

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary Public

Date: 6/26/2013

GAIN Report Number: RS1340

Russian Federation

Post: Moscow

Customs Union Technical Regulation on Specialized Foods

Report Categories:

Trade Policy Monitoring

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Approved By:

Christopher Riker

Prepared By:

Staff

Report Highlights:

The Technical Regulation of the Russia-Kazakhstan-Belarus Customs Union (CU) “On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food” (TR TS 027/2012) is a key CU regulation covering standards and requirements for specialized foods, e.g. foods for athletes, pregnant and nursing women, as well as therapeutic and preventive dietary foods. This Technical Regulation was adopted by Decision of the Council of the Eurasian Economic Commission No. 34 of June 15, 2012, and will come into effect as of July 1, 2013.

General Information

The Technical Regulation of the Russia-Kazakhstan-Belarus Customs Union (CU) “On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food” (TR TS 027/2012) is a key CU regulation covering standards and requirements for specialized foods, e.g. foods for athletes, pregnant and nursing women, as well as therapeutic and preventive dietary foods. This Technical Regulation was adopted by Decision of the Council of the Eurasian Economic Commission No. 34 of June 15, 2012, and will come into effect as of July 1, 2013.

Below is an unofficial translation of the following:

- Decision of the Council of the Eurasian Economic Commission No. 34 of June 15, 2012;
- CU Technical Regulation “On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food” (TR TS 027/2012) with 3 annexes;

BEGIN UNOFFICIAL TRANSLATION:

DECISION

June 15, 2012 **No. 34** St. Petersburg

On Adoption of the Technical Regulation of the Customs Union “On Safety of Certain Types of Specialized Food Products Including Therapeutic and Preventive Dietary Food”

In accordance with Article 3 of the Agreement of the Eurasian Economic Commission of 18 November 2011 the Council of the Eurasian Economic Commission **has resolved as follows:**

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

Members of the Council of the Eurasian Economic Commission:

From the Republic of Belarus	From the Republic of Kazakhstan	From the Russian Federation
S. Rumas	K. Kelimbetov	I. Shuvalov

END UNOFFICIAL TRANSLATION.

BEGIN UNOFFICIAL TRANSLATION:

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

**TECHNICAL REGULATION
OF THE CUSTOMS UNION**

TR TS 027/2012

**ON SAFETY OF CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS
INCLUDING THERAPEUTIC AND PREVENTIVE DIETARY FOOD**

Table of Contents

Foreword	4
Article 1 Scope	4
Article 2 Subjects of Technical Regulation	4
Article 3 Identification Rules	4
Article 4 Definitions	5
Article 5 Rules of Circulation on the Market	8
Article 6 Safety Requirements for Certain Types of Specialized Food Products, Including Therapeutic and Preventive Dietary Food	8
Article 7 Requirements for Packaging and Marking of Certain Types of Specialized Food Products, Including Therapeutic and Preventive Dietary Food	13
Article 8 Requirements for Processes of Production (Manufacturing), Storage, Shipment (Transport), Sales, and Disposal of Certain Types of Specialized Food Products, Including Therapeutic and Preventive Dietary Food	12
Article 9 Ensuring Compliance with Safety Requirements	14
Article 10 Assessment of conformity	14
Article 11 Marking by the Unified Mark of Products Circulation on the Market of the Customs Union Member-States	15
Article 12 Safeguard Clause	15
Annex 1	16
Annex 2	17
Annex 3	31

Chapter 1. GENERAL PROVISIONS

FOREWORD

1. The present Technical Regulation of the Customs Union on Safety of Certain Types of Specialized Food Products, Including Therapeutic and Preventive Dietary Food (hereinafter 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 certain types of food products, including the therapeutic and preventive dietary 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 certain types of specializes food products, including therapeutic and preventive dietary food that establish requirements for such products then the certain types of specialized 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

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 certain 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:

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

food products of therapeutic and preventive dietary food, 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 dietary food 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 certain types of specialized food products, including the therapeutic and preventive dietary food shall be carried out according to the procedure established by the Technical Regulation of the Customs Union "On Food Safety."

Article 4. DEFINITIONS

The present Technical Regulation uses the definitions established by the Technical Regulation of the Customs Union "On Food Safety" 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 nutrition - the liquid or dry (restored to the ready-to-use condition) food products of therapeutic or preventive dietary food 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 nutrition - the food products of therapeutic or preventive dietary food that do not contain or have a reduced content of the easily digested carbohydrates (monosaccharides - glucose, fructose, galactose, and of disaccharides - sucrose, 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 dietary food 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 food 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 food 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 Regulation, as well as other applicable technical regulations of the Customs Union.

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

Chapter 2. SAFETY REQUIREMENTS FOR FOOD PRODUCTS

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

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

While producing certain types of the specialized food products, including therapeutic and preventive dietary food 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, Flavorings and Technological Aids.”

2. The food products of therapeutic and preventive dietary food 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 chiseling and poultry meat raw materials containing collagen for production of therapeutic and preventive dietary food, 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 dietary 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 Annexes 1 and 2 to the present Technical Regulation.

5. Certain types of the therapeutic children nourishment products and preventive children nourishment products for young children must meet the requirements set in Annex 3 to the present Technical Regulation.

6. The composition of the salt substitutes must meet the requirements set in Annex 2 to 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. Certain 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. Certain 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 PACKAGING AND MARKING OF CERTAIN TYPES OF SPECIALIZED PRODUCTS INCLUDING THE THERAPEUTIC AND PREVENTIVE DIETARY FOOD

1. The packaging and marking of certain types of specialized food products including the therapeutic and preventive dietary food must meet the requirements of the technical regulations of the Customs Union “Technical Regulation on Food Product Labeling” and “On Safety of Packaging.”

2. Certain types of specialized food products including the therapeutic and preventive dietary food must be prepackaged 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 certain types of specialized food products including the therapeutic and preventive dietary food 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 food must be released only in the prepackaged form in the small-piece packing for one-time consumption.

5. The marking of certain types of the specialized food products including the therapeutic and preventive dietary food 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 dietary food after dissection of the packing must be given on the marking, if this is necessary to guarantee the completeness of properties and nutrient value 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 dietary 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 Annex 4 to the present Technical Regulation 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 “dietary 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 certain 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 (MANUFACTURING), STORAGE, SHIPMENT (TRANSPORT), SALES AND DISPOSAL OF THE CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS INCLUDING THERAPEUTIC AND PREVENTIVE DIETARY FOOD

Article 8. SAFETY REQUIREMENTS FOR THE PROCESSES OF PRODUCTION (MANUFACTURING), STORAGE, SHIPMENT (TRANSPORT), SALES AND DISPOSAL OF THE CERTAIN TYPES OF SPECIALIZED FOOD PRODUCTS INCLUDING THERAPEUTIC AND PREVENTIVE DIETARY FOOD

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

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 (CONFIRMATION) OF CONFORMITY

Article 9. ENSURING CONFORMITY WITH SAFETY REQUIREMENTS

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

2. The methods of studies (tests) and measurements of certain types of specialized food products including the therapeutic and preventive dietary food 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. ASSESSMENT OF CONFORMITY

1. The assessment of conformity of certain types of specialized food products including the therapeutic and preventive dietary food 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 Food Safety.”

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

3. The assessment of correspondence of the processes of production, storage, sales, transportation, disposal of certain types of specialized food products, including the therapeutic and preventive dietary food 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 BY THE UNIFIED MARK OF PRODUCTS CIRCULATION ON THE MARKET OF THE CUSTOMS UNION MEMBER STATES

1. The certain types of specialized food products including the therapeutic and preventive dietary food that meet the safety requirements of the present Technical Regulation and have passed the procedure of conformity assessment must be marked with the unified mark of products circulation on the market of the Customs Union member states.

2. The marking with the unified mark of products circulation on the market of the Customs Union member states is accomplished prior to release of certain types of specialized food products including the therapeutic and preventive dietary food into circulation on the market.

3. The unified mark 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 unified mark 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 certain types of specialized food products including the therapeutic and preventive dietary food 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.

Annex 1
to the Technical Regulation of the Customs Union
“On Safety of Certain Types
of Specialized Food Products
Including 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 certain types of the specialized unpreserved food products subjected to processing before sale 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 certain types of specialized food products during the entire period of their validity.

Table 1

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

Indices	Tolerance levels	Product Groups
Bifidobacteria and/or other probiotic microorganisms (of genera Lactobacillus, Propionibacterium)	1×10^6	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**

Indices	Tolerance levels	Product Groups
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	1×10^3	Meat (all animals): cooled - for production of therapeutic and preventive dietary food
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 dietary food
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 dietary food

2.2. Other products

Indices	Tolerance levels	Product Groups
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g, not more than	5×10^2	Pectin for dietary food products
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g, not more than	5×10^3	Dry products for preventive dietary food - cereal, dairy, meat mixtures (extrusion technology)
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g, not more than	1×10^4	Alimentary gelatin for dietary food products
Bacteria of the group of coliform bacteria (coliforms) are not allowed in the mass of products, g	0.1	Dry products for preventive dietary food - cereal, dairy, meat mixtures (extrusion technology)
Bacteria of the group of coliform bacteria (coliforms) are not allowed in the mass of products, g	1.0	Pectin for dietary food products; Alimentary gelatin for dietary food products
S. aureus, not allowed in the mass of the products, g	1	Dry products for preventive dietary food- cereal, dairy, meat mixtures (extrusion technology)

Indices	Tolerance levels	Product Groups
B.sereus, CFU/g, not more than	10	Dry products for preventive dietary food - cereal, dairy, meat mixtures (extrusion technology)
Yeast, CFU/g, not more than	10	Dry products for preventive dietary food - cereal, dairy, meat mixtures (extrusion technology)
Yeast, CFU/g, not more than	50	Pectin (dietary food products)
Mould, CFU/g, not more than	50	Pectin (dietary food products)
Mould, CFU/g, not more than	100	Dry products for preventive dietary food - 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	5×10^3	Herbal instant tea (on the vegetative basis)
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	$2,5 \times 10^4$	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products)
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	5×10^4	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.
Bacteria of the group of coliform bacteria (coliforms) shall not be allowed in the mass of a product, g	1.0 g	Milk and soy protein isolate based products: dry instant cooking products (in ready-to-eat products); Herbal instant tea
Bacteria of the group of coliform bacteria (coliforms) shall not be allowed in the mass of a product, g	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

Indicators	Tolerance levels	Product Groups
		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.
S. aureus, not allowed in the mass of products, g	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 allowed	Products based on milk and the isolate of soybean protein: liquid products based on sour milk and the soured soybean basis
	100	Herbal instant tea (on the vegetative basis)
	2×10^2	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
------------	------------------	----------------

Indicators	Tolerance levels	Product Groups
Quantity of mesophilic aerobic and optionally anaerobic microorganisms, CFU/g	1x10 ²	Adapted sterilized milk mixtures, sterilized milk and cream of non-aseptic bottling, calcinated cottage cheese prepared at dairy kitchens
	2x10 ²	Pasteurized small sausages on the meat basis
	5x10 ²	Restored pasteurized mixtures prepared at dairy kitchens.
	2x10 ³	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 ³	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 ⁴	Sublimated products on the meat basis for the children of up to 2 years.
	1,5x10 ⁴	Sublimated products on the meat basis for the children of over 2 years.
	2,5x10 ⁴	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 hydrolyzates. 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.)
E. coli not allowed in the mass of products, g	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 hydrolyzates. 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.

Indicators	Tolerance levels	Product Groups
Moulds, CFU/g	10	Low-protein products (starches, cereals and paste products).
	50	Products 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 hydrolyzates. Products without or with low content of phenylalanine. Low-protein products (except for starches, cereals and paste products)
	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.)
Yeast, CFU/g	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 hydrolyzates. 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 hydrolyzates. 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 ²	Low-lactose and lactose-free products. Sublimated products on the meat basis for the children of over 2 years.

Annex 2
to the Technical Regulation of the Customs Union
“On Safety of Certain Types
of Specialized Food Products
Including Therapeutic and
Preventive Dietary Food

Composition of salt substitutes

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 ₄ + 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 ⁺ , Ca, NH ₄ 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).

Annex 3
to the Technical Regulation of the Customs Union
“On Safety of Certain Types
of Specialized Food Products
Including Therapeutic and
Preventive Dietary Food

Requirements for the nutrition value of certain types of specialized food products including of therapeutic and preventive dietary food 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
Low-lactose (lactose-free) food products	LOW-LACTOSE AND LACTOSE-FREE PRODUCTION FOR THE CHILDREN OF THE FIRST YEAR OF LIFE			
	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		

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	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	
	ash	g/l	3-5	
	Vitamins:			
	retinol (A)	µg - equiv/l	400-1000	
	tocopherol (E)	mg/l	4-12	
	calcipherol (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	
LOW-LACTOSE PRODUCTS OF MILK PROCESSING FOR THE CHILDREN OF THE TENDER				

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	AGE			
	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 isolate of soybean protein for the children of the tender age	Protein	g/l	15-20	
	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	

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	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	
	Mixtures on the basis of the full protein hydrolyzates for the children of tender age	Taurin	mg/l	45-55
L- carnitine		The same	10-20	
Osmolality		mOsm/kg, not more	300	
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:				

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes	
	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 (low-phenylalanine content) for children in the first year of life	Protein (equiv.)	g/l	16-20		
	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		

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	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	
	Ascorbic acid (C)	mg/l	20-100	
	Osmolality	mOsm/kg, not	320	

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes	
		more			
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			

Description of products	Indices of nutrition value in 100g of products, ready to use	Units of measurement	Tolerance levels	Notes
	calcipherol (D)	µg/l	15 - 60	
	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	
	cyanocobalamin (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.

END UNOFFICIAL TRANSLATION.