Russian Federation Federal Law No. 88-Φ3 of June 12, 2008 "Technical Regulations for Milk and Milk Products"

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Chapter 1. General Provisions

Article 1. Scope of the Present Federal Law

1. The present Federal Law prescribes:

1) the subjects of the technical regulation, which are listed and described herein;

2) the safety requirements of the subjects of the technical regulation;

3) the rules for identifying the subjects of the technical regulation for the purpose of applying the present Federal Law;

4) the rules and forms for assessing and certifying that the subjects of the technical regulation conform hereto;

5) the requirements as to the packaging and marking of milk and milk products, including requirements as to consumer information on name, ingredients and consumer attributes provided on the package and in accompanying documents.

2. The present Federal Law also prescribes the rights and responsibilities of the parties involved in the matters regulated hereunder.

Article 2. The Subjects of Technical Regulation Listed and Described Herein

1. The subjects of technical regulation which are listed and described herein are:

1) milk and milk products, including milk-based children's food products released for circulation in the Russian Federation;

2) the production, storage, transportation, sale and disposal of milk and milk products.

2. The list of milk and milk products which are the subjects of technical regulation hereunder include:

1) raw milk and raw cream;

2) fluid milk and fluid cream;

3) fluid fermented milk products;

4) curds and curd products;

5) sour cream and sour cream-based products;

6) cow's milk butter;

7) butter paste;

8) cream-vegetable spread and cream-vegetable rendered mixture;

9) cheese and cheese products;

10) canned milk and milk-containing canned goods;

11) ice cream and ice cream mixes;

12) functionally necessary components;

13) milk-based children's food products;

14) secondary products of milk processing.

Article 3. Objectives of the Present Federal Law

The objectives of the present Federal Law are:

1) to protect the life and health of citizens;

2) to prevent actions that mislead consumers, and to ensure the accuracy of information on the name, ingredients and consumer attributes of milk and milk products.

Article 4. Basic Concepts Used Herein

For the purposes of the present Federal Law, use is made of the basic concepts set forth in Article 2 of Federal Law No. 184- Φ 3 of December 27, 2002 "On Technical Regulation" (hereafter – Federal Law "On Technical Regulation") and Article 1 of Federal Law No. 29- Φ 3 "On the Quality and Safety of Food Products," as well as of the following basic concepts:

1) milk – a product of the normal physiological secretion of the mammary glands of livestock obtained from one or several animals during lactation in one or more milking operations, with no additions thereto or extractions of any substances therefrom;

2) milk products – milk processing products, including dairy products, dairy component products, milk-containing products, and milk processing byproducts;

3) dairy product – a food which is made from milk and (or) its constituents without the use of nondairy fat or protein and which may contain components that are functionally necessary for milk processing;

4) dairy component product – a food made from milk and (or) dairy products with or without the addition of milk processing byproducts or nondairy components that are added for purposes other than replacement of milk constituents. In addition, milk constituents in this end product should be more than 50 percent, and in ice cream and sweet products of milk processing they should be more than 40 percent;

5) milk-containing product – a food made from milk and (or) dairy products and (or) milk processing byproducts and nondairy components, including nondairy fat and (or) proteins, with a dry solids mass fraction of milk in the dry solids of the end product of at least 20 percent;

6) secondary dairy raw material – milk processing byproducts and dairy products with partially lost identifying characteristics or consumer attributes (including such products recalled before their expiration date but conforming to the safety requirements for food raw materials) which are intended for use after processing;

7) milk processing by product – an incidental product obtained during the production of milk processing products;

8) raw milk – milk that has not undergone heat treatment at a temperature above 40 degrees Celsius or processing that has changed its constituents;

9) whole milk – milk whose constituents have not been amended through regulation;

10) skim milk – milk with a fat mass fraction of less than 0.5 percent obtained by removing fat from the milk;

11) fluid milk – milk with a fat mass fraction of up to 9 percent made from raw milk and (or) dairy products and heat or otherwise treated to regulate its constituents (without the use of dry whole milk or dry skim milk);

12) baked milk – fluid milk heat treated at a temperature of 85 to 99 degrees Celsius for at least three hours until specific organoleptic properties are achieved;

13) pasteurized milk, sterilized milk, ultra-pasteurized (ultra-high temperature processed) milk – fluid milk that has been heat treated to conform to statutory microbiological safety requirements;

14) milk beverage - a dairy product made from concentrated or evaporated milk or either dry whole milk or dry skim milk and water;

15) enriched milk beverage – a dairy beverage into which have been introduced additionally, separately or in combination such substances as protein, vitamins, micro- and macroelements, dietary fibers, polyunsaturated fatty acids, phospholipids, probiotics and prebiotics;

16) concentrated or evaporated whole milk - a concentrated or evaporated dairy product in which the dry solids mass fraction of the milk is at least 25 percent, the protein mass fraction in the dry skim milk solids is at least 34 percent, and the fat mass fraction is at least 7 percent;

17) concentrated or evaporated skim milk – a concentrated or evaporated dairy product in which the dry solids mass fraction of the milk is at least 20 percent, the protein mass fraction in the dry skim milk solids is at least 34 percent, and the fat mass fraction does not exceed 1.5 percent;

18) condensed milk – a concentrated or evaporated dairy product with sugar in which the protein

mass fraction in the dry skim milk solids is at least 34 percent;

19) dry whole milk – a dry dairy product in which the dry solids mass fraction of the milk is at least 95 percent, the protein mass fraction in the dry skim milk solids is at least 34 percent, and the fat mass fraction is at least 20 percent;

20) dry skim milk – a dry dairy product in which the dry solids mass fraction of the milk is at least 95 percent, the protein mass fraction in the dry skim milk solids is at least 34 percent, and the fat mass fraction does not exceed 1.5 percent;

21) nondairy components – foodstuffs which are added to milk processing products (mushrooms; sausages and meat products; seafood; honey, vegetables, nuts, fruits; eggs; jams, preserves, chocolate, and other confectioneries; coffee, tea, liquor, rum; sugar, salt, spices; other foodstuffs; food additives; vitamins; micro- and macroelements; proteins, fats, nondairy carbohydrates);

22) cream - a dairy product which is made from milk and (or) dairy products and is an emulsion of fat and milk plasma in which the fat mass fraction is at least 9 percent;

23) raw cream – cream that has not been heat treated at a temperature of more than 45 degrees Celsius;

24) half-and-half – cream that has been heat treated (at least pasteurized) and packaged for the consumer;

25) fermented milk product – a dairy product or dairy component product which is made by culturing milk and (or) dairy products, and (or) their mixes, which reduces the active acidity (pH) and coagulation of protein, using starter microorganisms and then adding or not adding nondairy components for purposes other than replacement of milk constituents, and which contains live starter microorganisms in the quantity prescribed in addenda 4, 6, 8 and 12 hereto;

26) ayran – a fermented milk product which is made by means of mixed (lactate and alcohol) fermentation using starter microorganisms - thermophilic lactic streptococci, Bulgarian bacillus, and yeast, followed by the addition or non-addition of water;

27) acidophilus milk – a fermented milk product made using equal amounts of starter microorganisms – acidophilus bacillus, lactococci and ferments prepared on kefir fungi;

28) varenets – a fermented milk product made by culturing milk and (or) dairy products that are first sterilized or otherwise heat treated at a temperature of 97 degrees Celsius plus-minus 2 degrees Celsius using starter microorganisms - thermophilic lactic streptococci – until characteristic organoleptic properties are achieved;

29) yogurt – a fermented milk product with a high concentration of dry skim milk solids made using a mixture of starter microorganisms – thermophilic lactic streptococci and Bulgarian bacillus;

30) kefir – a fermented milk product made by means of mixed (lactate and alcohol) fermentation using ferments prepared on kefir fungi without the addition of pure cultures of lactate microorganisms and yeast;

31) kumiss – a fermented milk product made by means of mixed (lactate and alcohol) fermentation and the culturing of mare's milk using starter microorganisms – Bulgarian and acidophilus bacillus and yeast;

32) kumiss product – a fermented milk product made from cow's milk in accordance with kumiss making technology;

33) curdled milk – a fermented milk product made using starter microorganisms – lactococci and (or) thermophilic lactic streptococci;

34) Mechnikov curdled milk – a fermented milk product made using starter microorganisms - thermophilic lactic streptococci and Bulgarian bacillus;

35) ryazhenka – a fermented milk product made by culturing baked milk with or without the addition of dairy products using starter microorganisms - thermophilic lactic streptococci with or without the addition of Bulgarian bacillus;

36) sour cream – a fermented milk product which is made by culturing cream with or without the addition of dairy products using starter microorganisms – lactococci or a mixture of lactococci and thermophilic lactic streptococci – and in which the fat mass fraction is at least 9 percent;

37) curds – a fermented milk product made using starter microorganisms - lactococci or a mixture of lactococci and thermophilic lactic streptococci – and acidic or acidic-abomasal protein coagulation methods, followed by removal of the whey by means of self-pressing, pressing, centrifugation and (or) ultrafiltration;

38) granular curds – a crumbly dairy product made from curd grain with the addition of cream and salt. It is not allowed to heat treat or add consistency stabilizers to the ready product;

39) curd mass – a dairy product or dairy component product made from curds with or without the addition of dairy butter, cream, condensed milk, sugar and (or) salt, with or without the addition of nondairy components for purposes other than replacement of milk constituents. It is not allowed to heat treat or add consistency stabilizers to these ready products;

40) curd product – a dairy product, dairy component product or milk-containing product made from curds and (or) milk processing products in accordance with curd making technology with or without the addition of dairy products, with or without the addition of nondairy components, including nondairy fats and (or) proteins, followed or not by heat treatment. If the ready dairy or nondairy component curd product contains at least a 75 percent mass fraction of milk constituents and such products have been heat treated and ripened to bring about specific organoleptic and physiochemical properties, such products are referred to as "curd cheese";

41) sweet curd cheese – a dairy or dairy component product made from a curd mass which is formed, covered or not covered with a food glaze, and weighs no more than 150 grams;

42) curd cheese bar – a curd product which is formed, covered or not covered with a food glaze, and weighs no more than 150 grams;

43) cultured product – a dairy or dairy component fermented milk product which is heat treated after culturing, or a milk-containing product that is made in accordance with the technology for making fermented milk products and is similar to them in organoleptic and physiochemical properties;

44) cow's milk butter – a dairy product or dairy component product on an emulsion fat base whose predominant constituent is milk fat, which product is made from cow's milk, dairy products and (or) milk processing byproducts by removing from them the fat phase and evenly distributing the milk plasma in the fat phase with or without the addition of nondairy components for purposes other than replacement of milk constituents;

45) dairy butter – butter from cow's milk in which the fat mass fraction is 50 to 85 percent inclusive;

46) sweet cream butter – dairy butter made from pasteurized cream;

47) cultured butter – dairy butter made from pasteurized cream using lactate microorganisms;

48) whey cream butter – dairy butter made from cream obtained in cheese making;

49) rendered butter – cow's milk butter whose fat mass fraction is at least 99 percent, which is made from dairy butter by rendering the fat phase and has specific organoleptic properties;

50) butter paste – a dairy product or dairy component product on an emulsion fat base whose fat mass fraction is 39 to 49 percent inclusive and which is made from cow's milk, dairy products and (or) milk processing byproducts using stabilizers with or without the addition of nondairy components for purposes other than replacement of milk constituents;

51) sweet-cream butter paste – a butter paste made from pasteurized cream;

52) sour-cream butter paste – a butter paste made from pasteurized cream with lactate microorganisms;

53) whey butter paste – a butter paste made from cream obtained in cheese making;

54) milk fat – a dairy product whose fat mass fraction is at least 99.8 percent, has a neutral taste and odor and is made from milk and (or) dairy products by removing the milk plasma;

55) cream-vegetable spread – a product of the processing of milk on an emulsion fat base whose total fat mass fraction is 39 to 95 percent and whose milk fat mass fraction in the fat phase is 50 to 95 percent;

56) cream-vegetable rendered mixture – a product of milk processing whose fat mass fraction is at least 99 percent and which is made from cream-vegetable spread by rendering the fat phase or

using other production methods;

57) cheese – a dairy product or dairy component product made from milk, dairy products and (or) milk processing byproducts using special starters and technologies to coagulate milk proteins with or without milk-clotting ferments, or by the acidic or thermoacidic method, followed by separation from the whey, formation, pressing, salting, ripening or non-ripening of the cheese mass, with or without the addition of nondairy components for purposes other than replacement of milk constituents;

58) processed cheese - a dairy product or dairy component product made from cheese and (or) curds with the use of dairy products and (or) milk processing byproducts, emulsifying salts or structure-forming agents by breaking up, blending, liquefying and emulsifying the mixture for processing with or without the addition of nondairy components for purposes other than replacement of milk constituents;

59) cheese product – a milk-containing product made in accordance with cheese making technology;

60) processed cheese product – a milk-containing product made in accordance with processed cheese making technology;

61) pickled cheese, cheese product – cheese, cheese product ripened and (or) stored in brine;

62) soft, medium-hard, extra-hard cheese, cheese product – cheese, cheese product that have specific organoleptic and physiochemical properties that conform to addenda 11 and 12 hereto;

63) mold cheese, cheese product – cheese, cheese product made with mold fungi located in and (or) on the surface of the ready cheese, cheese product;

64) slime cheese, cheese product – cheese, cheese product made with slime microorganisms that develop on the surface of the ready cheese, cheese product;

65) smoked cheese, processed cheese, cheese product, processed cheese product – cheese, processed cheese, cheese product, processed cheese product that has been smoked and has specific organoleptic properties characteristic of smoked food;

66) canned milk, dairy component, milk-containing canned goods – dry or concentrated packaged milk, dairy component, milk-containing products;

67) ice cream – a whipped and frozen sweet dairy product, dairy component product or milkcontaining product used frozen;

68) ice milk – ice cream (dairy product or dairy component product) whose milk fat mass fraction does not exceed 7.5 percent;

69) cream ice – ice cream (dairy product or dairy component product) whose milk fat mass fraction is 8 percent to 11.5 percent;

70) plombir – ice cream (dairy product or dairy component product) whose milk fat mass fraction is 12 percent to 20 percent;

71) sour milk ice cream – ice cream (dairy product or dairy component product) whose milk fat mass fraction does not exceed 7.5 percent and which is made with starter microorganisms or fermented milk products;

72) vegetable oil ice cream – ice cream (milk-containing product) whose vegetable oil or vegetable oil-milk fat mixture mass fraction does not exceed 12 percent;

73) soft ice cream – ice cream which has a temperature of minus 5 to minus 7 degrees Celsius and is sold directly from the freezer;

74) hardened ice cream – ice cream that is placed in the freezer and then frozen to a temperature of minus 18 degrees Celsius or below and maintains that temperature during storage, shipment and sale;

75) fluid ice cream mix - a fluid dairy product, dairy component product or milk-containing product containing all components needed to make ice cream;

76) dry ice cream mix – a dry dairy product, dry dairy component product or dry milk-containing product made by drying a fluid ice cream mix or mixing the necessary dry components and cream and (or) juice;

77) standardized milk processing product – a milk processing product whose fat, protein and (or)

dry skim milk solids mass fractions or their proportions confirm to the parameters set by the standards and regulatory documents of the federal authority, codes of practice, and (or) technical documents;

78) pasteurized, sterilized or ultra-pasteurized milk processing product – a milk processing product that is heat treated and conforms to the present Federal Law's requirements as to the allowable level of microorganisms in such a product;

79) concentrated, condensed, evaporated, or frozen milk processing product – a milk processing product made by partially removing water from it to bring its dry solids mass fraction to at least 20 percent;

80) concentrated milk processing product with sugar – a concentrated milk processing product made with the addition of sucrose and (or) other types of sugars;

81) dry milk processing product – a milk processing product made by partially removing water from the product to bring its dry solids mass fraction to at least 90 percent;

82) sublimated milk processing product – a milk processing product made by removing water from a frozen milk processing product to bring its dry solids mass fraction to at least 95 percent;

83) reconstituted milk processing product – a milk processing product made from a concentrated or dried milk processing product and water;

84) enriched milk processing product – a milk processing product to which are added, separately or in combination, such substances as protein, vitamins, micro- and macroelements, dietary fibers, polyunsaturated fatty acids, phospholipids, probiotics and prebiotics;

85) whipped milk processing product – a milk processing product made by whipping;

86) recombined milk processing product – a milk processing product made from milk processing products and (or) their separate constituents and water;

87) low-lactose milk processing product – a milk processing product in which lactose has been partially hydrolyzed or partially removed;

88) lactose-free milk processing product – a milk processing product in which lactose has been fully hydrolyzed or completely removed;

89) products based on full or partial protein hydrolyzates – milk processing products made from fully or partially hydrolyzed cow's milk and soy proteins;

90) buttermilk – a milk processing byproduct obtained when making cow's milk butter;

91) milk whey (cheese, curd or casein whey) – a milk processing byproduct obtained when making cheese (cheese whey), curds (curd whey), and casein (casein whey);

92) national dairy product – a dairy product that has a name that has been historically shaped in the Russian Federation and is defined by the specific technologies to make it, the composition of the starter used to make it, and (or) the name of the geographic area where the dairy product is common;

93) biological product (hereafter – bioproduct) – a milk processing product made with starter microorganisms and enriched by adding, during and (or) after culturing, live probiotic microorganisms (probiotics) in monocultures or associations and (or) prebiotics. It is not allowed to heat treat the ready product;

94) milk constituents – dry solids (milk fat, milk protein, milk sugar (lactose), ferments, vitamins, mineral substances), water;

95) residual milk solids – milk constituents, except water;

96) residual skim milk solids - milk constituents, except fat and water;

97) milk plasma – a colloidal system of milk proteins, milk sugar (lactose), mineral substances, ferments and vitamins in the water phase;

98) whey proteins – milk proteins that remain in milk whey after casein sedimentation;

99) whey protein concentrate – whey proteins obtained from milk whey through concentration or ultrafiltration;

100) case n - a milk processing product which is made from skim milk and is the major constituent of milk proteins;

101) albumin – a milk processing product which is made from milk whey and is a concentrate of

whey proteins of milk;

102) dairy substitute -a food mostly or partially made from nondairy components and used for the same purposes as a dairy product.

Chapter 2. Requirements for Raw Milk and Raw Milk Processing Products

Article 5. Safety Requirements for Raw Milk and Raw Cream

1. The conditions for obtaining milk from livestock, transporting, selling and utilizing raw milk and raw cream, and non-commercial dairy products must comply with the Russian Federation's animal health legislation.

2. Raw milk must be obtained from healthy livestock on territory that is free from infectious and other diseases common to humans and animals.

3. It is not allowed to use in food raw milk obtained during the first seven days after parturition or for five days prior to start of labor (before parturition) and (or) from animals that are diseased or in quarantine.

4. Producers must ensure the safety of raw milk so that it does not contain residual amounts of inhibitory, detergent, disinfectant, or neutralizing substances, animal growth stimulants (including hormone preparations), or drugs (including antibiotics) used in livestock rearing to feed and treat cattle and (or) prevent illness.

5. Milk obtained from various types of livestock, with the exception of cow's milk, must conform to the parameters set by the standards and regulatory documents of the federal authority, codes of practice, and (or) technical documents.

6. The dry skim solids mass fraction in cow's milk must be at least 8.2 percent. The density of cow's milk in which the fat mass fraction is 3.5 percent must be at least 1,027 kilograms per cubic meter at a temperature of 20 degrees Celsius or at least the equivalent value for milk in which the fat mass fraction is different.

7. The following additional requirements may be stipulated for raw milk used to make food with specific consumer attributes:

1) the raw milk of farm animals that is intended for the production of milk-based children's food products must conform to the requirements of the present Article, as well as the following requirements:

a) at least first class purity and at least third class heat stability based on the alcohol test in conformity with the national standard;

b) the number of mesophilic aerobic microorganism colonies and facultative anaerobic microorganisms shall not exceed the allowable level prescribed for premium grade raw milk and first grade raw milk pursuant to addendum 2 hereto;

c) the number of somatic cells shall not exceed the allowable level prescribed for premium grade raw milk pursuant to addendum 2 hereto;

d) raw milk that is intended for the production of milk-based children's food products shall be stored and transported in separate containers in conformity with Article 6;

e) it is not allowed to use raw milk whose identification parameters do not match the breed of farm animals from which the milk was obtained, and (or) whose safety parameters do not conform to the requirements hereof;

2) raw cow's milk intended for the production of sterilized milk, including concentrated milk or evaporated milk, shall conform to the requirements of the present Article and shall have third class heat stability based on the alcohol test in conformity with the national standard;

3) raw cow's milk intended for the production of cheese shall conform to the requirements of the present Article, as well as to the following requirements:

a) classes I and II rennet fermentation tests;

b) bacterial population based on classes I and II reductase test in conformity with the national standard; the number of colonies of mesophilic aerobic microorganisms and facultative anaerobic microorganisms shall not exceed 1*106 colony-forming units per cubic centimeter;

c) the number of spores of mesophilic anaerobic lactate-fermenting butyric microorganisms

shall:

for cheese with a low scalding temperature not exceed 13,000 spores per cubic decimeter; for cheese with a high scalding temperature not exceed 2,500 spores per cubic decimeter;

d) acidity not to exceed 19 Terner degrees;

e) protein mass fraction of at least 2.8 percent;

4) raw cow's milk intended for the production of dietary food products must conform to the requirements of the present Article, as well as with the following requirements:

a) the number of colonies of mesophilic aerobic microorganisms and facultative anaerobic microorganisms not to exceed 5*105 colony-forming units per cubic centimeter;

b) the number of somatic cells shall not exceed 5*105 per cubic centimeter;

c) at least class two heat stability based on the alcohol test in conformity with the national standard.

8. The chemical and radiological safety parameters of raw cow's milk and raw cream must be within the allowable level prescribed in addendum 1 hereto.

9. The microbiological safety parameters and somatic cell content of raw cow's milk and raw cream must be within the allowable level prescribed in addendum 2 hereto.

10. The decision to use raw milk or raw cream that does not meet the safety requirements as to allowable levels of potentially dangerous substances, microorganisms and somatic cells shall be taken by producers pursuant to Russian Federation animal health legislation, Russian Federation public health and disease control legislation, and environmental safety legislation.

Article 6. Requirements as to Special Technological Processes for the Production, Storage, Transportation and Disposal of Raw Milk and Raw Cream

1. Special technological processes used during the production of raw milk, the care, feeding and milking of farm animals, and the collection, cooling and storage of raw milk and raw cream must comply with Russian Federation animal health legislation.

2. After the milking of farm animals, raw milk must be refined and cooled to a temperature of 4 degrees Celsius plus-minus 2 degrees Celsius within 2 hours.

3. Producers may store raw milk at a temperature of 4 degrees Celsius plus-minus 2 degrees Celsius for up to 24 hours, inclusive of shipping time, and may store raw cream at a temperature not to exceed 8 degrees Celsius for up to 36 hours, inclusive of shipping time.

4. Producers may preliminarily heat treat, including pasteurize, raw milk, if:

1) the raw milk's acidity is 19 to 21 Terner degrees;

2) raw milk is stored for more than 6 hours;

3) raw milk shipment time exceeds the allowable storage period of chilled raw milk, but not by more than 25 percent.

5. When raw milk is preliminarily heat treated, including pasteurized, the heat treatment (temperature, duration) shall be specified in the accompanying documentation.

6. In the production of raw milk and raw cream, agricultural commodity producers must use equipment and materials that are permitted for contact with dairy products by the federal oversight authority for public health and disease control and consumer protection.

7. The temperature of chilled raw milk or raw cream must not exceed 10 degrees Celsius during shipment to the processing site and until the start of processing. Raw milk and raw cream that do not meet the prescribed requirements as to their temperature must be processed immediately.

8. Raw milk and raw cream shall be shipped in containers with tightly closing lids made from materials permitted for contact with milk by the federal oversight authority for public health and disease control and consumer protection, and sealed. Vehicles must be equipped with refrigeration systems that can maintain the temperature stipulated herein.

9. Raw milk and raw cream storage and shipment shall be accompanied by documentation of their safety, and the information stipulated in parts 23 and 24 of Article 36 hereof.

10. Prior to processing, manufacturers of milk processing products shall store raw milk, heat treated milk, and raw cream in separate marked containers at a temperature of 4 degrees Celsius

plus-minus 2 degrees Celsius until product expiration.

11. Producers or sellers shall dispose of raw milk or raw cream that does not conform to the present Federal Law in the manner prescribed by Russian Federation animal health legislation, Russian Federation public health and disease control legislation, and environmental safety legislation.

Article 7. Requirements for Milk Processing Products

1. Milk processing products shall be made from milk that conforms to the safety requirements prescribed herein and has been heat treated to obtain such ready products as shall conform to the requirements hereof.

2. The content of toxic elements, mycotoxins, antibiotics, pesticides, radionuclides, or microorganisms in milk processing products intended for sale, and oxidative deterioration must not exceed the standards prescribed herein.

3. The chemical and radiological safety parameters of milk processing products must be within the allowable level prescribed in addendum 3 hereto.

4. Microbiological safety parameters for milk processing products must be within the allowable level prescribed in addendum 4 hereto.

5. New milk processing products shall be developed and produced in conformity with international standards, or national standards, or industry standards. The requirements of these standards as regards such products or their related production, storage, shipment, sale, and disposal must conform to the requirements prescribed herein. Products which are being made in or imported into the Russian Federation for the first time shall be subject to national registration pursuant to Russian Federation public health and disease control legislation.

6. Nondairy components used in the production of milk processing products must comply with Russian Federation food quality and safety legislation.

7. Except for functionally necessary components, it is not allowed to use food additives or flavoring agents in the production of dietary food or national dairy products.

8. The content level of probiotics and prebiotics in enriched milk processing products shall be monitored by the methods used to monitor the content level of these components.

9. The decision to use milk processing products that do not conform to the safety requirements of the present Article shall be taken by producers or sellers pursuant to Russian Federation public health and disease control legislation, Russian Federation animal health legislation, and environmental safety legislation.

Chapter 3. Requirements as to Production and Special Technological Processes in the Production and (or) Sale of Milk Processing Products

Article 8. General Requirements as to Production of Milk Processing Products

1. The requirements as to production of milk processing products shall apply to all legal entities and physical persons engaged in the production and (or) sale of milk processing products in the Russian Federation.

2. Technological processes for the production of milk processing products, as well as those related to the production, use, storage, shipment, and sale of milk processing products, and the use, processing, and disposal of potentially dangerous milk processing products and production waste must comply with Russian Federation public health and disease control legislation, Russian Federation animal health legislation, and environmental safety legislation.

3. Equipment, inventory, packing and packaging materials that come into direct contact with milk processing products during production, storage and sale must be made from materials permitted for contact with dairy products by the federal oversight authority for public health and disease control and consumer protection pursuant to Russian Federation public health and disease control legislation.

4. Production and sale procedures for milk processing products shall be evaluated for conformity to safety requirements during their planning. Producers shall monitor conformity to such

requirements during the organization of production, as well as at all stages of production (production, storage, shipment, and sale of milk processing products, and processing or disposal of nonconforming milk processing products and waste materials).

5. In order to ensure that milk processing products conform to the requirements, their production includes aromatizing, bactofuging, fermenting, whipping, reconstituting, rendering, hydrolyzing, glazing, homogenizing, deaerating, demineralizing, adding components, hardening ice cream, freezing, isomerizing, coagulating, concentrating, smoking, membrane enriching, standardizing, enriching, cooling, refining, pasteurizing, shipping, melting, converting high fat cream, pressing, reserving, recombining, self-pressing, churning, clotting, evaporating, separating, culturing, mixing, ripening, stabilizing, sterilizing, drying, thermizing, heating, ultra-pasteurizing, packing, prepackaging, filtering, forming, freezing (ice cream), storing, cheddarizing, emulsifying (dispergating), and other procedures for making such products.

6. The present Federal Law defines the concepts of the production processes of milk processing products and the requirements as to those processes, which are related to the mandatory requirements as to raw milk and its processing products.

Article 9. Concepts of the Production Processes of Milk Processing Products and the Requirements as to the Processes, which are Related to the Mandatory Requirements as to Raw Milk and its Processing Products

The following concepts and requirements are defined with respect to the production processes of raw milk and its processing products:

1) refine raw milk – to free raw milk of mechanical impurities and (or) microorganisms. Raw milk producers or makers of milk processing products shall refine raw milk without the use of centrifugal force in order to make the raw milk conform to purity requirements, or shall use centrifugal force and special equipment to make the raw milk conform to purity requirements and free it of microorganisms;

2) filter – to free raw milk and milk processing products of mechanical impurities. Filtering does not use centrifugal force;

3) separate – to divide raw milk or milk processing products into two parts with reduced and enhanced fat content;

4) standardize – to regulate the content and ratio of milk constituents in raw milk or milk processing products so as to attain the parameters prescribed by the standards and regulatory documents of the federal authority, codes of practice, and (or) technical documents. Standardization is achieved by removing from or adding to a product the constituents of milk and dairy products and (or) separate constituents thereof in order to reduce or increase the fat mass fraction, protein mass fraction and (or) dry solids mass fraction;

5) thermize – to heat treat raw milk or milk processing products. Thermization shall be carried out at a temperature of 60 to 68 degrees Celsius for up to 30 seconds, while maintaining the milk's alkaline phosphatase activity;

6) pasteurize – to heat treat raw milk or its processing products. Pasteurization shall be carried out in different conditions (temperature, time) at a temperature of 63 to 120 degrees Celsius long enough to reduce the number of any pathogenic microorganisms in raw milk or its processing products to a level at which these microorganisms will not significantly harm human health. Low temperature pasteurization shall be carried out at a temperature that does not exceed 76 degrees Celsius and shall inactivate the alkaline phosphatase. High temperature pasteurization shall be carried out in different fashions (temperature, time) at a temperature of 77 to 100 degrees Celsius and shall inactivate both the phosphatase and the peroxidase. The effectiveness of pasteurization shall be monitored by one of the following methods:

a) biochemical method (depending on the pasteurization temperature, a phosphatase test or peroxidase test, enzyme tests) through the testing of samples of the milk or its processing products. Such samples shall be selected from each storage tank after it has been filled with the pasteurized product;

b) microbiological method through the testing of samples of the milk or its processing products for sanitary indicator microorganisms. Such samples shall be selected after the heat treated products have been cooled. The frequency of pasteurization effectiveness monitoring shall be prescribed by a production monitoring program;

7) sterilize – to heat treat raw milk or its processing products. Sterilization shall be carried out at a temperature above 100 degrees Celsius long enough to make the ready milk processing product conform to industrial sterilization requirements. The effectiveness of sterilization shall be monitored by testing samples of the milk and its processing products in order to verify that they conform to industrial sterilization requirements. The frequency of sterilization and ultra-pasteurization effectiveness monitoring shall be prescribed by a production monitoring program; 8) ultra-pasteurize – to heat treat raw milk and its processing products. Ultra-pasteurization shall be carried out in a flow in a closed system for at least two seconds by one of the following

methods:

a) by bringing the product into contact with a heated surface at a temperature of 125 to 140 degrees Celsius;

b) by directly mixing sterile steam with the product at a temperature of 135 to 140 degrees Celsius. Ultra-pasteurization followed by aseptic packaging shall bring the product into conformity with industrial sterilization requirements. The effectiveness of ultra-pasteurization shall be monitored by testing samples of the milk and its processing products in order to verify that they conform to the requirements herein. The frequency of ultra-pasteurization effectiveness monitoring shall be prescribed by a production monitoring program;

9) ripen – to keep milk, as well as cream, other milk processing products or a mixture thereof in specific conditions. The purpose of ripening is to bring about organoleptic, microbiological, physiochemical or structural-mechanical properties that are characteristic of a specific product;

10) culture – to form milk clots in milk and its processing products using starter microorganisms. Culturing reduces active acidity (pH) and increases milk acid content;

11) clot – to coagulate protein in milk and its processing products. Clotting is accomplished by using milk-clotting enzyme preparations and other substances and factors that promote protein coagulation;

12) heat – to keep milk or its processing products at a high temperature to give it characteristic organoleptic properties – cream or light-brown color and a specific taste and odor. Milk processing products (with the exception of butter and rendered mixtures) shall be heated at a temperature of 85 to 99 degrees Celsius for at least three hours or at a temperature above 105 degrees Celsius for at least 15 minutes;

13) convert high fat cream – to obtain dairy butter by changing the type of emulsion from "fat in milk plasma" to "milk plasma in fat." High fat cream is converted through intense thermodynamic or thermomechanical impact on high fat cream;

14) churn butter – to obtain dairy butter by separating the fat phase from the cream in the form of butter grain. Butter is churned at a temperature of 7 to 16 degrees Celsius, followed by clumping and plasticization through intense mechanical impact;

15) self-press - to change the configuration of a milk processing product. Self-pressing is accomplished by fluid phase removal, which is caused by the impact of the product's own weight;

16) press – to change the configuration of a milk processing product. Pressing is accomplished by fluid phase removal, which is caused by external physical impact on the product;

17) melt – to impact a milk processing product with heat so that it changes from a hard to a liquid state. Mixtures of primary products shall be melted to make processed cheese and processed cheese products as prescribed by regulatory and (or) technical documents, and at a temperature of at least 83 degrees Celsius;

18) smoke cheese – to process cheese, processed cheese, cheese products, and processed cheese products with smoke obtained from dry non-resinous tree species. Smoking shall be carried out in special chambers that maintain the temperature-humidity conditions prescribed by regulatory

and (or) technical documents. It is not allowed to use smoke flavoring;

19) enrich – to add to milk and its processing products vitamins, micro- and macroelements, prebiotic substances, protein, dietary fibers, polyunsaturated fatty acids, phospholipids, and probiotic microorganisms;

20) cool – to reduce the temperature of milk and its processing products to a level at which microorganisms and oxidative processes cease to develop in them. Heat treated milk and its processing products (with the exception of ice cream, cheese, cheese products, and dry, concentrated, evaporated, and sterilized milk processing products) shall be cooled to a temperature of not more than 6 Celsius for two hours. During the production of fermented milk products, the temperature of milk, cream or a standardized mixture of primary milk processing products at culturing temperature after pasteurization. It is not allowed to keep pasteurized milk, cream or a standardized mixture of primary milk processing products at culturing temperature without a ferment. Ice cream mixes shall be cooled to a temperature of 3 degrees Celsius plus-minus 3 degrees Celsius for up to two hours. Cooled ice cream mix must not be stored for longer than:

a) 48 hours at a temperature of 0 to 2 degrees Celsius;

b) 36 hours at a temperature of 2 to 4 degrees Celsius;

c) 24 hours at a temperature of 4 to 6 degrees Celsius;

21) freeze (ice cream) - to simultaneously churn and freeze an ice cream mix;

22) concentrate (evaporate) – a process used during the making of concentrated and evaporated milk processing products. Concentration (evaporation) is achieved by partially removing water from a milk processing product to bring the dry solids mass fraction to 20 to 90 percent;

23) dry - a process used during the making of dry milk processing products. Drying is achieved by removing moisture from a milk processing product to bring the dry solids mass fraction to 90 percent or greater;

24) sublimate – a process used during the making of sublimated milk processing products. Sublimation is achieved by removing moisture from a frozen milk processing product using a vacuum, followed by final drying at a temperature not to exceed 45 degrees Celsius to bring the dry solids mass fraction to 95 percent or greater;

25) reconstitute – a process used during the making of reconstituted milk processing products. Reconstitution is achieved by adding drinking water to a concentrated, evaporated or dry milk processing product to achieve the proper organoleptic and physiochemical properties of a product that has not been concentrated, evaporated or dried;

26) recombine – to make milk processing products from constituents of milk or dairy products, dairy component products, milk-containing products and water;

27) whip – a process used during the making of whipped milk processing products. Whipping is achieved by intensively mixing the product to increase its volume;

28) cheddarize – to profoundly demineralize the caseinate-calcium phosphate complex of milk and (or) a cheese mass using lactic acid, which forms when milk sugar (lactose) is fermented with a starter lactate microflora or organic acids (vinegar, milk, lemon) during direct milk acidification. Cheddarization is used in the making of medium-hard and soft cheese so that they acquire specific organoleptic properties;

29) milk processing products shall be stored during their shelf life in conditions which are established by producers and which shall ensure that the products are preserved in accordance with the safety parameters prescribed in Article 7 hereof;

30) milk processing products shall be shipped and sold under conditions determined by producers, and in accordance with Russian Federation food quality and safety legislation.

Article 10. Requirements as to the Washing and Disinfection of Production Areas and Equipment

1. Washing and disinfection of production areas, equipment, inventory, containers, and means of transportation must ensure the safety of milk processing products and obviate the possibility of

their secondary contamination, and shall be carried out as often as prescribed by a production monitoring program.

2. The means used to wash and disinfect must be environmentally safe and permitted for use in the food industry by the federal oversight authority for public health and disease control and consumer protection.

3. The tanks for making and storing milk and its processing products shall be washed and disinfected within 2 hours of each tank emptying. Equipment that is not used for more than 6 hours after washing and disinfection shall be re-disinfected prior to the start of operation.

4. If equipment is idle for more than 2 hours, the pasteurized milk or standardized mixture of its primary processing products must be sent for re-pasteurization, and the pipes and equipment must be thoroughly washed and disinfected.

5. The effectiveness of the washing and disinfection shall be determined by laboratory tests whose scope and frequency are established by a production monitoring program.

Chapter 4. Requirements as to the Functionally Necessary Components Used in the Production of Milk Processing Products

Article 11. Functionally Necessary Components

1. Functionally necessary components are understood to mean ferments, probiotic microorganisms (probiotics), prebiotic substances (prebiotics), enzyme preparations, and nondairy components which are introduced during the making of milk processing products and without which a specific milk processing product cannot be made.

2. A ferment is understood to mean nonpathogenic, nontoxic microorganisms and (or) association of microorganisms, mostly lactate microorganisms, which are specially selected and used to make milk processing products.

3. Probiotic microorganisms (probiotics) are understood to mean nonpathogenic, nontoxic microorganisms that enter the human intestinal tract with food, have a favorable effect on the human body, and normalize the composition and biological activity of the microflora of the alimentary canal (mostly Bifidobacterium, Lactobacillus, Propionibacterium, Lactococcus microorganism genus).

4. Prebiotic substances (prebiotics) are understood to mean a substance or complex of substances which, when systematically consumed in food, have a favorable effect on the human body by selectively stimulating growth and (or) increasing the biological activity of the normal microflora of the alimentary canal.

5. Enzyme preparations are understood to mean protein substances needed for the biochemical processes that take place during the making of milk processing products.

Article 12. Requirements for Ferments and Enzyme Preparations

1. Microorganisms, including probiotics, used in monocultures or as part of ferments to make milk processing products must be identifiable, nonpathogenic, and nontoxic and possess the properties needed to make milk processing products that conform to the requirements hereof.

2. Enzyme preparations used to make milk processing products must possess the activity and specificity needed for a particular production process, and conform to the standards and regulatory documents of the federal authority, codes of practice, and (or) technical documents.

3. The microbiological safety of ferments, enzyme preparations and culture media for cultivating starter and probiotic microorganisms must be within the allowable level prescribed by addendum 4 hereto.

4. Other safety parameters of ferments, probiotic microorganisms, prebiotic substances, enzyme preparations and culture media for making ferments must comply with Russian Federation food and safety legislation and the requirements hereof.

Article 13. Requirements as to Facilities for Ferment and Probiotic Microorganism Production 1. Ready-to-use ferments and probiotic microorganisms must be produced in companies or at the separate production facilities of companies that are detached from other companies. Producers of milk processing products must make commercial ferments and probiotic microorganisms from ready-to-use ferments at special production facilities in accordance with the requirements prescribed by the standards and regulatory documents of the federal authority, codes of practice, and (or) technical documents.

2. Makers of milk processing products must ensure the safety of ferments, probiotic microorganisms, their production, and the making from them of commercial ferments through design features (location, number and condition of the facilities), organizational arrangements (work routine, production control), and conformity with health and disease control requirements as to conditions for working with microorganisms and the condition of equipment.

3. Makers of milk processing products shall produce commercial ferments and (or) probiotic microorganisms in a special production facility that must meet the following requirements:

1) housed in the same production building with, but separated from, the main production facilities in which the commercial ferments and (or) probiotic microorganisms are used;

2) availability of several production facilities where conditions are created and maintained to protect the ferments and (or) probiotic microorganisms from being contaminated by unwanted microorganisms, bacteriophages and similar extraneous agents;

3) balanced ventilation and an effective air purification and conditioning system.

4. At all stages of production, makers of milk processing products shall monitor the safety of ferments and (or) probiotic microorganisms during their production and the making from them of commercial ferments and activated bacterial concentrates using workers who have been specially trained and certified.

5. The entire process of making commercial ferments and (or) probiotic microorganisms (including reconstitution of dry culture media or dry milk, pasteurization and (or) sterilization, cooling, souring, cultivation and cooling of ferments) shall take place in a closed system.

6. The washing and disinfection routine for the production facilities, equipment and inventory at the facility referred to in part 3 of the present Article must conform to the requirements of Article 10 of the present Federal Law and be stipulated by a production monitoring program.

7. It is not allowed to use commercial ferments and (or) probiotic microorganisms which do not conform to the requirements hereof, have not been fully used up from open packages, or have expired.

8. Each lot of commercial ferments and (or) probiotic microorganisms that is to be transferred from the facility referred to in part 3 of the present Article to other production facilities must be accompanied by documentation of the hour and date of its production, composition, application, volume, and activity.

Chapter 5. Requirements as to Milk-Based Children's Food Products and their Production

Article 14. Concepts of Children's Food Products

1. The present Article contains general concepts that characterize children's food products. Concepts characterizing children's food products shall be prescribed by national standards using the basic general concepts of milk processing products, including children's food products, prescribed by the present Federal Law.

2. Children's food products are understood to mean food which is intended for children up to 14 years of age and meets the physiological requirements of a child's body.

3. Milk-based children's food products are understood to mean children's food products made from cow's milk or the milk of other farm animals with or without the addition of nondairy components in an amount not to exceed 20 percent of the total weight of these products.

4. Baby food products are understood to mean baby food products intended for infants from birth to three years of age.

5. Adapted infant formula (women's milk substitute) is understood to mean baby food products which are made in fluid or powdered form from the milk of farm animals and soy protein (except for proteins obtained from raw material containing genetically modified organisms), approximate women's milk as closely as possible in chemical composition and properties, and meet the physiological requirements of infants in the first year of life.

6. Supplemental feeding products are understood to be infant food products which are introduced into the diet to supplement women's milk, adapted infant formulas (women's milk substitute) and (or) follow-up formulas, and are made from animal and (or) vegetable products based on the age-related physiological characteristics of children.

7. Follow-up formula is understood to mean infant food products based on the milk of farm animals and soy protein (with the exception of proteins obtained from raw material containing genetically modified organisms) and adapted or partially adapted for babies over the age of six months.

8. Instant baby food products are understood to mean dry baby food products which are reconstituted at home through dilution with drinking water, milk, adapted infant formula or juice, whose temperature must be below 30 degrees Celsius. It is not allowed to use the concept "instant product."

9. Preschool children's food products are understood to mean children's food products for children three to six years of age.

10. School age children's food products are understood to mean children's food products for children six to 14 years of age.

11. Ready-to-use milk-based porridges are understood to mean milk-based baby food products made from different cereals, dairy products and (or) milk-containing products with or without the addition of nondairy components.

12. Lactose-free products are understood to mean special children's food products whose lactose content does not exceed 0.1 gram per liter of such ready-to-use product.

13. Low-lactose products are understood to mean special children's food products whose lactose content does not exceed 10 grams per liter of such ready-to-use product.

Article 15. Requirements for Milk-Based Children's Food Products

1. The nutritional value of milk-based children's food products must be appropriate for the functional status of a child's body based on age. Milk-based children's food products must be safe for children's health.

2. Milk-based children's food products and their components must conform to the safety and nutritional requirements prescribed by the present Federal Law and by Russian Federation food quality and safety legislation.

3. Milk-based children's food products must not contain components obtained using genetically modified organisms or artificial colorings or flavorings.

4. The parameters for potentially dangerous substances as well as oxidative spoilage in milkbased baby food products must be within the allowable level prescribed by addendum 5 hereto.

5. Microbiological safety parameters in milk-based baby food products must be within the allowable level prescribed in addendum 6 hereto.

6. Only L-amino acid, taurine, nucleotide, prebiotics (galacto- and fructo-oligosaccharide, lactulose), bifidobacterium, and other probiotics, as well as fish oil and other polyunsaturated fatty acid concentrates may be included in the ingredients of adapted milk formula (women's milk substitute) and follow-up formulas to make them most closely approximate the composition of women's milk.

7. Addendum 15 hereto prescribes the form of use of the vitamins and minerals used to make milk-based baby food products. The vitamin and mineral content of children's food products must correspond to the level prescribed in addendum 16 hereto.

8. The food additives listed in addendum 17 hereto may be used to make milk-based baby food products.

9. The requirements as to the nutritional value of milk-based children's food products, including dairy products, dairy component products and milk-containing products, shall be based on age and an evaluation of the health risk for children of various age groups (babies, preschool children, and school age children).

10. The parameters of oxidative spoilage and chemical and radiological safety of milk-based food products for preschool and school age children must be within the allowable level prescribed in addendum 7.

11. The microbiological safety parameters of milk-based food products for preschool and school age children must be within the allowable level prescribed in addendum 8 hereto.

12. Nondairy components used to produce children's food products must comply with Russian Federation food quality and safety legislation.

Article 16. Requirements as to Organization of the Production and Production Processes of Milk-Based Children's Food Products

1. Milk-based baby food products shall be produced in companies or at the separate production facilities of companies that are detached from other companies.

2. The location of companies and production facilities that make milk-based baby food products must eliminate the possibility that they could be adversely impacted by other companies or production facilities. It is not allowed to collocate on the premises of businesses and production facilities where milk-based children's food products are made buildings or structures unrelated thereto. These businesses and production facilities must be equipped in such a way as to ensure that measures are taken to comply with Russian Federation public health and disease control legislation, and Russian Federation food quality and safety legislation. Separate production facilities must be made available if needed for the production, sterilization, prepackaging, or cooling of milk-based children's food products. These production facilities must be furnished with waterproof, nonabsorbent, washable, nonslip and nontoxic materials with no cracks. The number of such production facilities must be sufficient for the production of high quality milk-based children's food products.

3. Companies and production facilities that make milk-based children's food products must have: 1) a water supply, including hot water of a temperature of at least 80 degrees Celsius;

2) a system for making and supplying steam that does not contain substances which are harmful to humans or which contaminate milk-based children's food products when the steam is used in close proximity to them or to surfaces that come into contact with milk-based children's food products;

3) an industrial water drainage system that is completely separate and marked with a special color;

4) lighting, ventilation, plumbing.

4. Plant and equipment (including product pipes, water pipes and steam pipes) and inventory must be marked, accessible for sanitization in accordance with sanitation standards, and made of noncorrosive nontoxic materials that are permitted for food contact, are able to withstand repeated cleaning and disinfection, are free of foreign odors and taste, and do not impart same to milk-based children's food products.

5. Milk-based food products for preschool and school age children shall be made using industrial facilities (at shift start or on a separate shift after the equipment and inventory have been washed and disinfected) in accordance with requirements similar to those for milk processing products.

6. The packaging of milk-based children's food products must carry the information stipulated in Article 36 hereof.

Chapter 6. Requirements as to the Sale and Disposal of Milk and its Processing Products

Article 17. Requirements as to the Sale of Milk and its Processing Products

1. Milk processing products that are compliant with Russian Federation food quality and safety legislation and the present Federal Law may be sold.

2. When a producer or a person acting for a foreign producer delivers milk processing products to a seller, he must simultaneously present copies of documents which certify that the products are compliant with the present Federal Law.

3. Prior to selling milk processing products, sellers must verify that the product information stipulated herein is present and corresponds to the producer's documents.

4. When selling milk processing products for which some product information is included on package inserts, sellers must provide the consumer with such information.

5. Sellers shall abide by the terms stipulated by the producer for storing and selling milk processing products.

6. Milk-based baby food products must only be sold through retail outlets, pharmacies, and distribution counters if such retail outlets, pharmacies and counters provide the product storage conditions stipulated by the producer.

7. Sellers who cannot provide the product storage conditions stipulated by the producer are not allowed to sell milk processing products.

8. Sellers of milk processing products do not have the right to set a sell-by date beyond the expiration date stipulated by the producer. It is not allowed to sell expired milk processing products.

9. Individuals, including sole proprietors, who sell nonindustrial milk processing products at markets, including farmers' markets, must ensure that these products conform to the present Federal Law's requirements as to safety and identification, and must also provide consumers with information on the production site (address), names and date of production of the products.

10. Sellers of raw milk at farmers' markets must present to consumers documents issued by an executive agency of a constituent entity of the Russian Federation authorized to monitor (oversee) animal health and certifying the safety of the raw milk, and must also provide consumers with the information that it is imperative to boil raw milk.

11. Milk processing products shall be recalled by producers or sellers of these products voluntarily or upon a mandatory recall by the federal monitoring and oversight authority for public health and disease control and consumer rights.

Article 18. Suspension of the Production and Sale of Milk Processing Products

1. The production and sale of milk processing products that are noncompliant with Russian Federation food quality and safety legislation, Russian Federation consumer rights legislation, or the present Federal Law and endanger the health, life or property of citizens, the environment, or the health or life of animals shall be suspended by the producers or sellers of these products voluntarily or at the direction of the federal monitoring and oversight authority for public health and disease control and consumer rights, or by court order in the form and manner and for the period stipulated by Russian Federation legislation.

2. If the federal monitoring and oversight authority for public health and disease control and consumer rights receives information on nonconformity of milk processing products with the requirements hereof, it shall have the right to issue an order to suspend the sale of these products for the period of time necessary to obtain a product test report at an accredited testing laboratory (center).

Article 19. Requirements as to Disposal of Milk Processing Products

1. Producers or sellers of milk processing products that are out of compliance with the present Federal Law shall dispose of these products in the form and manner stipulated by Russian Federation public health and disease control legislation, Russian Federation animal health legislation, and environmental safety legislation.

2. The disposal method for milk processing products shall be approved by the federal monitoring and oversight authority for public health and disease control and consumer rights, the federal monitoring and oversight authority for animal health, and (or) the federal authority for national environmental safety monitoring (oversight).

3. The federal monitoring and oversight authority for public health and disease control and consumer rights, the federal monitoring and oversight authority for animal health, and (or) the federal authority for national environmental safety monitoring (oversight) which decrees that mandatorily recalled milk processing products must be disposed of shall monitor their disposal in order to avert the danger of disease outbreak and spread or of harm to the life or health of citizens or animals, as well as to prevent environmental pollution.

Chapter 7. Requirements as to the Setting Up of Production Monitoring

Article 20. Obligations of Producers and Sellers to Set Up Production Monitoring

1. Producers or sellers who make and (or) sell milk processing products in the Russian Federation must draw up a production control program and set up production monitoring of compliance with the present Federal Law internally and (or) by engaging an accredited testing laboratory (center).

2. The production monitoring program shall be approved by the company director, individual proprietor or duly authorized individual.

3. Legal entities and individual entrepreneurs that are producers or sellers of milk processing products must submit production monitoring data to the federal monitoring and oversight authority for public health and disease control and consumer rights, and the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) public health and disease control and consumer rights at their request.

4. In the event of an emergency or danger thereof, or of a disruption of production processes that jeopardizes the life or health of citizens, the property of physical persons or legal entities, federal or municipal property, the environment, or the life or health of animals or plants, producers or sellers must inform the federal monitoring and oversight authority for public health and disease control and consumer rights, the federal monitoring and oversight authority for animal health, and (or) the federal monitoring and oversight authority for environmental safety, and the local government body.

Article 21. Content of a Production Monitoring Program

1. Production shall be monitored in accordance with the program prescribed by part 2 Article 20 hereof.

2. A production monitoring program must stipulate:

1) implementation parameters for the production processes related to the mandatory requirements for milk products prescribed herein, and the frequency and scope of monitoring;

2) parameters for the quality and safety of the raw material, components and ready milk products in accordance with the requirements for safety, identifying marks, storage and shipment conditions and shelf life of raw material, components, and ready product, and the frequency and scope of monitoring;

3) schedules and routines for sanitizing, cleaning, disinfecting, disinfecting and deratting production facilities, equipment, and inventory;

4) schedules and routines for maintaining equipment and inventory;

5) methods of recalling, improving and reprocessing raw material and ready milk products;

6) measures to forestall and identify breakdowns in the organization and implementation of production processes;

7) sanitation measures;

8) monitored stages (critical check points) of production processes;

9) measures to prevent harm to the life or health of citizens, the property of physical persons or legal entities, national or municipal property, the environment, or the life or health of animals and plants;

10) methods for disposing of milk processing products that do not conform to the requirements hereof;

11) other routines, programs and methods to prevent unacceptable risk to the life or health of

citizens, the property of physical persons or legal entities, national or municipal property, the environment, or the life or health of animals or plants;

12) a list of the officers who are personally responsible for the production monitoring program.

3. The production monitoring program shall be amended in the event of organizational, engineer or technical changes in production conditions, production processes or the conditions of sale of milk processing products.

Chapter 8. Requirements as to Employees of Producers and Sellers of Milk and its Processing Products

Article 22. Sanitary Requirements as to the Employees of Producers or Sellers of Milk and Milk Processing Products

Employees engaged in the production, storage, shipment, sale and disposal of milk and its processing products must:

1) undergo preliminary medical examinations (checkups) upon being hired and periodical medical examinations (checkups);

2) undergo sanitation training and be duly certified before starting work;

3) have a standard personal medical record.

Article 23. Qualification Requirements as to Employees of Producers or Sellers of Milk and its Processing Products

Employees engaged in the production, storage, shipment, sale and disposal of milk and its processing products must:

1) have professional training and meet the qualification requirements for positions, professions and specialties in accordance with the designations and requirements stipulated in skills manuals approved in the manner prescribed by the Russian Federation Government;

2) know and follow job descriptions, technology guidelines, and the sanitation and animal health rules and standards as to food quality and safety;

3) follow the rules for operating equipment for the production of milk and milk products;

4) take the measures stipulated under Russian Federation law to prevent harm to the life or health of citizens, the property of physical persons or legal entities, or the life or health of animals or plants.

Chapter 9. Identification of Milk and its Processing Products

Article 24. Objectives of Milk and Milk Processing Products Identification

1. Milk and its processing products are identified in order to:

1) place milk and its processing products in the scope of the present Federal Law;

2) determine the conformity of milk and its processing products, including their names and identification parameters, to the requirements hereof;

3) determine the conformity of milk and its processing products to the consumer information, conformity declaration, or conformity certificate provided by producers or sellers.

2. Milk and its processing products whose accompanying document or label information does not correspond to the name and (or) identification parameters prescribed by the present Federal Law, or is inaccurate, shall be deemed adulterated and subject to mandatory recall.

3. In the manner prescribed by Russian Federation legislation, the monitoring and oversight authority for public health and disease control and consumer rights shall take measures to suspend the production and sale of adulterated milk and its processing products and shall notify consumers of said action.

Article 25. Rules and Procedures for Identifying Milk and its Processing Products

1. Milk and its processing products shall be identified during assessment and validation of conformity to the requirements hereof, as well as in the event that information about a specific product contains an incomplete description.

2. Milk and its processing products shall be identified:

1) by agencies certifying that these products conform to the present Federal Law;

2) by the federal monitoring and oversight authority for public health and disease control and consumer rights, the federal monitoring and oversight authority for animal health, and the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) public health and disease control and consumer rights;

3) on the initiative of legal entities or physical persons as appropriate to establish that these products conform to the information furnished about them, as well if such information is called into question or in order to conduct a preliminary assessment of these products.

3. Milk and its processing products shall be identified with due account for the attributes set forth in addenda 9-14 hereof, as well as the product descriptions provided by producers.

4. Regulatory documents of federal authorities, international standards, national standards or industry standards, accompanying documents, supply agreements, contracts, product specifications, retail package label information, and other descriptive documents may be used as descriptions of milk and its processing products.

5. The following identification procedures shall be used depending on the purpose and specific nature of the identification of milk and its processing products:

1) expert evaluation of the documents to which a specific product conforms;

2) product tests;

3) expert evaluation of the documents specified in clause 1 of the present part and product test results.

6. When identifying milk and its processing products by means of expert evaluation of the documents specified in clause 1, part 5 of the present Article, the accompanying documents for milk and its processing products and their correspondence to the marking on the retail package and shipping container and to the appearance of the product and packaging shall be scrutinized in order to establish that a specific product conforms to a variety or a specific lot, and to certify the uniformity of the product lot.

7. If the information obtained from an expert evaluation of the documents specified in clause 1, part 5 of the present Article is inadequate or inaccurate, and also when milk and its processing products are being certified compliant with the present Federal Law, the milk products shall be checked (tested) with regard to the parameters prescribed in Article 26 hereof.

8. If it becomes necessary to corroborate that milk or its processing products have been adulterated, they shall be checked (tested) with regard to the following identification and other parameters prescribed herein:

1) content of dry milk solids (dry milk residue) in the ready dairy product, dairy component product or milk-containing product, and their mass fraction in such ready products in percentages (with the exception of milk processing products containing dairy butter);

2) presence and content of fats of nondairy origin, and their mass fraction in milk and its processing products in percentages;

3) fatty acid composition of the fat phase of milk processing products (excluding milk processing products whose fat mass fraction is less than 1.5 percent, and ice cream whose fat mass fraction does not exceed 8 percent;

4) protein content in the dry milk residue in canned milk and milk-containing canned goods, and its mass fraction in such products in percentages;

5) ratio of whey protein and casein in canned milk and milk-containing canned goods.

9. Certified measuring methods which provide objective and accurate results of the checks (tests) must be used to determine the identification parameters of milk and its processing products.

10. The results of the identification of a specific milk processing product shall be analyzed and documented in the form of an identification report which must include:

1) information on the organization that identified the milk or its milk processing products;

2) information on the producer of the milk or milk processing product, including the location (address) and contact details of a legal entity, or the address and last name, first name and

patronymic of a physical person, including an individual entrepreneur;

3) the product name and the name of its classification attributes;

4) information on the milk or milk processing product that is needed to identify it;

5) the date of production, expiration date, storage life (where applicable), sell-by date (where applicable), storage conditions, specific marking instruction, and special marking (where applicable) of the milk or milk processing product;

6) the results of the checks (tests) of the product in an accredited testing laboratory (center) (if required), including organoleptic parameter checks (tests);

7) packaging information, including type of packaging, net weight or volume of the product in the retail package or shipping container;

8) product lot size;

9) information on conformity of the marking to the present Federal Law;

10) name of the standards and regulatory and (or) technical documents to which the product conforms (where applicable), or other documents containing a description of the product, including a product imported into the Russian Federation (supply contract, health certificate, certificate of origin, document certifying the product's safety parameters, the product's certificate of quality, specifications for the product);

11) findings on the conduct of additional checks (tests) (if required);

12) findings on the product's conformity to its stated name and (or) specific lot and declared parameters.

Article 26. Identification Parameters of Milk, its Processing Products, Ferments, Probiotic Microorganisms, and Enzyme Preparations

1. The following groups of property parameters shall be used to identify milk, its processing products, ferments, probiotic microorganisms and enzyme preparations:

1) organoleptic – appearance, consistency, taste, odor, color and other organoleptic parameters specified in the standards and regulatory and (or) technical documents for the production of a specific product (where applicable) and (or) other documents containing a description of the product;

2) physiochemical – the constituent mass fractions of milk and its processing products, acidity, density, temperature, solubility index, viscosity and other physiochemical parameters specified in the standards and regulatory and (or) technical documents for the production of a specific product or other documents containing a description of the product;

3) microbiological – the specie and genus composition of microorganisms, the number of microorganisms of a particular specie or genus in a unit of weight or volume of a specific product in accordance with the present Federal Law, and the standards, regulatory and (or) technical documents for the production of a specific products (where applicable) and (or) other documents containing a description of the product.

2. The following parameters shall be used to identify raw milk:

1) the identification parameters of milk obtained from various types of farm animals which are set forth in addendum 9 hereto and determine its name (cow's milk, goat's milk, sheep's milk, mare's milk, buffalo's milk);

2) the organoleptic and physiochemical indicators set forth in addenda 9 and 10 hereto and used to identify raw cow's milk and cream;

3) the indicators specified in the standards and regulatory and (or) technical documents used to identify milk obtained from other types of farm animals.

3. The following parameters shall be used to identify milk processing products:

1) the organoleptic indicators specified in clause 1, part 1 of the present Article, inclusive of the parameters listed in addendum 11 hereto;

2) the physiochemical and microbiological parameters specified in clause 2, part 1 of the present Article, inclusive of the parameters listed in addendum 12 hereto.

4. The presence of glaze and food products used for decoration (wafers, chocolate, milk or fruit

glaze, caramel, nuts, biscuits, fruits, candied fruits, chocolate, and other foods that are not constituents of milk processing products) shall be disregarded during identification of glazed and decorated milk processing products.

5. During identification of enriched milk processing products, a determination shall be made as to the presence and content level of substances added thereto and the correspondence of the level of those substances to the information contained on the label or packaging.

6. Milk-based children's food products shall be identified with due account for the physiochemical parameters set forth in addendum 13 hereto. Milk-based products that are preschool children's food products and school age children's food products shall be identified with due account for the physiochemical parameters set forth in addendum 14 hereto.

7. Enzyme preparations shall be identified by expert evaluation of the producer documents specified in clause 1, part 5, Article 25 of the present Federal Law based on the following parameters:

1) substrate specificity;

2) enzyme preparation activity;

3) nature of enzyme origin.

8. Ferments and probiotic microorganisms (probiotics) shall be identified by expert evaluation of the producer documents specified in clause 1, part 5, Article 25 of the present Federal Law based on the following parameters:

1) nature of microorganism origin;

2) specie and genus of microorganism composition;

3) number of viable cells in a gram or unit of ferment activity.

Chapter 10. Conformity Assessment of Milk and its Processing Products to the Present Federal Law

Article 27. Rules for Conformity Assessment of Milk and its Processing Products to the Present Federal Law

1. A conformity assessment of milk and its processing products, as well as their production processes related to the mandatory requirements for such products prescribed by the present Federal law, shall be made in the form of government monitoring (oversight) of compliance with the mandatory requirements and in the form of validation of the conformity of milk and its processing products to the prescribed requirements in the form and manner stipulated by chapter 11 hereof.

2. A conformity assessment of milk and its processing products, as well as their production processes related to the mandatory requirements for such products prescribed by the present Federal law, shall be made in the form of government monitoring (oversight) by the federal monitoring and oversight authority for public health and disease control and consumer rights, the federal monitoring and oversight authority for animal health, and the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) public health and disease control and consumer rights, and animal health.

3. If violations of the present Federal Law are uncovered, the federal authorities exercising monitoring and oversight functions and the functions specified in part 2 of the present Article shall have the right:

1) to issue a violation correction order and set a reasonable deadline for correction taking into account the nature of the violation;

2) to take measures under Russian Federation law to prevent harm to the life or health of citizens, the property of physical persons or legal entities, national or municipal property, the environment, or the life or health of animals and plants;

3) to inform the agencies that issued the conformity certificate or the agencies that registered the conformity declaration of the need to suspend or cancel the validity of the conformity declaration or conformity certificate;

4) to call the producer (seller, person acting for a foreign producer) to account under Russian

Federation law;

5) to decide to take legal recourse to force a mandatory recall of milk and its processing products that do not conform to the present Federal Law.

4. It is not allowed to demand from a producer (seller) documents for assessing or certifying the conformity of milk and its processing products to the present Federal Law other than those specified in Articles 31 and 32 hereof.

Article 28. Subjects of Government Monitoring (Oversight)

Government monitoring (oversight) of conformity with the present Federal Law shall be exercised in relation to:

1) the production processes, storage, shipment, sale and disposal of nonindustrial raw milk, raw cream, and milk processing products – by the federal monitoring and oversight authority for animal health, and the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) animal health;

2) the production processes, storage, shipment, sale and disposal of milk and its processing products intended for use in food (at the stage of acceptance and commissioning of industrial facilities and periodic verification of compliance by the producer (seller, person acting for a foreign producer) with the present Federal Law and the arrangements for averting harm) – by the monitoring and oversight authority for public health and disease control and consumer rights;

3) milk and its processing products in circulation if information on their nonconformity at the production stage with the requirements hereof is found to be accurate – by the monitoring and oversight authority for public health and disease control and consumer rights, and the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) public health and disease control and consumer rights.

Chapter 11. Conformity Validation of Milk and its Processing Products to the Present Federal Law

Article 29. Forms of Conformity Validation of Milk and its Processing Products to the Present Federal Law

1. Milk and its processing products sold in the Russian Federation shall be subject to mandatory conformity validation to the present Federal Law in the form of acceptance of a conformity declaration (hereafter – declared conformity) or mandatory validation as prescribed herein.

2. Secondary milk raw material and milk processing byproducts not intended for use in food shall not be subject to mandatory conformity validation in the form of declared conformity or certification.

3. In addition to other proofs of the conformity of milk and its processing products to the present Federal Law, conformity validation may also use as a proof compliance with international standards and (or) national standards which contain similar requirements.

4. A declarant shall initiate voluntary conformity validation to national standards, industry standards, codes of practice, voluntary certification systems or the terms of agreements for milk and its processing products and their production processes, storage, shipment, sale and disposal in the form of a voluntary certification.

5. Voluntary certification of milk and its processing products and their production processes, storage, shipment, sale and disposal shall be based on the terms of the agreement between the declarant and the certification agency.

6. Voluntary conformity validation of milk and its processing products and their production processes, storage, shipment, sale and disposal may not supersede mandatory validation of their conformity to the requirements hereof.

Article 30. Rights and Responsibilities of Declarants as Regards Validation of the Conformity of Milk and its Processing Products to the Present Federal Law

1. The declarant of the conformity of milk and its processing products may be a legal entity or individual entrepreneur registered under Russian Federation law that is the producer or seller or

has been contracted to act for a foreign producer with regard to ensuring conformity of supplied milk and its processing products to the requirements hereof and with regard to liability for nonconformity of milk and its milk processing products thereto.

2. The declarant of the conformity of milk and its processing products to the requirements hereof may be the persons specified in part 1 of the present Article, as well as foreign physical persons or legal entities that have undertaken to ensure the conformity of supplied milk and its processing products to the requirements of the present Federal Law and to be liable for nonconformity thereto of the milk and its processing products supplied under supply agreements duly formalized under Russian Federation law.

3. The declarant shall have the right to choose the form of conformity validation and the conformity validation schedule stipulated herein for milk and its processing products.

4. The declarant must ensure that the milk and its processing products conform to the requirements hereof.

5. The declarant may have other rights and responsibilities under Russian Federation law.

Article 31. Mandatory Conformity Validation of Milk and its Processing Products in the Form of a Conformity Declaration

1. A conformity declaration of milk and its processing products shall be effected by means of acceptance of a conformity declaration based on self-provided proof and (or) based on proof obtained in cooperation with a certification agency and (or) accredited testing laboratory (center) (hereafter – third party).

2. The validity of a conformity declaration of a lot of raw milk or raw cream sold under long-term supply agreements or under contracts shall not exceed one year.

3. The validity of a conformity declaration of a lot of milk or its processing products shall be commensurate with the shelf life of those products.

4. The validity of a conformity declaration of commercially made milk processing products shall not exceed five years.

5. A conformity declaration may be applied to a lot of milk or a lot of similar milk products for which the same conformity requirements have been stipulated.

6. The following conformity declaration procedure shall be established for validating the conformity of milk and milk products to the requirements hereof:

1) 2d – conformity declaration of milk or milk products based on self-provided proof and the positive results of checks (tests) of samples of the milk or its processing products obtained with the participation of a third party;

2) 3d – conformity declaration of milk or its processing products based on the positive results of checks (tests) of samples of the products obtained with the participation of a third party, and a quality system certificate obtained at the production stage of the products;

3) 4d – conformity declaration of milk or its processing products based on the positive results of checks (tests) of product samples of the products obtained with the participation of a third part, and a quality system certificate obtained at the inspection and testing stage of the products;

4) 5d – conformity declaration of milk or its processing products based on the positive results of checks (tests) obtained by means of representative sampling of lots of the products with the participation of a third party;

5) 7d – conformity declaration of milk or its processing products on the basis of the positive results of checks (tests) of samples of the products conducted internally or by engaging other companies on the declarant's instructions, and a quality system certificate at the planning and production stage of the products.

7. Upon selection of any conformity declaration procedure for milk or its processing products, the declarant shall assemble a set of documents which must contain:

1) registration documents and contact information of the declarant;

2) name, general description and purpose (where applicable) of the products;

3) the national standard or industry standards for the milk or its processing products (for Russian

producers) or the international standard or detailed description of the products specifying their main properties, storage conditions, and shelf life (for foreign producers) voluntarily used to ensure compliance with the requirements hereof;

4) reports of the checks (tests) and measurements of samples of the milk or its processing products conducted in an accredited testing laboratory (center) - for conformity declaration of the products to the requirements hereof using procedures 2d, 3d, and 4d, or reports of the checks (tests) and measurements obtained by means of representative sampling of the milk or its processing products in an accredited testing laboratory (center) - for conformity declaration of the products to the requirements hereof using procedure 5d, or reports of the checks (tests) and measurements of samples of the products conducted internally or by engaging other companies on the declarant's instructions - for conformity declaration of the products to the requirements hereof using procedure 7d;

5) a quality system certificate at the production stage of the products - for conformity declaration of the milk or its milk processing products using procedure 3d;

6) a quality system certificate at the stage of inspection and checking (testing) and measurement of the products - for conformity declaration of the milk or its processing products using procedure 4d;

7) a quality system certificate at the planning (development) and production stage of the products - for conformity declaration of milk processing products using procedure 7d;

8) documentation of the arrangement and conduct of production monitoring by the declarant, as well as the arrangement and conduct of government monitoring in relation to the declarant and the products by the federal monitoring (oversight) authority for public health and disease control and consumer rights - for any conformity declaration procedure for milk and its processing products, except for procedure 5d;

9) waybills, agreements (contracts) to supply milk or its processing products duly formalized under Russian Federation law, certificate of origin of the products, health certificate, and government registration certificate of the newly formulated milk processing products or ones being imported (supplied) for the first time to validate that these products conform to the requirements hereof - for conformity validation of the milk or its processing products using procedure 5d;

10) animal health certificates or statutory certificates to validate that the raw milk or raw cream conforms to the requirements hereof.

8. In addition to a characterization of the milk or its processing products, reports of checks (tests) and measurements of samples or a representative sampling of those products must contain:

1) a description of the milk or its processing products directly or in the form of a reference to the national standards, industry standards or international standards to which they conform;

2) a finding on conformity of the samples or representative sampling of the milk or milk processing products to the requirements of the documents specified in clause 3, part 7 of the present Article, to which these products conform, and to the requirements of the present Federal Law;

3) the results of the checks (tests) of the samples or representative sampling of the milk or milk processing products obtained internally, by engaging a third party and (or) when the conformity of these products to the requirements hereof is validated by another company at the declarant's instruction using procedure 7d.

9. If the selected conformity declaration procedure stipulates a quality system certificate but one is not available, the declarant shall apply to the quality system certification agency for a quality system certificate. The certification agency shall certify the quality system and issue a quality system certificate if the results are positive.

10. Upon selection of any conformity declaration procedure, the declarant shall take the necessary measures to ensure that the production and sale of the milk and its processing products conform to the requirements hereof.

11. The declarant shall accept and duly register the conformity declaration under Russian

Federation law.

12. The declarant shall mark the milk and its processing products for which the conformity declaration is accepted with a conformity sign.

13. The quality system certification agency shall inspect the certified quality system at the stages stipulated under procedures 3d, 4d, and 7d with the regularity set by agreement between the declarant and the quality system certification agency, but at least once a year.

14. The declarant shall keep the conformity declaration and the documentation thereof for three years from the expiration of the conformity declaration. A copy of the conformity declaration shall be kept at the federal authority which builds and maintains a single conformity declaration registry.

Article 32. Mandatory Conformity Validation in the Form of Mandatory Certification of Milk Processing Products

1. Mandatory certification of milk processing products shall be carried out by a product certification agency whose area of accreditation extends to food, including milk processing products, on the basis of an agreement between the declarant and the product certification agency according to the procedures set forth herein.

2. The certification agency shall issue a conformity certificate for commercially made milk processing products for a period that is dependent on the products' state of production and consistency of quality but shall not exceed three years.

3. The conformity certificate for a lot of milk processing products shall be issued for the duration of their shelf life.

4. The declarant shall keep the conformity certificate, and the issuing certification agency shall keep a copy of the conformity certificate and the underlying documentation for at least two years from the certificate's expiration.

5. The following mandatory certification procedures are prescribed for validating milk processing products' conformity to the requirements hereof:

1) 3s – certify commercially made milk processing products on the basis of the positive results of sample testing obtained with the participation of an accredited testing laboratory (center), with follow-up monitoring of the certified milk processing products by the certification agency;

2) 4s – certify commercially made milk processing products on the basis of the positive results of sample testing obtained with the participation of an accredited testing laboratory (center) and an analysis of the state of production of the products, with follow-up monitoring of the certified milk processing products and, if needed, their state of production by the certification agency;

3) 5s - certify commercially made milk processing products on the basis of the positive results of sample testing of the products obtained with the participation of an accredited testing laboratory (center), and certification of the declarant's quality control system, with follow-up monitoring of the certified milk processing products by the certification agency and of the declarant's certified quality control system by a quality control system certification agency;

4) 6s – certify lots of milk processing products on the basis of the positive results of checks (tests) of a representative sampling of the products obtained with the participation of an accredited laboratory (center).

6. Upon selection of any mandatory certification procedure for milk processing products, the declarant shall assemble a set of documents which must contain:

1) registration documents and contact information of the declarant;

2) name, general description and purpose (where applicable) of the products;

3) the national standard or industry standard for the products (for Russian producers) or the international standard or detailed description of the products specifying their main properties, storage conditions, and shelf life (for foreign producers) voluntarily used to ensure compliance with the requirements hereof;

4) conformity certificates and (or) conformity declarations for the raw material, components, and packaging materials used to make the milk processing products;

5) conformity certificate for the producer's quality control system - for procedure 5s. In the absence of a certificate, the declarant shall apply to an accredited quality control system certification agency for a quality system certificate. The agency shall certify the producer's quality system and issue him a quality system certificate if the results are positive;

6) documentation of the organization and implementation of production monitoring by the producer, as well as government monitoring in relation to the declarant and the milk processing products by the federal monitoring (oversight) authority for public health and disease control and consumer rights - for any mandatory certification procedure, except for procedure 6s;

7) waybills duly formalized under Russian Federation law, an agreement (contract) to supply milk processing products, certificate of origin of the products, health certificate, and government registration certificate for new milk processing products or ones being imported (supplied) for the first time - for procedure 6s.

7. Upon selection of any mandatory certification procedure, the declarant shall apply to certify the milk processing products and simultaneously submit the set of documents stipulated in part 6 of the present Article to an accredited product certification agency.

8. The product certification agency shall review the set of documents submitted by the declarant and take a decision regarding the application. If the application is approved, the certification agency shall select commercially made milk processing product samples or a representative sampling from a lot of those products, identify them, set up a check (test) program and send the samples or representative sampling of the products to be checked (tested) by an accredited testing laboratory (center).

9. The accredited testing laboratory (center) shall check (test) the samples or representative sampling of the products and issue a report of the checks (tests) and measurements.

10. In addition to a characterization of the product samples or a representative sampling of the milk processing products, the report on the checks (tests) and measurements thereof must include a description of the products directly or with reference to the national standard, industry standards or international standard or description (if available) to which these products conform, as well as a finding on the conformity of the product samples or representative sampling to the requirements of the documentation and the requirements hereof.

11. For certification of milk processing products using procedure 3s, on the basis of the positive results of an analysis of the set of submitted documents, identification of the milk processing products to be certified, and the positive results of the checks (tests) of the product samples conducted at an accredited testing laboratory (center), the product certification agency shall issue to the declarant a conformity certificate for up to three years, taking into account the stability of the declarant's work.

12. For certification of milk processing products using procedure 4s, the certification agency shall analyze the state of production of the products to check the conditions necessary to make and sell them in accordance with the prescribed requirements, and shall issue a conformity certificate to the declarant on the basis of the positive results of an analysis of the set of submitted documents, identification of the milk processing products to be certified, the positive results of the checks (tests) of the product samples conducted in an accredited testing laboratory (center) and the positive results of an analysis of the state of their production.

13. For certification of milk processing products using procedure 5s, on the basis of the positive results of an analysis of the set of submitted documents, identification of the milk processing products to be certified, and the positive results of the checks (tests) of product samples conducted in an accredited testing laboratory (center), and contingent upon the availability of a quality system certificate, the certification agency shall issue a conformity certificate to the declarant.

14. For certification of milk processing products using procedure 6s, the certification agency shall issue a conformity certificate to the declarant on the basis of the positive results of an analysis of the set of submitted documents, identification of the milk processing products to be certified, and the positive results of the checks (tests) of a representative sampling of the

products conducted in an accredited testing laboratory (center).

15. The declarant shall mark the milk processing products with the conformity sign when he receives the conformity certificate for the milk processing products.

16. The declarant shall take the necessary measures to ensure that the production and sale of the milk processing products conform to the requirements hereof.

17. Throughout the conformity certificate's term of validity, the product certification agency shall monitor the certified milk processing products by means of periodic checks (tests) of product samples selected at the producer's ready product warehouse (if the products were certified using procedures 4s and 5s) or at the producer's and seller's warehouses (if the products were certified using procedure 3s) in accordance with an approved monitoring schedule, and, if necessary, shall reevaluate the products' state of production (if the milk processing products were certified using procedure 4s).

18. Based on the results of its monitoring of the certified milk processing products, the certification agency shall take one of the following decisions vis-à-vis such products:

1) confirm the validity of the conformity certificate;

2) suspend the conformity certificate;

3) invalidate the conformity certificate.

19. The quality control system certification agency that certified the declarant's quality control system shall monitor the declarant's certified quality control system.

Article 33. Specific Issues Associated with Validation of the Conformity of Milk and its Processing Products to the Present Federal Law

1. Validation of the conformity of raw milk and raw cream to the requirements hereof shall be effected in the form of a conformity declaration using any of the procedures stipulated herein.

2. A producer shall make a declaration of conformity of raw milk and raw cream to the requirements hereof provided he complies with Russian Federation animal health legislation and article 5 hereof, and taking into consideration the results of the animal health checks (tests) conducted annually by the authorities of constituent entities of the Russian Federation empowered to monitor (oversee) animal health.

3. Conformity to the requirements hereof of fluid milk and its processing products with a shelf life of up to 30 days shall be validated in the form of a conformity declaration using procedure 3d, 4d or 7d or in the form of mandatory certification using procedure 4s or 5s.

4. Conformity to the requirements hereof of fluid milk and its processing products with a shelf life of more than 30 days shall be validated in the form of a conformity declaration using procedure 3d, 4d, 5d or 7d or in the form of mandatory certification using procedure 4s, 5s or 6s.

5. Conformity to the requirements hereof of milk-based children's food products shall be validated in the form of a conformity declaration using procedure 3d or 4d or in the form of mandatory certification using procedure 4s, 5s or 6s.

6. Conformity to the requirements hereof of milk processing products supplied for government needs shall be validated in the form of a conformity declaration using procedure 5d or in the form of mandatory certification using procedure 6s.

Article 34. Acceptance of Conformity Validation Results

1. Conformity declarations and conformity certificates have equal validity in law irrespective of the mandatory conformity validation procedure and are applicable throughout the Russian Federation.

2. Conformity validation results obtained outside the Russian Federation shall be accepted pursuant to article 30 of the Federal Law "On Technical Regulation."

Chapter 12. Requirements as to the Packaging, Marking, and Labeling of Milk and its Processing Products

Article 35. Packaging Requirements for Milk and its Processing Products

1. Milk and its processing products intended for sale must be prepackaged and packed into containers and (or) packages which are made from environmentally safe materials permitted for food contact by the federal monitoring and oversight authority for public health and disease control and consumer rights, and which ensure the safety and quality of milk and its processing products throughout their shelf life.

2. Milk-based baby food products must only be prepackaged and packaged in small airtight individual packaging that does not exceed the following volume:

1) 1 kilogram – dry products (adapted infant formula, follow-up formula, supplemental feeding products, instant products, milk-based cereals);

2) 0.2 liter - fluid adapted, partially adapted formulas, follow-up formulas;

3) 0.25 liter – fluid milk, fluid cream, fermented milk products;

4) 0.1 kilogram – milk-based children's spreads.

3. Milk-based food products for preschool and school age children must only be prepackaged in airtight packages. Fluid milk-based foods for preschool and school age children must be in packages of at least 0.2 liter and no more than 2 liters; children's spreads – up to 200 grams.

4. It is not allowed to use consumers' (end users') containers when selling perishable milk processing products in bulk or unpackaged.

5. Producers or sellers shall package sliced milk processing products in conditions that keep the products safe and ensure that their organoleptic properties are maintained.

6. Each milk processing product package must have a marking and label and, when needed, an insert or tag containing consumer information pursuant to article 36 hereof.

7. Milk processing products in damaged containers or packaging shall be recalled.

Article 36. Requirements as to the Marking of Milk and its Processing Products

1. Milk and its processing products must be accompanied by consumer information that complies with Russian Federation consumer rights law and the requirements of the present Federal Law.

2. Consumer information shall be placed on each unit of a milk or milk product multiunit package, each reusable container or shipping container unit, as well as on each retail unit of such a product.

3. Each unit in a multiunit package and each reusable container or shipping container of such a product must be marked with the following consumer information:

1) name of the milk or milk products pursuant to the requirements hereof;

2) producer's name and location;

3) producer's trademark;

4) net weight and gross weight of the multiunit package, reusable container or shipping container;

5) number of retail units in a multiunit package, reusable container or shipping container;

6) expiration date;

7) date of production;

8) storage conditions;

9) retail unit net weight;

10) identifying mark of the standard or regulatory or technical documents to which the product conforms;

11) lot number;

12) information on validation of the product's conformity to the requirements hereof;

13) necessary warnings or handling marks – "Keep away from sunlight," "Temperature limitation," "Keep dry."

4. Marking may be omitted from a milk product multiunit package or shipping container that is wrapped in transparent protective polymer materials. In this case the consumer information will be the information on the labels, with the labels containing additional data on the number of retail units and weight of the product in the multiunit package or shipping container.

Markings that cannot be viewed, including handling marks, shall be placed on an insert or provided to the consumer by any other available method.

5. Milk or milk product multiunit packages or shipping or retail containers shall be marked by affixing labels that have been printed or otherwise made so that they are clearly readable.

6. The names of milk and its processing products must correspond to the concepts defined in Article 4 hereof. Producers' assortment marks and trade name may be added to the names of such products.

7. The type of farm animal, with the exception of cows, from which the milk has been obtained must be included on the labels before or after the concept "milk."

8. Concepts related to the heat treatment of milk or its processing products shall be placed after the product name, for example "milk pasteurized," "cream sterilized."

9. In addition to a concept related to the heat treatment method of milk and milk products, other product-related concepts, for example "milk pasteurized aromatized (with aroma)," may follow the names of such products.

10. The names of dairy component products must correspond to the concepts defined for dairy products, and must contain in immediate proximity to those concepts clear descriptions of other concepts characteristic of the product, for example "curds with fruit bits," "kefir fruity," "processed cheese with ham."

11. The concept "bioproduct" shall be placed on the labels and packaging of such milk products in any convenient spot in the form of a single word or compound words using the first part of "bio…" compound words and the name of the product, for example "biokefir," "bioryazhenka."

12. Concepts used to characterize the production methods of such products or the specific attributes of the composition of the raw materials or the composition of a ferment shall be stated in its name – "milk beverage," "milk whole," "cream recombined," "fermented milk beverage."

13. Information on partial use of dry dairy products, except for the use of dry dairy products for standardization purposes, shall be placed alongside the information on ready product components in the form of a printed message: "Made with dry milk (cream, whey)."

14. It is not allowed to use the concepts of fermented milk products defined herein when labeling milk-containing and fermented products in whose names the concept "milk-containing" or the concept "fermented" have to be replaced by concepts characterizing the technology for producing such products, for example "kefir," "kefir heat-treated," "yogurt," "yogurt heat-treated."

15. The concept "product" in the names of milk-containing products may be replaced, or, in the names of dairy component products, supplemented by a concept characterizing the product's consistency or form, as the case may be (jelly, kisel, cocktail, creme, mousse, beverage, paste, roll, sauce, soufflé, torte), for example "milk-juice cocktail," "sour cream sauce," "milk kisel," "curd soufflé with nuts," "cheese roll with herbs."

16. Definitions of the concepts of varieties and types of cheese (hard, medium-hard, soft, fresh (not aged), chunk, spreadable) shall be used in the names of cheeses at the discretion of the producer.

17. The concept "enriched" shall be used in combination with the names of applicable products and shall be accompanied by information on the presence and amount of additives, including their recommended daily allowance, as well as by recommendations for the use of such products. 18. The concepts defined in Article 4 hereof must not be used in assortment marks or other additional names of milk and its processing products if such products do not correspond to the identification parameters prescribed herein.

19. Parts of the milk or dairy product names defined in Article 4 hereof may be written on the front of the package of such products provided that the full names are written on the same units of the retail unit.

20. It is not allowed to use the concepts defined herein in the names of products that are not milk or dairy products or dairy component products, including words that are a part of those names or their various combinations in producers' trade names, when marking such products, on their labels, or for advertising or other purposes that could mislead consumers.

21. It is not allowed to use the concept "butter," including in producers' trade names, when marking butter pastes or cream-vegetable spreads, on the labels of such products, or for advertising or other purposes that could mislead consumers. It is not allowed to use the concept "rendered butter," including in producers' trade names, when marking cream-vegetable rendered mixtures, on the labels of such products, or for advertising or other purposes that could mislead consumers.

22. It is not allowed to use the concepts "milk," "creamy," or "plombir" when marking ice cream that contains vegetable oil.

23. Raw milk and raw cream sold by physical persons or legal entities for processing must be marked on the shipping container and be accompanied by waybills containing the following information:

1) product name;

2) identification parameters (except for the dry solids mass fraction of milk);

3) name of the producer – physical person, including individual entrepreneur (last name, first name, patronymic), name of the producer – legal entity (agricultural organization, peasant (farm) holding);

4) address of the producer;

5) volume (in liters) or weight (in kilograms);

6) date and time (hours, minutes) of shipment;

7) temperature when shipped;

8) lot number.

24. Noncommercial raw milk, raw cream, and milk processing products sold by physical persons, including individual entrepreneurs, at markets, including farmers' markets, must be accompanied by information on the production site (address), names and date of production of the products.

25. Milk and its processing products prepackaged in retail units and wholesaled or retailed in the Russian Federation must be marked with the following information:

1) name of the products using the concepts defined in Article 4 hereof and complying with the requirements as to their use prescribed by the present Article;

2) fat mass fraction in percentages;

3) fat mass fraction in percentages in the fat phase (for milk-containing products);

4) the producer's name and location (address, including country and (or) place of origin of such products) and the company in the Russian Federation authorized by the producer to accept consumer complaints (if any) regarding the milk and its processing products in the Russian Federation;

5) trademark (if any) of the producer of the milk and its processing products;

6) the products' net weight or volume. The net weight shall be shown for the products if they have a free-flowing, hard, spreadable or viscoplastic consistency or if there is no method for measuring their density. The volume or net weight (at the producer's discretion) shall be shown for products which have a fluid consistency if there are methods for measuring the density and (or) batch measuring equipment for such products;

7) the products' composition, including their components.

The list of such products' components shall be in the descending order of their mass fraction at the time the product is made. If a component is a food comprised of two or more components it may be included under its own name in the composition of milk processing products.

Dairy products which are a constituent of a dairy component product or milk-containing product shall be shown under their own names in the list of components. Components which are functionally necessary for the production process and are not a constituent of the ready product shall be shown after the word "using." The product composition shall show the names of foods, food additives, flavorings, and components of a non-traditional composition.

The components of glazes shall be shown separately;

8) nutritional value (fat, protein, and carbohydrate, including sucrose, content in the ready product) in percentages or in grams per 100 grams of the products, caloric value in calories or kilocalories;

9) content of microorganisms (lactate, Bifidobacterium and other probiotic microorganisms, as well as yeasts – colony-forming units in a gram of such product) in a ready fermented or cultured product;

10) content in the ready enriched product of micro- and macroelements, vitamins and other substances used to enrich the product showing the ratio of the amount of substances added to the product to the daily consumption of those substances and the specifics of the product usage;

11) information on the presence of components obtained using genetically modified organisms (if they amount to more than 0.9 percent);

12) storage conditions of milk and milk products (including prior to the opening of milk-based children's food products if open packages are stored, and mandatorily after the opening of those packages, and for perishable products with a shelf life of up to 30 days – if the storage conditions for such products are different for unopened and opened packages);

13) date of production and date of packaging of the milk products (if these dates differ) in twodigit numbers – hour, date, month (for perishable milk products with shelf life in hours), date, month, year (for perishable milk products with a shelf life of up to 30 days), month, year (for nonperishable milk products, including canned products);

14) expiration date shown in two-digit numbers – hour, date, month (for perishable milk products with shelf life in hours), date, month, year (for perishable milk products with a shelf life of up to 30 days), month, year (for nonperishable milk products, including canned products). The expiration date shall be shown after the words "Expires," "Best before" or "Use before." The shelf life may be shown in hours, days, months ("Shelf life 36 hours," "Shelf life 14 days," "Shelf life 6 months," "Good for 14 days," "Good for 6 months");

15) methods and conditions for use of the milk products (where applicable);

16) document to which the product conforms and which can be used to identify it;

17) information on validation of conformity of the product to the requirements hereof;

18) information on the use of dry whole milk or dry skim milk to make the milk product (the concepts are to be found in Article 4 hereof) shall be placed alongside the name of the applicable type of milk product on the front of the retail pack in the same lettering. It is not allowed to use the concept "milk" on retail pack of milk and its processing products if dry whole milk or dry skim milk is used.

26. Milk processing products, concentrated (evaporated) and dry milk processing products must be marked with the following additional information:

1) date of production and expiration date of the products shall be placed on the top or bottom of cans or packs. If the expiration date uses the words "Expires" or "Use before," next to it shall be indicated the place where such information can be found using the words "See line one or two on top or bottom of can" or "See top or bottom of pack." If the expiration date uses the words "Good for" or "Sell within," next to it shall be placed the shelf life in months and the words "Date of production on line one or two on top or bottom of can" or "Date of production on top or bottom of pack";

2) type of sugars (sucrose, fructose, glucose, lactose) for concentrated (condensed) milk processing products with sugar.

27. Information may be placed on a cheese covering or cheese coating using an indelible innoxious color or self-adhesive labels duly permitted for contact with dairy products, or by other available method. Cheese, processed cheese, and cheese products must be marked with the following additional information:

1) assortment marks or the name of the variety of cheese ("Rossiisky," "Uglichsky," "Suluguni," and such);

2) fat mass fraction (in dry solids equivalent) in percentages;

3) genus of the main starter microflora and nature of the origin of the milk-clotting enzyme

preparations;

4) shelf life of soft, pickled and processed cheese;

5) shelf life and storage life (within the shelf life) of extra-hard, medium-hard, hard and dry cheeses.

28. Milk-based baby food products must be marked with the following additional information:

1) recommendations for use;

2) preparation conditions (where applicable), storage conditions and conditions of use after opening;

3) the age of the children for whom the products are intended:

a) from birth – adapted formulas;

b) over six months – follow-up formulas;

c) over six months – curds and curd-based products;

d) over eight months – unadapted dairy products.

29. The labels of milk-based children's food products must say: "For children." The size of the lettering must be at least as large as the main lettering used. Packages of adapted formulas and follow-up formulas must carry the warning: "Breast feeding is better for babies."

30. With the exception of the products specified in part 28 of the present Article, information on other dairy products, dairy component products, and milk-containing children's food products intended for babies or preschool or school age children must comply with the present Federal Law and the regulatory and (or) technical documents to which such milk products conform.

31. The allowable deviations in a milk processing product's nutritional value from the actual nutritional value shown on its packaging or label must not exceed the level specified in addendum 18 hereto. A milk processing product's labeled nutritional value must be based on the weighted averages obtained by the computational method based on known values, or weighted averages obtained by the producer's checks (tests) of the product or by the computational method based on tabulated values taken from official sources, or by the computational method with an analysis of the nutritional value of the components used.

32. The amount of the substances added to enriched milk processing products shall be shown based on their content level at the end of the products' shelf life. Due to the natural reduction in the amount of vitamins in milk processing products during their shelf life, the vitamin content level may be increased when making such products but by no more than 50 percent for fat-soluble vitamins and no more than 100 percent for water-soluble vitamins in relation to the declared parameters.

Article 37. Labeling Rules

1. Labels shall be placed on each unit of a retail pack and (or) shipping container and positioned in the same easily readable location. The label must be in Russian. Additional information may be in the official languages of the republics, in the languages of the peoples of the Russian Federation, or in foreign languages. Milk processing product information in other languages must be identical to the information in Russian.

2. Label information must comply with article 36 hereof. The name of the milk processing product shall be included on a label positioned on the front of the retail pack using at least 9.5 size lettering, and on retail packs with a volume or weight of at least 100 milliliters (grams) using at least 8.5 size lettering. If all the necessary information cannot fit on a label, some of the information may be placed on an insert, except for the producer's name, milk processing product name, net weight or volume, composition, nutritional value, date of production, shelf life or storage life, storage conditions, name of the document to which the product conforms, and the conformity sign. The label must say: "Additional information – see insert."

3. When milk and milk products are sold by retail outlets or public food service establishments, inserts for each unit of prepackaged milk or its processing products which contain consumer information pursuant to article 36 hereof may be substituted for the labels of the shipping container and (or) multipack and (or) large retail packages.

Chapter 13. International Standards and National Standards

Article 38. International Standards

International standards for milk and its processing products and their production, storage, shipment, sale and disposal shall be applied as prescribed by Russian Federation legislation on technical regulation and on the basis of the Russian Federation's international instrument.

Article 39. National Standards

National standards for milk and its processing products and their production, storage, shipment, sale and disposal shall be applied voluntarily and to an extent that is not at variance with the present Federal Law.

Article 40. International Instruments

If the Russian Federation's international instrument, duly ratified pursuant to Russian Federation legislation, establishes rules other than those stipulated herein, the rules of the Russian Federation's international instrument shall apply.

Chapter 14. Liability for Noncompliance with the Present Federal Law. Redress of Injury

Article 41. Liability for Noncompliance with the Present Federal Law

1. Producers (sellers, persons under contract to act for a foreign producer to ensure conformity of supplied products to the requirements hereof) shall be liable under Russian Federation law for noncompliance herewith.

2. Employees of producers (sellers, persons under contract to act for a foreign producer to ensure conformity of supplied products to the requirements hereof) who violate the present Federal Law shall be held materially, disciplinarily and administratively liable under Russian Federation law.

Article 42. Redress of Injury Related to Noncompliance with the Present Federal Law

1. Producers (sellers, persons under contract to act for a foreign producer to ensure conformity of supplied products to the requirements hereof) shall redress injury to the life or health of citizens, the property of physical persons or legal entities, national or municipal property, the environment, or the life or health of animals or plants related to noncompliance herewith pursuant to Russian Federation law.

2. Producers (sellers, persons under contract to act for a foreign producer to ensure conformity of supplied products to the requirements hereof) shall, at their expense, correct the deficiencies of milk processing products, ship them to where the deficiencies are corrected and return them to the consumers, and dispose of substandard milk processing products that do not conform to the requirements hereof.

Chapter 15. Final Provisions

Article 43. Final Provisions

1. Technical regulation of the use of production facilities, equipment, and means of transportation shall be effected in accordance with regulatory and (or) technical documents and (or) codes of practice prior to entry into force of the federal laws on technical regulations for the production, storage, shipment, sale and disposal of food.

2. Pending entry into force of the present Federal Law, the Russian Federation Government shall draw up and approve the rules and methods for checking (testing) and measuring milk and milk products, as well as the rules for selecting samples to be checked (tested) and measured, which are necessary to implement the present Federal Law.

3. Milk and milk products released for circulation in the Russian Federation shall be subject to mandatory conformity validation as stipulated herein from the day the present Federal Law enters into force.

4. The provisions of Russian Federation Law No. 4979-I of May 14, 1993 "On Animal Health,"

Federal Law No. 52- Φ 3 of March 30, 1999 "On Public Health and Disease Control," and Federal Law No. 29- Φ 3 of January 2, 2000 "On Food Quality and Safety" as they pertain to conformity assessment and validation of milk and milk products and to the mandatory requirements as to related production, storage, shipment, sale and disposal shall no longer be applicable from the day the present Federal Law enters into force.

Article 44. Entry into Force of the Present Federal Law The present Federal Law shall enter into force six months from the day it is officially published. President Russian Federation

D. Medvedev

Note! The following files are attached to this document:

Addendum 1 Addendum 10 Addendum 11 Addendum 12 Addendum 13 Addendum 14 Addendum 15 Addendum 16 Addendum 17 Addendum 18 Addendum 2 Addendum 3 Addendum 4 Addendum 5 Addendum 6 Addendum 7 Addendum 8 Addendum 9

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