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**ENGLISH TEXT OF TECHNICAL REGULATIONS  
OF THE CUSTOMS UNION**

**TR CU 027/2012**

**«On safety of certain types of specialized food products, including foods for  
dietary treatment and dietary preventive nutrition»**

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## **Chapter 1. GENERAL PROVISIONS**

### **PREFACE**

1. The present Technical Regulation of the Customs Union on Safety of Specific Forms of Specialized Food Products, including the Therapeutic and Preventive Dietary Food (further the "Technical Regulation") has been developed in accordance with the Agreement On the Common Principles and Rules of Technical Regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation dated November 18, 2010.

2. The present Technical Regulations has been developed for the purpose of establishment of common compulsory requirements for specific types of food products, including the therapeutic and preventive dietetic food in the common customs area of the Customs Union, assurance of free movement of the products supplied for the circulation in the common customs area of the Customs Union.

3. If other technical regulations of the Customs Union are adopted with respect to specific types of specialized food products, including therapeutic and preventive dietary food that establish requirements for such products then the specific types of specialised food products, including therapeutic and preventive dietary food should meet the requirements of all the technical regulations of the Customs Union that are applicable to such products.

#### **Article 1. SCOPE OF APPLICATION**

1. The present Technical Regulation shall establish:

- 1) the subjects of technical regulation;
- 2) the safety requirements (including sanitary and epidemiological and hygienic requirements) for the subjects of technical regulation;
- 3) the rules of identification of the objects of technical regulation;
- 4) the forms and the rules of assessment of the correspondence of the objects of technical regulation to the requirements of the present Technical Regulation.

2. The purposes of the adoption of the present Technical Regulations are:  
the protection of life and (or) human health;  
the prevention of the actions misleading the purchasers (customers).

3. During application of the present Technical Regulation the requirements for food products to the extent of its marking, the materials, which come into contact with the food products, including the packing, and the applied raw food material as established by the appropriate technical regulations of the Customs Union must be considered.

4. During the application of the present Technical Regulation the requirements of the Technical Regulations of the Customs Union, which establish the obligatory requirements for food products and their specific types must be applied.

#### **Article 2. SUBJECT OF TECHNICAL REGULATION**

1. The subjects of technical regulation of the present Technical Regulation shall be the following items, which are supplied for the circulation and are in circulation in the common customs territory of the member states of the Customs Union:

the specialized food products for the nourishment of athletes, pregnant and breast-feeding women;

the food products of therapeutic and preventive dietetic nourishment, including for the children's nourishment.

2. The requirements of the present Technical Regulation shall not be applicable to:

food products for children's nourishment, with exception of food products for therapeutic and preventive dietetic nourishment for the children's nourishment;  
the food products manufactured by food enterprises (public nutrition, within organized associations);  
natural mineral water, therapeutic water, therapeutic mineral water with the mineralization over 1 mg/dm or with less mineralization that contains biologically active constituents in the quantity that does not go below the balneological standards;  
biologically active food additives.

### **Article 3 . IDENTIFICATION RULES**

1. For the purpose of designation of certain types of specialized food products, including therapeutic and preventive dietary food to the subject of technical regulation subject to application of the present Technical Regulation food products shall be identified by interested parties.

2. The identification of specific types of specialized food products, including the therapeutic and preventive dietetic food shall be carried out according to the procedure established by the Technical Regulation of the Customs Union On Safety of Food Products.

### **Article 4. DEFINITIONS**

The present Technical Regulation uses the definitions established by the Technical Regulation of Customs Union On Safety of Food Products as well as the following terms and definitions:

1) therapeutic dietary food products - specialized food products with the assigned food and energy value, the physical and organoleptic properties that are intended for use as a part of therapeutic diets;

2) preventive dietary food products - the specialized food products that are intended for the adjustment of carbohydrate, fat, protein, vitamin and other types of metabolism, in which the content and (or) the ratio of specific substances has been changed as regards the natural content, and (or) that include the substances or components that were not originally included, as well as the food products intended for reduction in the risk of disease development;

3) food products for the nourishment of athletes - specialized food products of the assigned chemical composition, with increased food nourishment value and (or) of targeted effectiveness consisting of a complex of products or represented by their specific forms, which has a specific effect on an increase in the adaptive possibilities of a human as regards the physical and neuroemotional loads;

4) food products for the nourishment of pregnant and breast-feeding women - specialized food products, in which the content and (or) the ratio of specific substances has been changed against their natural content, and (or) the composition of which has been supplemented by the substances or components that were not originally included, intended for the satisfaction of physiological needs of a pregnant and feeding woman;

5) food products of enteral nourishment - the liquid or dry (restored to the ready-to-use condition) food products of therapeutic or preventive dietetic nourishment intended for the direct peroral use or introduction through a probe where the organism cannot be supplied with food substances and the energy in the usual way;

6) food products of diabetic nourishment - the food products of therapeutic or preventive dietetic nourishment that do not contain or have a reduced content of the easily digested carbohydrates (monosaccharides - glucose, fructose, galactose, and of disaccharides - saccharose, lactose) against their content in similar food products and (or) in which the carbohydrate composition has been changed;

7) anti-reflux mixtures - the mixtures that contain the thickener (thickeners) and are intended for averting possetting of food by the children of tender age;

8) mixture for the nourishment of premature and (or) low birth-weight babies - the food products for the children's nourishment produced on the basis of cow's milk or milk of other productive animals and (or) of the products of milk processing that are intended for the satisfaction of physiological needs of the premature and (or) low birth-weight children;

9) low-lactose (lactose-free) food products - the food products of therapeutic or preventive dietetic nourishment produced on the basis of cow's milk or the milk of other productive animals and (or) the products of milk processing, in which the content of lactose has been reduced in comparison with similar food products;

10) food products without (or with the low content of) specific amino acids - food products of therapeutic or preventive dietary nourishment obtained on the basis of the hydrolyzates of proteins free from (or with the low content of) specific amino acids and (or) the mixture of amino acids without the phenylalanine, and (or) with the use of components with the reduced content of phenylalanine.

## **Article 5. RULES OF CIRCULATION ON THE MARKET**

1. Specialized food products, including preventive and therapeutic dietary nourishment referred to in Paragraph 1 Article 2 of the present Technical Regulation shall be put into circulation on the market when it is in compliance with the present Technical Regulations, as well as other technical regulations of the Customs Union that are applicable to such food products.

2. The specialized food products, including therapeutic and preventive dietetic nourishment, indicated in Paragraph 1 Article 2 of the present Technical Regulation, which correspond to the requirements of the present Technical Regulation, other technical regulations of the Customs Union applicable to such products and have passed the assessment (confirmation) of conformity shall be marked by the common sign of products circulation on the market of the Customs Union member states.

## **Chapter 2. SAFETY REQUIREMENTS FOR THE FOOD PRODUCTS**

### **Article 6. SAFETY REQUIREMENTS FOR PARTICULAR TYPES OF SPECIALIZED FOOD PRODUCTS, INCLUDING THERAPEUTIC AND PREVENTIVE DIETARY FOOD**

1. The raw food material, food additives used in the production of specific types of specialized food products, including the therapeutic and preventive dietetic nourishment must meet the safety requirements established by the Technical Regulation of the Customs Union On Safety of Food Products.

While producing specific forms of the specialized food products, including therapeutic and preventive dietetic nourishment it is permitted to use food additives, which meet the requirements of the present Technical Regulation and the Technical Regulation of the Customs Union On Safety Requirements for Food Additives, Flavours and Technological Booster Agents.

2. The food products of therapeutic and preventive dietary nourishment must satisfy the physiological needs of the human organism as regards the necessary food substances and energy taking into account the factors of risk and pathogenesis of diseases, correspond to the established hygienic requirements as regards the permissible content of contaminants and biologically active substances and compounds, microorganisms and other biological organisms that represent danger to the health of present and future generations.

3. The following products shall not be allowed to be used:

1) poultry meat except for the cooled products, poultry meat of mechanical chiselling and poultry meat raw materials containing collagen for production of therapeutic and preventive dietary nourishment, food products for the nourishment of pregnant and breast-feeding women;

2) commodity raw food material, which contains GMO and (or) the components obtained from GMO for production of food for the pregnant and breast-feeding women, therapeutic and preventive dietetic food products for the children's nourishment.

4. The food products for nourishment of pregnant and breast-feeding women must correspond to the requirements established in Appendices 1 and 2 to the present Technical Regulation.

5. Specific forms of the therapeutic children nourishment products and preventive children nourishment products for young children must meet the requirements set in Appendix 3 of the present Technical Regulation.

6. The composition of the salt substitutes must meet the requirements set in Appendix 2 of the present Technical Regulation.

The content of sodium in salt substitutes must not exceed 120 mg/100 g of the mass of the salt substitute mixture.

7. The addition of iodine containing compounds to the salt and the salt substitutes must meet the standards of the national laws of the Customs Union member state, in which the products are sold.

8. Specific types of specialized food products, including for nourishment of athletes must not contain any psychotropic, drug, poisonous, strong, doped substances and/or their metabolites, other forbidden substances included in the list of WADA (World Anti-Dope Agency).

9. Specific types of specialized gluten free food products must consist or be prepared of one or more components, which do not contain wheat, ryes, barley, oats or their cross bred versions (obtained via their crossing) and (or) must consist of or be prepared in a special (for a decrease in the level of gluten) way from one or more components, which are obtained from the wheat, the rye, the barley, the oats or their cross bred versions, and in which the level of gluten in the ready-to-eat products does not exceed 20 mg/kg.

10. Certain types of specialized food products with low content of gluten should contain or be produced in a special (to reduce the level of gluten) way from one or more ingredients that are derived from wheat, rye, barley, oats or their cross bred versions, and in which the level of gluten in ready-to-eat products is more than 20 mg/kg however does not exceed 100 mg/kg.

### **Chapter 3. MARKING OF FOOD PRODUCTS**

#### **Article 7. REQUIREMENTS FOR THE PACKING AND MARKING OF SPECIFIC TYPES OF SPECIALIZED PRODUCTS INCLUDING THE THERAPEUTIC AND PREVENTIVE DIETARY NOURISHMENT**

1. The packing and marking of specific types of specialized food products including the therapeutic and preventive dietary nourishment must meet the requirements of the technical regulations of the Customs Union Technical Regulations for the Food Products as regards Its Marking and On the Safety of Packing.

2. Specific types of specialized food products including the therapeutic and preventive dietary nourishment must be prewrapped and packed using the method, which makes it possible to ensure their safety and consumer properties declared on the marking by the best before date subject to observance of the conditions for their transportation and storage.

3. While packing specific types of specialized food products including the therapeutic and preventive dietary nourishment the materials and the items that meet the safety requirements for the materials and the items that come into contact with food products as established by the appropriate Technical Regulation of the Customs Union must be used.

4. The perishable food products of therapeutic and preventive dietary nourishment must be released only in the prewrapped form in the small-piece packing for one-time consumption.

5. The marking of specific types of the specialized food products including the therapeutic and preventive dietetic nourishment must contain the information about the designation of the products in accordance with the definitions established in Article 4 of the

present Technical Regulation, the category of the persons for whom that products are designated and (or) the information about changes in the composition of such products, the recommendations on their usage.

6. The instruction on storage of the food products of therapeutic and preventive dietetic nourishment after dissection of the packing must be given on the marking, if this is necessary to guarantee the completeness of properties and nutritiousness of products. If the products cannot be stored after the packing dissection, or they cannot be stored in the packing after dissection the respective warning must be mentioned.

7. In addition to all indications on the marking, which concern the dietetic products with low content of sodium (with exception of the salt substitutes as such) the following specific instructions concerning the marking must be fulfilled:

1) if substitutes are present, the information on the presence of salt substitutes listed in Appendix 4 to the present Technical Regulations must be indicated;

2) if salt substitute, which consists of potassium salt in full or in part has been added it is necessary to indicate on the marking the summary content of potassium expressed in milligrams of cation to 100 grams of products.

8. The salt substitutes must be called “the substitute of salt with low content of sodium” or the “dietetic salt with low content of sodium”. The marking of salt substitutes must contain the full list of ingredients, and also the content of cations (sodium, potassium, calcium, magnesium, ammonium and choline) in 100 grams of the mass of the mixture of substitutes.

9. The marking of food products for the nourishment of athletes must include the following additional information:

- for the products that have the assigned food and energy value and the designated effectiveness, consist of a set of nutrients or representatives of their specific types the following information is indicated: "specialized food products for the nourishment of athletes";

- the following information will be additionally indicated on the consumer packing: the information on the food and energy value of products, the portion of the physiological need; the recommended dosages, the methods of preparation (if necessary), the conditions and the duration of application.

#### **Chapter 4. REQUIREMENTS FOR THE PROCESSES OF PRODUCTION (MANUFACTURE), STORAGE, CARRIAGE (TRANSPORTATION), REALIZATION AND DISPOSAL OF THE SPECIFIC TYPES OF SPECIALIZED FOOD PRODUCTS INCLUDING THERAPEUTIC AND PREVENTIVE DIETETIC NOURISHMENT**

##### **Article 8. SAFETY REQUIREMENTS FOR THE PROCESSES OF PRODUCTION, STORAGE, CARRIAGE (TRANSPORTATION), REALIZATION AND DISPOSAL OF SPECIFIC TYPES OF SPECIALIZED FOOD PRODUCTS INCLUDING THE THERAPEUTIC AND PREVENTIVE DIETETIC NOURISHMENT**

1. The processes of production (manufacture), storage, transportation, realization and disposal of certain types of specialized food products, including the therapeutic and preventive dietary nourishment that ensure their safety shall comply with the requirements of the present Technical Regulation and the Technical Regulation of the Customs Union On Safety of Food Products.

2. All friable components must be passed through the magnet snatchers before their use.

3. For the work with living microorganisms separate premises shall be provided.

#### **Chapter 5. ASSESSMENT (VALIDATION) OF CONFORMITY**

## **Article 9. ASSURANCE OF CONFORMITY TO SAFETY REQUIREMENTS**

1. The correspondence of specific types of specialized food products including the therapeutic and preventive dietetic nourishment to the present Technical Regulation is ensured by fulfilling its safety requirements.

2. The methods of studies (tests) and measurements of specific forms of specialized food products including the therapeutic and preventive dietetic nourishment are established in the standards included in the list of standards that specify the rules and methods of studies (tests) and measurements including the rules of sampling necessary for application and performance of the requirements of the present Technical Regulation and assessment (validation) of products conformity.

## **Article 10. CONFORMITY ASSESSMENT**

1. The assessment of conformity of specific types of specialized food products including the therapeutic and preventive dietetic nourishment to the requirements of the present Technical Regulation is accomplished in the form of state registration following the procedure established by the Technical Regulation of the Customs Union On Safety of Food Products.

2. In the course of state registration of the products of therapeutic and preventive dietetic nourishment the document(s) confirming the declared therapeutic and (or) preventive properties are submitted.

3. The assessment of correspondence of the processes of production, storage, realization, transportation, disposal of specific types of specialized food products, including the therapeutic and preventive dietetic nourishment is conducted in the form of state supervision (control) of the observance of the requirements for the food products established by the present Technical Regulation and other Technical Regulations in the field of food safety.

## **Article 11. MARKING WITH THE COMMON SIGN OF PRODUCT CIRCULATION ON THE MARKET OF THE CUSTOMS UNION MEMBER STATES**

1. The specific types of specialized food products including the therapeutic and preventive dietetic nourishment that meet the safety requirements of the present Technical Regulation and have passed the procedure of conformity assessment must be marked with the common sign of product circulation on the market of the Customs Union member states.

2. The marking with the common sign of product circulation on the market of the Customs Union member states is accomplished prior to release of specific types of specialized food products including the therapeutic and preventive dietary nourishment into circulation on the market.

3. The common sign of product circulation on the market of the Customs Union member states is put on each unit of output (market container, and (or) tag, and (or) label) and (or) transportation documentation. The common sign of product circulation on the market of the Customs Union member states is applied by any method, which ensures a clear and distinct image during the entire period of the product validity.

## **Chapter 6. SAFEGUARD CLAUSE**

### **Article 12. SAFEGUARD CLAUSE**

1. The member states of the Customs Union are obliged to undertake measures to avoid the release of specific types of specialized food products including the therapeutic and preventive dietary nourishment that do not meet the requirements of the present Technical Regulation into circulation in the common territory of the Customs Union, as well as their withdrawal from circulation.



2. The authorized body of the member state of the Customs Union shall notify the Eurasian Economic Commission and competent authorities of other member states of the Customs Union of the decision specifying the reasons for the adoption of such decision and providing the evidence explaining the need for the measure.

3. Grounds for the application of this article may be the following:

failure to comply with the requirements of the present Technical Regulation;

incorrect application of the standards interlinked with the present Technical Regulation if the standards have been applied.

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## Appendix 1

to the Technical Regulation of the Customs Union On Safety of  
Specific Types of Specialized Food Products Including the  
Therapeutic and Preventive Dietary Food

### Microbiological safety standards (conditionally pathogenic)

In some types of specialized food products produced using technological and/or probiotic microflora the content and species composition of lactic and probiotic microorganisms is standardized - table 1.

In specific forms of the specialized unpreserved food products subjected to processing before realization the conditionally pathogenic microorganisms, the sanitary exponential microorganisms and the spoilage microorganisms that characterize the safety, the sanitary and hygienic state of the production and the stability of products during storage shall be normalized - see table 2.

The conformity to the indicated indices is evaluated at the stage of circulation of specific types of specialized food products during the entire period of their validity.

Table 1

Requirements for the content of biotechnological and probiotic microorganisms in specific types of specialized food products

Indices	Tolerance levels	Product Groups
Bifidobacteria and/or other probiotic microorganisms (kinds of Lactobacillus, Propionibacterium)	$1 \times 10^6$	Products based on milk and the isolate of soybean protein: liquid products based on sour-milk and the soured soybean basis for pregnant and breast-feeding women.

Table 2

Requirements for the conditionally pathogenic and sanitary exponential microorganisms in food products

2.1 Meat and meat products, poultry and the products of their processing

<b>Indices</b>	<b>Tolerance levels</b>	<b>Product Groups</b>
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	$1 \times 10^3$	Meat (all animals): cooled - for production of therapeutic and preventive dietetic nourishment
Bacteria of the group of coliform bacteria (coliforms) shall not be allowed in the mass of a product, g	0.1	Meat (all animals): cooled - for production of therapeutic and preventive dietetic nourishment
Bacteria of the kind of Proteus, not allowed in the mass of products, g	1.0	Meat (all animals): cooled - for the products of therapeutic and preventive dietetic nourishment

## 2.2. Other products

<b>Indices</b>	<b>Tolerance levels</b>	<b>Product Groups</b>
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g, not more than	5x10 <sup>2</sup>	Pectin for dietetic nourishment products
	5x10 <sup>3</sup>	Dry products for preventive dietetic nourishment - cereal, dairy, meat mixtures (extrusion technology)
	1x10 <sup>4</sup>	Alimentary gelatin for dietetic nourishment products
Bacteria of the group of coliform bacteria (coliforms) are not allowed in the mass of products, g	0.1	Dry products for preventive dietetic nourishment - cereal, dairy, meat mixtures (extrusion technology)
	1.0	Pectin for dietary food products; Alimentary gelatine for dietary food products
S. aureus, not allowed in the mass of the products, g	1	Dry products for preventive dietary nourishment- cereal, dairy, meat mixtures (extrusion technology)
B.sereus, CFU/g, not more than	10	Dry products for preventive dietary nourishment - cereal, dairy, meat mixtures (extrusion technology)
Yeast, CFU/g, not more than	10	Dry products for preventive dietary nourishment - cereal, dairy, meat mixtures (extrusion technology)
	50	Pectin (dietary food products)
Mould, CFU/g, not more than	50	Pectin (dietary food products)
	100	Dry products for preventive dietary nourishment - cereal, dairy, meat mixtures (extrusion technology).

### 2.3. Products for the nutrition of pregnant and nursing women

Indicators	Tolerance levels	Product Groups
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	5x10 <sup>3</sup>	Herbal instant tea (on the vegetative basis)
	2,5x10 <sup>4</sup>	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)
	5x10 <sup>4</sup>	Porridges on the milk and cereal basis (instant preparation)
Bacteria of the group of coliform bacteria (coliforms) shall not be allowed in the mass of a product, g	3.0 g	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis for pregnant and feeding women.
	1.0 g	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products); Herbal instant tea
	0,1 g	Porridges on the milk and cereal basis (instant preparation)
E. coli not allowed in the mass of products, g	10 g	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)
S. aureus, not allowed in the mass of products, g	10 g	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis for pregnant and feeding women.
	1.0 g	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)
Mould, CFU/g, not more than	10	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis.
	50	Herbal instant tea
	100	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)
	200	Porridges on the milk and cereal basis (instant preparation)

Yeast, CFU/g, not more than	10	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis.
	50	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products); Herbal instant tea (on vegetative basis)
	100	Porridges on the milk and cereal basis (instant preparation)
B.cereus, not allowed in the volume of products, cub.cm	1.0	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis.
B. cereus, CFU/g, not more than	In 1.0 g not	Products based on milk and the isolate of soybean protein: liquid products
	allowed	based on sour milk and the soured soybean basis
	100	Herbal instant tea (on the vegetative basis)
	2x10 <sup>2</sup>	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)

#### 2.4. Specialized products for therapeutic nourishment of children, for the premature and (or) low birth-weight children

Indicators	Tolerance levels	Product Groups
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	1x10 <sup>2</sup>	Adapted sterilized milk mixtures, sterilized milk and cream of non-aseptic bottling, calcinated cottage cheese prepared at dairy kitchens
	2x10 <sup>2</sup>	Pasteurized small sausages on the meat basis
	5x10 <sup>2</sup>	Restored pasteurized mixtures prepared at dairy kitchens.
	2x10 <sup>3</sup>	Production based on the isolate of soybean protein. Products based on complete or partial hydrolyzates of protein; products without phenylalanine or a low content thereof; products for premature and (or) low birth-weight children restored at 37-50°C

	3x10 <sup>3</sup>	Low-protein products (starches, cereals and paste products and another products), the products for premature and (or) low birth-weight children restored at 70-85°C
	1x10 <sup>4</sup>	Sublimated products on the meat basis for the children of up to 2 years.
	1,5x10 <sup>4</sup>	Sublimated products on the meat basis for the children of over 2 years.
	2,5x10 <sup>4</sup>	Low-lactose and lactose-free products, dry milk high-protein production
Bacteria of the group of coliform bacteria (coliforms) shall not be allowed in the mass of a product, g	1.0	Low-lactose and lactose-free products. Products based on the isolate of soybean protein. Low-protein products (starches, cereals and paste products and other products). Products on the basis of full or partial protein hydrolysates. Products without or with low phenylalanine content. Sublimated products on the meat basis. Products for premature and (or) low birth-weight children
	0.3	Dry milk high-protein products. Sublimated milk based products (cottage cheese etc.)
<b>E. coli not allowed in the mass of products, g</b>	10	Products for premature and (or) low birth-weight children
S. aureus, not allowed in the mass of products, g	10	Products for premature and (or) low birth-weight children
	1.0	Low-lactose and lactose-free products. Dry milk high-protein products. Products based on the isolate of soybean protein. Products on the basis of full or partial protein hydrolysates. Products without or with low phenylalanine content. Sublimated meat and milk based products (cottage cheese etc.)
	0.1	Low-protein products (starches, cereals and paste products and other products).
Sulphite-reducing Clostridia, not allowed in the mass of a product, g	0.1	Sublimated products on the meat basis.
Moulds, CFU/g	10	Low-protein products (starches, cereals and paste products).
	50	Production based on the isolate of soybean protein. Sublimated products on the meat basis for the children of up to 2 years. Products for premature and (or) low birth-weight children Products on the basis of full or partial protein hydrolysates. Products without or with low content of phenylalanine. Low-protein products (except for starches, cereals and paste products)

Yeast(s), CFU/g	100	Low-lactose and lactose-free products. Dry milk high-protein products. Sublimated products on the meat basis for the children of over 2 years. Sublimated milk based products (cottage cheese etc.)
	10	Products based on soy protein isolate, Products for premature and (or) low birth-weight children Products on the basis of full or partial protein hydrolysates. Products without or with low phenylalanine content.
	50	Low-lactose and lactose-free products. Dry dairy high-protein production, low-protein products (starches, cereals and paste products and other products). Sublimated meat and milk based products (cottage cheese etc.) Sublimated meat and milk based products (cottage cheese etc.)
	100	Sublimated products on the meat basis for the children of over 2 years.
B. cereus, CFU/g	100	Products based on the isolate of soybean protein. Low-protein products (starches, cereals and paste products and other products). Products on the basis of full or partial protein hydrolysates. Products without or with low phenylalanine content. Sublimated products on the meat basis for the children of up to 2 years. Products for premature and (or) low birth-weight children
	2x10 <sup>2</sup>	Low-lactose and lactose-free products. Sublimated products on the meat basis for the children of over 2 years.



## Appendix 2

to the Technical Regulation of the Customs Union On Safety of Specific Types of Specialized Food Products Including the Therapeutic and Preventive Dietary Food

### Composition of salt substitutes salt

Composition of salt substitutes	Application conditions
1	2
a) potassium sulfate, potassium, calcium and ammonium salts the adipic, glutamic and carbon, amber, lactic, wine, citric, acetous, hydrochloric, orthophosphoric acids	Not limited, however the phosphorus content in the mixture of substitutes should not exceed 4%, and for NH <sub>4</sub> + 3% of the total mass of substitutes.
b) magnesium salts of adipic, glutamic, carbon, citric, amber, acetous, wine, lactic, hydrochloric and orthophosphoric acids, in the mixture with other substitutes, which do not contain magnesium	The content Mg must not exceed 20% in the mass of the general content of cations of K <sup>+</sup> , Ca, NH <sub>4</sub> present in the mixture of substitutes, and the content of P must not exceed 4% of the total mass of substitutes.
c) cholinic salts of acetous, carbon lactic, wine, citric and hydrochloric acids, in the mixture with other substitutes, which do not contain choline,	The content of choline must not exceed 3% of the mass of substitutes mixture
g) free adipic, glutamic, citric, lactic and malonic acids	Not limited

The salt substitutes can also contain:

- 1) colloidal silicon or silicate of calcium not exceeding 1% of the mass of substitutes mixture, individually or in combination;
- 2) fillers: safe and suitable food products of common use (for example, sugar, grain flour).

### Appendix 3

to the Technical Regulation of the Customs Union on Safety of Specific Types of Specialized Food Products Including the Therapeutic and Preventive Dietary Food

Requirements for the nutrition value of specific types of specialized food products including of therapeutic and preventive dietetic nourishment for the children of tender age

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes	
<b>LOW-LACTOSE AND LACTOSE-FREE PRODUCTION FOR THE CHILDREN OF THE FIRST YEAR OF LIFE</b>					
Low-lactose (lactose-free) food products	Protein	g/l	12-21		
	Taurin	mg/l, not exceeding	80		
	L- carnitine	The same	20 (upon inclusion)		
	Fat	g/l	30-40		
	Linoleic acid	% of the fat acids	14-20		
		mg/l, not exceeding	4000-8000		
	Carbohydrates	g/l	65-80		
	Lactose	g/l, not exceeding	10	In low-lactose products	
		the same	0.1	In lactose-free products	
	Mineral substances:				
		calcium	mg/l	330-700	
		phosphorus	The same	150-400	
		potassium	The same	400-800	
		sodium	The same	150 - 300	
		magnesium	The same	30-90	
		copper	The same	0,3-1,0	
		manganese	µg/l	10-300	
	iron	mg/l	3-14		
	zinc	The same	3-10		
	chlorides	The same	400-800		
	iodine	µg/l	50-150		

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	ash	g/l	3-5	
	Vitamins:			
	retinol (A)	µg - equiv/l	400-1000	
	tocopherol (E)	mg/l	4-12	
	calciferol (D)	µg/l	7,5-12,5	
	vitamin K	The same	25-60	
	thiamine (B1)	The same	400-1000	
	riboflavin (B2)	The same	500-1500	
	pyridoxine (B6)	The same	300-1000	
	Pantothenic acid	The same	2700-5000	
	folic acid (Bc)	The same	60-150	
	cyanocobalamin (B12)	µg/l	1,0-3,0	
	niacin (PP)	mg/l	2-10	
	Ascorbic acid (C)	mg/l	60-150	
	biotin	µg/l	10-40	
	carnitine	mg/l	10-20	
	inositol	mg/l	20-60	
	choline	The same	50-150	
	Osmolality	mOsm/kg, not more	300	
<b>LOW-LACTOSE PRODUCTS OF MILK PROCESSING FOR THE CHILDREN OF THE TENDER AGE</b>				
	Protein	g/l	40-47	
	Casein/serum proteins	-	80:20	
	Fat	g/l	20-38	
	Linoleic acid	% of the fat acids, not over	15	
		mg/l	5000-6000	
	Carbohydrates	g/l	60-65	
	Glucose	The same	25-28	
	Galactose	The same	6-7	
	Lactose	g/l, not exceeding	16	
	Energy value	kcal/l	600-680	
Mixtures on the basis of the	Protein	g/l	15-20	

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes	
isolate of soybean protein for the children of the tender age	Methionine	the same	0,25-0,35		
	Fat	g/l	30-38		
	Linoleic acid	% of the fat acids, not over	14		
		mg/l, not less	4000		
	Carbohydrates (dextrin-maltose)	g/l	65-80		
	Energy value	kcal/l	650-720		
	Mineral substances:				
	calcium	mg/l	450-750		
	phosphorus	The same	250-500		
	potassium	The same	500-800		
	sodium	The same	200-320		
	magnesium	The same	40-80		
	copper	The same	0,4-1,0		
	iron	mg/l	6-14		
	zinc	The same	4-10		
	ash	g/l	3-5		
	Vitamins:				
	retinol (A)	µg - equiv/l	500-800		
	tocopherol (E)	mg/l	5-15		
	calcipherol (D)	µg/l	8-12		
	vitamin K	The same	25-100		
	thiamine (B1)	The same	300-600		
	riboflavin (B2)	The same	600-1000		
	pyridoxine (B6)	The same	300-700		
	folic acid (Bc)	The same	60-150		
	cyanocobalamin (B12)	µg/l	1,5-3,0		
	niacin (PP)	mg/l	4-8		
	Ascorbic acid (C)	mg/l	60-150		
	Taurin	mg/l	45-55		
	L- carnitine	The same	10-20		
Osmolality	mOsm/kg, not more	300			

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes	
Mixtures on the basis of the full protein hydrolysates for the children of tender age	Protein (equiv.)	g/l	12-22		
	Taurin	mg/l	40-55		
	L- carnitine	The same	10-25		
	Fat	g/l	25-35		
	Linoleic acid	% of the fat acids, not over		14	
		mg/l, not less		4000	
	Carbohydrates	g/l	70-95		
	Energy value	kcal/l	650-720		
	Mineral substances:				
	calcium	mg/l	330-980		
	phosphorus	The same	150-600		
	potassium	The same	400-1000		
	sodium	The same	150-350		
	magnesium	The same	50-100		
	copper	The same	0,3-1,0		
	iron	mg/l	6-14		
	zinc	The same	3-10		
	ash	g/l	4-5		
	Vitamins:				
	retinol (A)	µg - equiv/l	500-800		
	tocopherol (E)	mg/l	6-14		
	calciferol (D)	µg/l	5-15		
	thiamine (B1)	The same	400-600		
	riboflavin (B2)	The same	600-1000		
	pyridoxine (B6)	The same	500-700		
	folic acid (Bc)	The same	50-100		
	cyanocobalamin (B12)	µg/l	1,5-3,0		
	niacin (PP)	mg/l	3-8		
	Ascorbic acid (C)	mg/l	50-150		
	Osmolality	mOsm/kg, not more	320		
Mixtures without phenylalanine	Protein (equiv.)	g/l	16-20		

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
(low-phenylalanine content) for children in the first year of life	Phenylalanine	mg/l, not exceeding	500	In products based on amino acid mixture - absence
	Taurin	mg/l	40-55	
	L- carnitine	The same	10-25	
	Fat	g/l	30-38	
	Linoleic acid	% of the fat acids, not over	14	
		mg/l, not less	5000	
	Carbohydrates	g/l	65-80	
	Energy value	kcal/l	570-720	
	Mineral substances:			
	calcium	mg/l	300-700	
	phosphorus	The same	300-500	
	potassium	The same	500-800	
	sodium	The same	150 - 300	
	magnesium	The same	40-60	
	copper	The same	0,3-1,0	
	iron	mg/l	3-14	
	zinc	The same	4-10	
	ash	g/l	4-5	
	iodine	µg/l	50-120	
	Vitamins:			
	retinol (A)	µg - equiv/l	500-800	
	tocopherol (E)	mg/l	4-12	
	calcipherol (D)	µg/l	8-12	
	thiamine (B1)	The same	350-700	
	riboflavin (B2)	The same	500-1000	
	pyridoxine (B6)	The same	300-700	
	folic acid (Bc)	The same	50-100	
	cyanocobalamin (B12)	µg/l	1,5-3,0	
	niacin (PP)	mg/l	3-8	

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	Ascorbic acid (C)	mg/l	20-100	
	Osmolality	mOsm/kg, not more	320	
Mixtures for nursing premature and (or) low birth-weight children	Protein	g/l	19-31	
	Taurin	mg/l	Not more than 90	
	Fat	g/l	33-45	
	Linoleic acid	g/l	2.6-10.5	
	Alpha-linolenic acid	mg/l	Not less than 375	
	Docosahexaenoic acid	mg/l	80 - 205	
	Arachidonic acid	mg/l	120 - 295	
	Eicosatrienoic acid	%	Not more than 30 of the level of Docosahexaenoic acid	
	Carbohydrates	g/l	72 - 94	
	Energy value	kcal/l	660 - 890	
	Mineral substances:			
	calcium	mg/l	800 - 1400	
	phosphorus	The same	400 - 700	
	potassium	The same	450 - 1200	
	sodium	The same	300 - 800	
	magnesium	The same	50 - 130	
	copper	The same	0,6 - 1,6	
	iron	mg/l	13 - 20	
	zinc	The same	7 - 13	
	chlorides	The same	400 - 1200	
	manganese	µg/l	45 - 200	
	iodine	The same	75 - 325	
	selenium	The same	13 - 70	
	Vitamins:			
	retinol (A)	µg - equiv/l	1500 - 3000	
	tocopherol (E)	mg/l	15 - 60	
	calcipherol (D)	µg/l	15 - 60	

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	vitamin K	The same	30 - 200	
	thiamine (B1)	The same	750 - 2000	
	riboflavin (B2)	The same	600 - 4000	
	pantothenic acid	mg/l	2,3 - 14,0	
	pyridoxine (B6)	The same	200 - 2000	
	folic acid (Bc)	The same	225 - 600	
	cyancobalamin (B12)	µg/l	0,6 - 5,3	
	niacin (PP)	mg/l	2,5 - 38	
	ascorbic acid (C)	mg/l	60 - 300	
	inositol	The same	30 - 350	
	biotin	µg/l	10 - 300	
	choline	mg/l	50 - 350	
	L-carnitine	mg/l	15 - 45 (upon inclusion)	
	nucleotides	mg/l	Not more than 35 (upon inclusion)	
	Osmolality	mOsm/kg, not more	310	

Laboratory control of casein is accomplished subject to availability of the control method approved according to the established procedure.