 74%; probability of neural tube defects by 41% [40].

According to other meta-analysis data, despite the high heterogeneity and small sample size, compared with placebo or control sample, the consumption of foods fortified with several micronutrients can reduce the occurrence of anemia by 32%, iron deficiency anemia by 72%, iron deficiency by 56%, vitamin A deficiency by 58%, B vitamins deficiency by 64%, vitamin  $B_6$  deficiency by 91%, vitamin  $B_{12}$  deficiency by 58% [41]. At the same time, it is emphasized that none of the included studies reported on disease incidence, adverse effects, mortality from all or any specific causes.

Results of randomized clinical trials involving people, who consume dairy products fortified with phytosterols and PUFAs of omega-3 family, showed the improved biological markers of cardio-metabolic risk (i. e. lowering of low density lipoprotein cholesterol and triglycerides in blood plasma) [42].

Unfortunately, the majority of the population is still not sufficiently aware of the possibilities and role of fortified foods in health maintaining, which issue requires wide educational activity among the consumers. The population's conscious choice of fortified food products will serve as an incentive to increase the production of such food products and expansion of their assortment.

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