

Technical Regulations TR CU 027/2012

In accordance with Article 3 of the Treaty on the Eurasian Economic Commission dated 18 November 2011, the Council of the Eurasian Economic Commission decided:

1. To adopt the Customs Union Technical Regulation “On the Safety of Certain Types of Specialized Food Products, Including Dietary Therapeutic and Dietary Preventive Nutrition” (TR CU 027/2012) (attached).
2. To establish that the Customs Union Technical Regulation specified in Clause 1 of this Decision shall enter into force on 1 July 2013.
3. This Decision shall enter into force upon the expiry of 30 calendar days from the date of its official publication.

Members of the Council of the Eurasian Economic Commission:

<i>For the Republic of Belarus</i>	<i>For the Republic of Kazakhstan</i>	<i>For the Russian Federation</i>
<i>S. Rumas</i>	<i>K. Kelimbetov</i>	<i>I. Shuvalov</i>

ADOPTED

by the Decision of the Council of the Eurasian
Economic Commission
dated 15 June 2012 No. 34

TECHNICAL REGULATION OF THE CUSTOMS UNION

TR CU 027/2012 ON THE SAFETY OF CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS, INCLUDING DIETARY THERAPEUTIC AND DIETARY PREVENTIVE NUTRITION

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Chapter 1. GENERAL PROVISIONS

FOREWORD

1. This Customs Union Technical Regulation “On the Safety of Certain Types of Specialized Food Products, Including Dietary Therapeutic and Dietary Preventive Nutrition” (hereinafter referred to as the Technical Regulation) was developed in accordance with the Agreement on Common Principles and Rules of Technical Regulation in the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation dated 18 November 2010.
2. This Technical Regulation was developed for the purpose of establishing, within the single customs territory of the Customs Union, uniform mandatory requirements for application and compliance to certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, and ensuring the free movement of products placed on the market within the single customs territory of the Customs Union.
3. If other Customs Union Technical Regulations establishing requirements for certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, are adopted, such certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall comply with the requirements of all Customs Union Technical Regulations applicable to them.

Article 1

SCOPE OF APPLICATION

1. This Technical Regulation establishes:
 - 1) objects of technical regulation;
 - 2) safety requirements (including sanitary and epidemiological and hygienic requirements) for objects of technical regulation;
 - 3) identification rules for objects of technical regulation;
 - 4) forms and rules for conformity assessment of objects of technical regulation against the requirements of this Technical Regulation.
2. The purposes of adopting this Technical Regulation are:
protection of human life and/or health;
prevention of actions that mislead purchasers (consumers).
3. When applying this Technical Regulation, the requirements for food products concerning their marking, materials in contact with food products, including packaging, and the food raw materials used, established by the relevant Customs Union Technical Regulations, shall be taken into account.
4. When applying this Technical Regulation, the requirements of the Customs Union Technical Regulations establishing mandatory requirements for food products and certain types thereof shall be taken into account.

Article 2

OBJECTS OF TECHNICAL REGULATION

1. The objects of technical regulation under this Technical Regulation are specialized food products placed on the market and in circulation within the single customs territory of the Member States of the Customs Union:
specialized food products for sports nutrition and for pregnant and breastfeeding women;
food products for dietary therapeutic and dietary preventive nutrition,

including food products for infants and children.

2. The requirements of this Technical Regulation do not apply to:
food products for infants and children, except for food products for dietary therapeutic and dietary preventive nutrition for infants and children;
food products manufactured by catering establishments (public catering establishments, organized groups);
natural mineral water, medicinal table water, medicinal mineral water with a mineral content exceeding 1 mg/dm³ or, at a lower mineral content, containing biologically active components in quantities not lower than the balneological standards;
food supplements.

Article 3

IDENTIFICATION RULES

1. For the purposes of classifying certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, as objects of technical regulation to which this Technical Regulation applies, interested parties shall carry out identification of the food products.

2. Identification of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall be carried out in accordance with the procedure established by the Customs Union Technical Regulation “On the Safety of Food Products”.

Article 4

DEFINITIONS

This Technical Regulation uses the definitions established by the Customs Union Technical Regulation “On the Safety of Food Products”, as well as the following terms and definitions:

1) food products for dietary therapeutic nutrition – specialized food products with specified nutritional and energy value and physical and

organoleptic properties, intended for use as part of therapeutic diets;

2) food products for dietary preventive nutrition – specialized food products intended to correct carbohydrate, fat, protein, vitamin and other types of metabolism, in which the content and/or ratio of certain substances has been changed relative to their natural content, and/or which contain substances or components not originally present, as well as food products intended to reduce the risk of disease development;

3) food products for sports nutrition – specialized food products of a specified chemical composition, increased nutritional value and/or targeted effectiveness, consisting of a complex of products or represented by individual types thereof, which have a specific effect on increasing the human body's adaptive capacity to physical and neuro-emotional loads;

4) food products for pregnant and breastfeeding women – specialized food products in which the content and/or ratio of certain substances has been changed relative to their natural content, and/or which contain substances or components not originally present, intended to satisfy the physiological needs of the body of a pregnant or breastfeeding woman;

5) food products for enteral nutrition – liquid or dry food products for dietary therapeutic or dietary preventive nutrition (reconstituted to a ready-to-use form), intended for oral consumption directly or administration through a tube when it is impossible to provide the body with nutrients and energy by conventional means;

6) food products for diabetic nutrition – food products for dietary therapeutic or dietary preventive nutrition in which easily digestible carbohydrates (monosaccharides – glucose, fructose, galactose, and disaccharides – sucrose, lactose) are absent or present in reduced amounts relative to their content in similar food products and/or whose carbohydrate composition has been changed;

7) anti-reflux formulas – formulas containing a thickener (thickeners) and intended to prevent regurgitation of food in infants;

8) formulas for preterm and/or low-birth-weight infants – food products for

infants and children produced on the basis of cow's milk or the milk of other productive animals and/or milk-processing products and intended to satisfy the physiological needs of preterm and/or low-birth-weight infants;

9) low-lactose (lactose-free) food products – food products for dietary therapeutic or dietary preventive nutrition produced on the basis of cow's milk or the milk of other productive animals and/or milk-processing products, in which the lactose content is reduced compared with similar food products;

10) food products free from specific amino acids (or with a low content thereof) – food products for dietary therapeutic or dietary preventive nutrition obtained on the basis of protein hydrolysates free from specific amino acids (or with a low content thereof) and/or from a mixture of amino acids free from phenylalanine, and/or using components with a reduced phenylalanine content.

Article 5

RULES FOR PLACING ON THE MARKET

1. Specialized food products, including dietary therapeutic and dietary preventive nutrition, specified in Clause 1 of Article 2 of this Technical Regulation, shall be placed on the market if they comply with this Technical Regulation and with other Customs Union Technical Regulations applicable to them.

2. Specialized food products, including dietary therapeutic and dietary preventive nutrition, specified in Clause 1 of Article 2 of this Technical Regulation, which comply with the requirements of this Technical Regulation and other Customs Union Technical Regulations applicable to them and have undergone conformity assessment (confirmation), shall bear the single mark of product circulation on the market of the Member States of the Customs Union.

Chapter 2

SAFETY REQUIREMENTS FOR FOOD PRODUCTS

Article 6

SAFETY REQUIREMENTS FOR CERTAIN TYPES OF SPECIALIZED

FOOD PRODUCTS, INCLUDING DIETARY THERAPEUTIC AND DIETARY PREVENTIVE NUTRITION

1. Food raw materials and Food Additives used in the production of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall comply with the safety requirements established by the Technical Regulation of the Customs Union "On Safety of Food Products".

In the production of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, it is permitted to use Food Additives that comply with the requirements of this Technical Regulation and of the Technical Regulation of the Customs Union "Safety Requirements for Food Additives, Flavourings and Processing Aids".

2. Food products for dietary therapeutic and dietary preventive nutrition shall meet the physiological needs of the human body for essential nutrients and energy, taking into account the risk factors and pathogenesis of diseases. They shall comply with the established hygienic requirements for the permissible content of contaminants, biologically active substances and compounds, microorganisms and other biological organisms that pose a danger to the health of present and future generations.

3. The following is not permitted:

1) the use of poultry meat, except chilled poultry meat, as well as mechanically deboned poultry meat and collagen-containing raw materials from poultry meat, for the production of food products for dietary

therapeutic and dietary preventive nutrition and of food products for pregnant and breastfeeding women;

2) the use of food raw materials containing GMOs and (or) components derived from GMOs for the production of food products for pregnant and breastfeeding women and of food products for dietary therapeutic and dietary preventive nutrition intended for infants and children.

4. Food products for pregnant and breastfeeding women shall comply with the requirements established in Annexes 1 and 2 to this Technical Regulation.

5. Certain types of products for children's dietary therapeutic and children's dietary preventive nutrition for young children shall comply with the requirements established in Annex 3 to this Technical Regulation.

6. The composition of salt substitutes shall comply with the requirements established in Annex 2 to this Technical Regulation.

The sodium content of salt substitutes shall not exceed 120 mg/100 g of the weight of the salt substitute mixture.

7. The addition of iodine-containing compounds to salt and salt substitutes shall comply with the national legislation of the Member State of the Customs Union in which the products are sold.

8. Certain types of specialized food products, including products for sports nutrition, shall not contain psychotropic substances, narcotic drugs, poisonous or potent substances, doping agents and/or their metabolites, or other prohibited substances included in the WADA list (World Anti-Doping Agency).

9. Certain types of gluten-free specialized food products shall consist of, or be made from, one or more ingredients that do not contain wheat, rye, barley, oats or their crossbred varieties (obtained by crossing them), and (or) shall consist of, or be specially processed (to reduce the gluten level) from, one or more ingredients obtained from wheat, rye, barley, oats or their crossbred varieties, in which the gluten level in the ready-to-eat product does not exceed 20 mg/kg.

10. Certain types of specialized food products with a low gluten content shall consist of, or be specially processed (to reduce the gluten level) from, one or more ingredients obtained from wheat, rye, barley, oats or their crossbred varieties, in which the gluten level in the ready-to-eat product is more than 20 mg/kg but not more than 100 mg/kg.

Chapter 3. LABELLING OF FOOD PRODUCTS

Article 7

REQUIREMENTS FOR PACKAGING AND LABELLING OF CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS, INCLUDING DIETARY THERAPEUTIC AND DIETARY PREVENTIVE NUTRITION

1. The packaging and labelling of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall comply with the requirements of the Technical Regulations of the Customs Union "Food Products in Terms of Their Labelling" and "On Safety of Packaging".
2. Certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall be portioned and packaged in a manner that ensures their safety and the consumer properties declared in the labelling throughout the shelf life, provided that the conditions of their transportation and storage are observed.
3. Materials and articles used for packaging certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall comply with the safety requirements for materials and articles in contact with food products established by the relevant Technical Regulation of the Customs Union.
4. Perishable food products for dietary therapeutic and dietary preventive nutrition shall be released only in pre-packaged form, in small single-

serving packages.

5. The labelling of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, shall contain information on the intended purpose of the products in accordance with the definitions established in Article 4 of this Technical Regulation, the category of persons for whom they are intended and (or) information on changes in the composition of such products, and recommendations for their use.

6. Instructions for storing food products for dietary therapeutic and dietary preventive nutrition after opening the package shall be given in the labelling if this is necessary to preserve the full properties and nutritional value of the products. If the products cannot be stored after opening the package, or cannot be stored in the package after opening, an appropriate warning shall be provided.

7. In addition to all labelling indications relating to low-sodium dietary products (except salt substitutes as such), the following special labelling indications shall be complied with:

- 1) where salt substitutes are present, the presence of the salt substitutes listed in Annex 4 to this Technical Regulation shall be indicated;
- 2) where a salt substitute consisting wholly or partly of a potassium salt is added, the total potassium content, expressed in milligrams of cation per 100 grams of product, shall be indicated in the labelling.

8. Salt substitutes shall be designated as "low-sodium salt substitute" or "low-sodium dietary salt". The labelling of salt substitutes shall contain a complete list of ingredients, as well as the content of cations (sodium, potassium, calcium, magnesium, ammonium and choline) per 100 grams of the weight of the substitute mixture.

9. The labelling of food products for sports nutrition shall include the following additional information:

- for products with a specified nutritional and energy value and targeted effectiveness, consisting of a set of nutrients or represented by individual

types of nutrients, the following information shall be indicated:

"specialized food product for sports nutrition";

- the following information shall additionally be placed on the consumer packaging: information on the nutritional and energy value of the product and the proportion of the physiological requirement; recommended dosages, methods of preparation (where necessary), and conditions and duration of use.

Chapter 4. REQUIREMENTS FOR THE PROCESSES OF PRODUCTION (MANUFACTURE), STORAGE, CARRIAGE (TRANSPORTATION), SALE AND DISPOSAL OF CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS, INCLUDING DIETARY THERAPEUTIC AND DIETARY PREVENTIVE NUTRITION

Article 8 SAFETY REQUIREMENTS FOR THE PROCESSES OF PRODUCTION, STORAGE, CARRIAGE (TRANSPORTATION), SALE AND DISPOSAL OF CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS, INCLUDING DIETARY THERAPEUTIC AND DIETARY PREVENTIVE NUTRITION

1. The processes of production (manufacture), storage, carriage, sale and disposal of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, that ensure their safety shall comply with the requirements established by this Technical Regulation and by the Technical Regulation of the Customs Union "On Safety of Food Products".

2. All free-flowing ingredients shall be passed through magnetic separators before use.
3. Separate premises shall be allocated for work with live microorganisms.

Chapter 5. CONFORMITY ASSESSMENT (CONFIRMATION)

Article 9

ENSURING COMPLIANCE WITH SAFETY REQUIREMENTS

1. The conformity of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, with this Technical Regulation is ensured by fulfilling its safety requirements.
2. The methods for research (testing) and measurement of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, are established in the standards included in the List of standards containing rules and methods for research (testing) and measurement, including sampling rules, necessary for the application and fulfilment of the requirements of this Technical Regulation and for the conformity assessment (confirmation) of products.

Article 10

CONFORMITY ASSESSMENT

1. The conformity assessment of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, for compliance with the requirements of this Technical Regulation is carried out in the form of State Registration in accordance with the procedure established by the Technical Regulation of the Customs Union "On Safety of Food Products".
2. For the State Registration of products for dietary therapeutic and dietary preventive nutrition, a document (documents) confirming the declared therapeutic and (or) preventive properties shall be submitted.

3. The conformity assessment of the processes of production, storage, sale, carriage and disposal of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition, is carried out in the form of state supervision (control) of compliance with the requirements for food products established by this Technical Regulation and by other Technical Regulations in the field of food product safety.

Article 11

MARKING WITH THE SINGLE MARK OF PRODUCT CIRCULATION ON THE MARKET OF THE MEMBER STATES OF THE CUSTOMS UNION

1. Certain types of specialized food products, including dietary therapeutic nutrition and dietary preventive nutrition, that comply with the safety requirements of this Technical Regulation and have undergone the conformity assessment procedure must be marked with the single mark of product circulation on the market of the Member States of the Customs Union.

2. Marking with the single mark of product circulation on the market of the Member States of the Customs Union is performed before certain types of specialized food products, including dietary therapeutic nutrition and dietary preventive nutrition, are placed on the market.

3. The single mark of product circulation on the market of the Member States of the Customs Union is applied to each unit of product (consumer container and/or tag and/or label) and/or to the shipping documentation. The single mark of product circulation on the market of the Member States of the Customs Union is applied by any method that ensures a clear and legible image throughout the entire shelf life of the product.

Chapter 6. SAFEGUARD CLAUSE

Article 12

SAFEGUARD CLAUSE

1. The Member States of the Customs Union shall take measures to prevent the placing on the market within the single customs territory of the Customs Union of certain types of specialized food products, including dietary therapeutic nutrition and dietary preventive nutrition, that do not comply with the requirements of this Technical Regulation, and to withdraw such products from circulation.
2. The authorized body of a Member State of the Customs Union shall notify the Eurasian Economic Commission and the authorized bodies of the other Member States of the Customs Union of the decision taken. The notification shall state the reasons for the decision and provide evidence explaining the need for this measure.
3. The following cases may constitute grounds for applying this Article: non-compliance with the requirements of this Technical Regulation; incorrect application of standards interrelated with this Technical Regulation, if these standards were applied.

Annex 1

to the Technical Regulation of the Customs Union

“On the Safety of Certain Types

of Specialized Food Products,

Including Dietary Therapeutic and Dietary

Preventive Nutrition”

Microbiological safety standards (opportunistic pathogens)

In certain types of specialized food products manufactured using technological and/or probiotic microflora, the content and species composition of lactic acid and probiotic microorganisms are regulated -

Table 1.

In certain types of specialized non-preserved food products that are processed before sale, the following are regulated: opportunistic pathogens, sanitary indicator microorganisms and spoilage microorganisms. These characterize the safety, the sanitary and hygienic condition of production and the storage stability of the products - Table 2.

Compliance with these indicators is assessed at the circulation stage of certain types of specialized food products throughout their entire shelf life.

Table 1

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

Indicators	Permissible levels	Product groups
Bifidobacteria and/or other probiotic microorganisms (genera Lactobacillus, Propionibacterium)	1×10^6	Milk-based products and products based on soy protein isolate: liquid fermented milk products and products on a fermented soy basis for pregnant and breastfeeding women

Table 2

Requirements for opportunistic pathogens and sanitary indicator

microorganisms in food products

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

Indicators	Permissible levels	Product groups
Number of mesophilic aerobic and facultative anaerobic microorganisms, CFU/g	1×10^3	Meat (all animal species): chilled – for dietary therapeutic and dietary preventive nutrition products
Coliform group bacteria (coliforms) not permitted in product mass, g	0,1	Meat (all animal species): chilled – for dietary therapeutic and dietary preventive nutrition products
Bacteria of the genus <i>Proteus</i> , not permitted in product mass, g	1,0	Meat (all animal species): chilled - for dietary therapeutic and dietary preventive nutrition products

2.2. Other products

Indicators	Permissible levels	Product groups
Number of mesophilic aerobic and facultative anaerobic microorganisms, CFU/g, not more than	5×10^2	Pectin for dietary nutrition products
	5×10^3	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology)
	1×10^4	Edible gelatin for dietary nutrition products
Coliform group bacteria (coliforms) not permitted in product mass, g	0,1	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology)

1,0	Pectin for dietary nutrition products; Edible gelatin for dietary nutrition products	
S.aureus, not permitted in product mass, g	1	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology)
B.sereus, CFU/g, not more than	10	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology)

Yeasts, CFU/g, not more than	10	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology)
	50	Pectin (for dietary nutrition products)
Moulds, CFU/g, not more than	50	Pectin (for dietary nutrition products)
	100	Dry products for dietary preventive nutrition - cereal, milk and meat mixtures (extrusion technology).

2.3. Products for the Nutrition of Pregnant and Breastfeeding Women

Indicators	Permissible levels	Product groups
Count of mesophilic aerobic and facultatively anaerobic microorganisms, CFU/g	5×10^3	Herbal instant teas (plant-based)
	$2,5 \times 10^4$	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product)
	5×10^4	Porridges based on milk and cereals (for instant preparation)

Coliform bacteria (coliforms) are not permitted in a product mass of, g	3,0 g	Milk-based products and soy protein isolate-based products: liquid fermented milk products and products based on fermented soy
	1,0 g	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product); herbal instant teas
	0,1 g	Porridges based on milk and cereals (for instant preparation)

E.coli are not permitted in a product mass of, g	10 g	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product)
S.aureus are not permitted in a product mass of, g	10 g	Milk-based products and soy protein isolate-based products: liquid fermented milk products and products based on fermented soy
	1,0 g	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product)

Moulds, CFU/g, not more than	10	Milk-based products and soy protein isolate-based products: liquid fermented milk products and products based on fermented soy
	50	Herbal instant teas
	100	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product)
	200	Porridges based on milk and cereals (for instant preparation)

Yeasts, CFU/g, not more than	10	Milk-based products and soy protein isolate-based products: liquid fermented milk products and products based on fermented soy
	50	Milk-based products and soy protein isolate-based products dry products for instant preparation (in the ready-to-eat product); herbal instant teas (plant-based)
	100	Porridges based on milk and cereals (for instant preparation)

B.cereus are not permitted in a product volume of, cm ³	1,0	Milk-based products and soy protein isolate-based products: liquid products, fermented milk products and products based on fermented soy
B.cereus, CFU/g, not more than	Not permitted in 1,0 g	Milk-based products and soy protein isolate-based products: liquid fermented milk products and products based on fermented soy
	100	Herbal instant teas (plant-based)

2x102	Milk-based products and soy protein isolate-based products: dry products for instant preparation (in the ready-to-eat product)
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2.4. Specialized products for therapeutic nutrition of children, for preterm and (or) low-birth-weight infants

Count of mesophilic aerobic and facultative anaerobic microorganisms, CFU/g	1x10 ²	Sterilized adapted milk formulas, sterilized milk and cream, non-aseptically filled, calcium-enriched cottage cheese, produced at dairy kitchens
	2x10 ²	Pasteurized meat-based sausages
	5x10 ²	Reconstituted pasteurized formulas, produced at dairy kitchens.

2x10 ³	Products based on soy protein isolate. Products based on full or partial protein hydrolysates; products free from phenylalanine or with a low phenylalanine content; products for preterm and (or) low-birth-weight infants, reconstituted at 37-50° C
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3x10 ³	Low-protein products (starches, cereals and pasta and other products), products for preterm and (or) low-birth-weight infants, reconstituted at 70-85° C
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1x104	Freeze-dried meat-based products for children under 2 years.
1,5x104	Freeze-dried meat-based products for children over 2 years

2,5x104	Low-lactose and lactose-free products, dry dairy high-protein products
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Coliform bacteria (coliforms are not permitted in the product mass, g)	1,0	Low-lactose and lactose-free products. Products based on soy protein isolate. Low-protein products (starches, cereals and pasta and other products). Products based on full or partial protein hydrolysates. Products free from phenylalanine or with a low phenylalanine content. Freeze-dried products based on meat. Products for preterm and (or) low-birth-weight infants
	0,3	Dry dairy high-protein products. Freeze-dried products based on milk (cottage cheese, etc.)
E.coli are not permitted in the product mass, g	10	Products for preterm and (or) low-birth-weight infants

S.aureus are not permitted in the product mass, g	10	Products for preterm and (or) low-birth-weight infants
	1,0	Low-lactose and lactose-free products. Dry dairy high-protein products. Products based on soy protein isolate. Products based on full or partial protein hydrolysates. Products free from phenylalanine or with a low phenylalanine content. Freeze-dried products based on meat and milk (cottage cheese, etc.)
	0,1	Low-protein products (starches, cereals and pasta and other products)
Sulphite-reducing clostridia are not permitted in the product mass, g	0,1	Freeze-dried products based on meat

Moulds, CFU/g	10	Low-protein products (starches, cereals and pasta).
	50	Products based on soy protein isolate. Freeze-dried meat-based products for children under 2 years. Products for preterm and (or) low-birth-weight infants. Products based on full or partial protein hydrolysates. Products free from phenylalanine or with a low phenylalanine content. Low-protein products (except starches, cereals and pasta)
	100	Low-lactose and lactose-free products. Dry dairy high-protein products. Freeze-dried meat-based products for children over 2 years. Freeze-dried milk-based products (cottage cheese, etc.)
Yeasts, CFU/g	10	Products based on soy protein isolate. Products for preterm and (or) low-birth-weight infants. Products based on full or partial protein hydrolysates. Products free from phenylalanine or with a low phenylalanine content.

50

Low-lactose and lactose-free products. Dry dairy high-protein products. Low-protein products (starches, cereals and pasta and other products). Freeze-dried products based on meat and milk (cottage cheese, etc.). Freeze-dried products

100	Freeze-dried meat-based products for children over 2 years	
B.cereus, CFU/g	100	Products based on soy protein isolate. Low-protein products (starches, cereals and pasta and other products). Products based on full or partial protein hydrolysates. Products free from phenylalanine or with a low phenylalanine content. Freeze-dried meat-based products for children under 2 years. Products for preterm and (or) low-birth-weight infants
	2×10^2	Low-lactose and lactose-free products. Freeze-dried meat-based products for children over 2 years

Annex 2
to the Technical Regulation of the Customs Union
“On the Safety of Certain Types
of Specialized Food Products,

Including Dietary Therapeutic and Dietary
Preventive Nutrition”

Composition of Salt Substitutes

Composition of salt substitutes	Conditions of use
1	2
a) potassium sulphate; potassium, calcium and ammonium salts of adipic, glutamic, carbonic, succinic, lactic, tartaric, citric, acetic, hydrochloric and orthophosphoric acids	Not limited; however, the content of phosphorus in the mixture of substitutes shall not exceed 4%, and that of NH_4^+ shall not exceed 3% of the total mass of the substitutes.
b) magnesium salts of adipic, glutamic, carbonic, citric, succinic, acetic, tartaric, lactic, hydrochloric and orthophosphoric acids, in a mixture with other substitutes that do not contain magnesium	The content of Mg^{++} shall not exceed 20% by mass of the total content of the cations K^+ , Ca^{++} , NH_4^+ , present in the mixture of substitutes, and the content of P shall not exceed 4% of the total mass of the substitutes.

c) choline salts of acetic, carbonic, lactic, tartaric, citric and hydrochloric acids, in a mixture with other substitutes that do not contain choline,	The content of choline shall not exceed 3% of the mass of the mixture of substitutes
d) free adipic, glutamic, citric, lactic and malonic acids	

Salt substitutes may also contain:

- 1) colloidal silicon dioxide or calcium silicate, not more than 1% of the mass of the mixture of substitutes, individually or in combination;
- 2) fillers: safe and suitable food products for general consumption (for example, sugar, cereal flour).

Annex 3

to the Technical Regulation of the Customs Union

"On safety of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition"

Requirements for the nutritional value of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition for young children

Product name	Nutritional value indicators per 100 g of product ready for consumption	Units of measurement	Permissible levels	Notes
Low-lactose (lactose-free) food products	LOW-LACTOSE AND LACTOSE-FREE PRODUCTS FOR INFANTS IN THE 1ST YEAR OF LIFE			
	Protein	g/l	12-21	
	Taurine	mg/l, max.	80	
	L-carnitine	Same	20 (if added)	
	Fat	g/l	30-40	
	Linoleic acid	% of total fatty acids	14-20	

mg/l, max.	4000-8000		
Carbohydrates	g/l	65-80	
Lactose	g/l, max.	10	In low-lactose products
	same	0,1	In lactose-free products
Minerals:			
calcium	mg/l	330-700	
phosphorus	Same	150-400	
potassium	Same	400-800	
sodium	Same	150 - 300	
magnesium	Same	30-90	
copper	Same	0,3-1,0	
manganese	µg/l	10-300	

iron	mg/l	3-14	
zinc	Same	3-10	
chlorides	Same	400-800	
iodine	µg/l	50-150	
ash	g/l	3-5	
Vitamins:			
retinol (A)	µg-eq/l	400-1000	
tocopherol (E)	mg/l	4-12	
calciferol (D)	µg/l	7,5-12,5	
vitamin K	Same	25-60	
thiamine (B1)	Same	400-1000	
riboflavin (B2)	Same	500-1500	
pyridoxine (B6)	Same	300-1000	

Pantothenic acid	Same	2700-5000		
folic acid (Bc)	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	Same	50-150		
Low-lactose (lactose-free) food products	Osmolality	mOsm/kg, max.	300	
	LOW-LACTOSE PROCESSED MILK PRODUCTS FOR YOUNG CHILDREN			

Protein	g/l	40-47	
Casein/ whey proteins	-	80:20	
Fat	g/l	20-38	
Linoleic acid	% of total fatty acids, min.	15	
	mg/l	5000-6000	
Carbohydrates	g/l	60-65	
Glucose	Same	25-28	
Galactose	Same	6-7	
Lactose	g/l, max.	16	
Energy value	kcal/l	600-680	

Soy protein isolate-based formulas for young children	Protein	g/l	15-20	
	Methionine	same	0,25-0,35	
	Fat	g/l	30-38	
	Linoleic acid	% of total fatty acids, min.	14	
		mg/l, min.	4000	
	Carbohydrates (dextrin-maltose)	g/l	65-80	
	Energy value	kcal/l	650-720	
	Minerals:			
	calcium	mg/l	450-750	
	phosphorus	Same	250-500	
	potassium	Same	500-800	

sodium	Same	200-320	
magnesium	Same	40-80	
copper	Same	0,4-1,0	
iron	mg/l	6-14	
zinc	Same	4-10	
ash	g/l	3-5	
Vitamins:			
retinol (A)	µg-eq/l	500-800	
tocopherol (E)	mg/l	5-15	
calciferol (D)	µg/l	8-12	
vitamin K	Same	25-100	
thiamine (B1)	Same	300-600	
riboflavin (B2)	Same	600-1000	

pyridoxine (B6)	Same	300-700		
folic acid (Bc)	Same	60-150		
cyanocobalamin (B12)	µg/l	1,5-3,0		
niacin (PP)	mg/l	4-8		
Ascorbic acid (C)	mg/l	60-150		
Taurine	mg/l	45-55		
L-carnitine	Same	10-20		
Osmolality	mOsm/kg, max.	300		
Formulas based on complete protein hydrolysates for young children	Protein (equiv.)	g/l	12-22	
	Taurine	mg/l	40-55	
	L-carnitine	Same	10-25	
	Fat	g/l	25-35	

Linoleic acid	% of total fatty acids, min.	14	
	mg/l, min.	4000	
Carbohydrates	g/l	70-95	
Energy value	kcal/l	650-720	
Minerals:			
calcium	mg/l	330-980	
phosphorus	Same	150-600	
potassium	Same	400-1000	
sodium	Same	150-350	
magnesium	Same	50-100	
copper	Same	0,3-1,0	

iron	mg/l	6-14	
zinc	Same	3-10	
ash	g/l	4-5	
Vitamins:			
retinol (A)	µg-eq/l	500-800	
tocopherol (E)	mg/l	6-14	
calciferol (D)	µg/l	5-15	
thiamine (B1)	Same	400-600	
riboflavin (B2)	Same	600-1000	
pyridoxine (B6)	Same	500-700	
folic acid (Bc)	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 than	320		
Phenylalanine-free formulas (low-phenylalanine formulas) for infants in the first year of life	Protein (equiv.)	g/l	16-20	
	Phenylalanine	mg/l, not more than	500	In products based on an amino acid mixture - absent
	Taurine	mg/l	40-55	
	L-carnitine	Same	10-25	
	Fat	g/l	30-38	

Linoleic acid	% of total fatty acids, not less than	14	
	mg/l, not less than	5000	
Carbohydrates	g/l	65-80	
Energy value	kcal/l	570-720	
Minerals:			
calcium	mg/l	300-700	
phosphorus	Same	300-500	
potassium	Same	500-800	
sodium	Same	150-300	
magnesium	Same	40-60	
copper	Same	0,3-1,0	

iron	mg/l	3-14	
zinc	Same	4-10	
ash	g/l	4-5	
iodine	µg/l	50-120	
Vitamins:			
retinol (A)	µg-eq/l	500-800	
tocopherol (E)	mg/l	4-12	
calciferol (D)	µg/l	8-12	
thiamine (B1)	Same	350-700	
riboflavin (B2)	Same	500-1000	
pyridoxine (B6)	Same	300-700	
folic acid (Bc)	Same	50-100	
cyanocobalamin (B12)	µg/l	1,5-3,0	

niacin (PP)	mg/l	3-8		
Ascorbic acid (C)	mg/l	20-100		
Osmolality	mOsm/kg, not more than	320		
Formulas for preterm and (or) low-birth-weight infants	Protein	g/l	19 - 31	
	Taurine	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	

Eicosapentaenoic acid	%	Not more than 30 of the level of docosahexaenoic acid	
Carbohydrates	g/l	72 - 94	
Energy value	kcal/l	660 - 890	
Minerals:			
calcium	mg/l	800 - 1400	
phosphorus	Same	400 - 700	
potassium	Same	450 - 1200	
sodium	Same	300 - 800	
magnesium	Same	50 - 130	
copper	Same	0,6 - 1,6	
iron	mg/l	13 - 20	

zinc	Same	7 - 13	
chlorides	Same	400 - 1200	
manganese	µg/l	45 - 200	
iodine	Same	75 - 325	
selenium	Same	13 - 70	
Vitamins:			
retinol (A)	µg-eq/l	1500 - 3000	
tocopherol(E)	mg/l	15 - 60	
calciferol (D)	µg/l	15 - 60	
Vitamin K	Same	30 - 200	
thiamine (B1)	Same	750 - 2000	
riboflavin (B2)	Same	600 - 4000	
pantothenic acid	mg/l	2,3 - 14,0	

pyridoxine (B6)	Same	200 - 2000	
folic acid (Bc)	Same	225 - 600	
cyanocobalamin (B12)	µg/l	0,6 - 5,3	
niacin(PP)	mg/l	2,5 - 38	
ascorbic acid (C)	mg/l	60 - 300	
inositol	Same	30 - 350	
biotin	µg/l	10 - 300	
choline	mg/l	50 - 350	
L-carnitine	mg/l	15 - 45 (if added)	

Formulas for preterm and (or) low-birth-weight infants	nucleotides	mg/l	Not more than 35 (if added)	
	Osmolality	mOsm/kg, not more than	310	

Laboratory control of casein is carried out where a control method approved in accordance with the established procedure is available.

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