

Federal Law No.88-FL
of 12 June 2008

“Technical Regulation on Milk and
Milk Products”

Technical Regulation on Milk and Milk Products

The Federal Law is adopted for the purposes of
(Article 3):

- ⦿ protection of citizens' life and health;
- ⦿ prevention of consumer misleading actions and providing valid information on name, composition and consumer attributes of milk and milk products.

Technical Regulation on Milk and Milk Products

This Federal Law sets up
(Article 1, p.1):

- ⦿ Objects subjected to the technical regulation, the list and descriptions of which are contained in this Federal Law;
- ⦿ requirements to the safety of objects subjected to technical regulation;
- ⦿ rules for identification of objects subjected for technical regulation for the purpose of this Federal Law enforcement;

Technical Regulation on Milk and Milk Products

This Federal Law lays down

(Article 1, p.1):

- ⦿ rules and forms for evaluation and confirmation of compliance of objects subjected to technical regulation with this Federal Law requirements;
- ⦿ requirements to nomenclature, package, labeling of milk and milk products including requirements to name, composition and consumer attributes provided for consumers on these product packages and in documents accompanying them.

Technical Regulation on Milk and Milk Products

This Federal Law also lays down rights and obligations of participants of relations governed by this Federal Law (Article 1, p.2).

Technical Regulation on Milk and Milk Products

Objects of technical regulation the list and descriptions of which are contained in this Federal Law (Article 2, p.1) are as follows:

- ⦿ milk and milk products including milk-based baby food products put into circulation in the territory of the Russian Federation;
- ⦿ processes of manufacturing, storage, transportation, marketing and disposal of milk and milk products.

Technical Regulation on Milk and Milk Products

List of milk and milk products that are objects of technical regulation under this Federal Law (Article 2, p.2) comprises :

- ⦿ raw milk and raw cream
- ⦿ drinking milk and drinking cream;
- ⦿ liquid fermented-milk products;
- ⦿ curd and curd products;
- ⦿ sour cream and sour cream-based products;
- ⦿ cream-vegetable spread and cream-vegetable rendered mixture;

Technical Regulation on Milk and Milk Products

List of milk and milk products that are objects of technical regulation under this Federal Law (Article 2, p.2) includes :

- ⦿ butter spread;
- ⦿ cheese and cheese products;
- ⦿ canned milk, milk-containing products;
- ⦿ ice-cream and mixtures for ice-cream;
- ⦿ functionally essential components;
- ⦿ milk-based baby food products;
- ⦿ secondary products of milk processing.

Technical Regulation on Milk and Milk Products

Basic definitions

used for the purpose of this Federal Law (Article 4):

- ① milk – a product of normal physiological secretion of farm animal mammary glands, obtained from one or several animals during lactation period by one or several milkings, without any additives to or extraction of any substances from it;
- ② milk products – milk-processing products comprising milk product, milk composite product, milk-containing product, milk-processing by-product;
- ③ raw milk – milk that was not subjected to heat treatment at more than 40 °C or treatment that alters its composition;

Technical Regulation on Milk and Milk Products

Basic definitions

used for the purpose of this Federal Law

(Article 4):

- ⊙ pasteurized milk, sterilized milk, ultra-pasteurized (ultra-heat-treated) milk – drinking milk subjected to heat treatment for the purpose of compliance with specified requirements to microbiological safety parameters;
- ⊙ raw cream – cream not subjected to heat treatment at more than 45⁰C;

Technical Regulation on Milk and Milk Products

Basic definitions

used for the purpose of this Federal Law (Article 4):

fermented milk product - milk product or milk composite product produced in a way that reduces the index of active acidity (pH) and coagulation of milk fermentation protein, and/or milk products, and/or their mixtures using starter microorganisms and with subsequent adding milk ingredients of non-milk components, not for the purpose of replacement, or without their adding, and contain live starter microorganisms at the amounts specified in Annexes 4, 6, 8 and 12 to this Federal Law;

Technical Regulation on Milk and Milk Products

Basic definitions,
used for the purpose of this Federal Law (Article 4):

- ◎ cow milk butter - milk product or milk composite product based on fat emulsion, with milk fat as a predominant component, produced from cow milk, milk products and/or milk processing by-products by separation of fat phase and even distribution of milk plasma in it, with adding milk ingredients of non-milk components not for the purpose of replacement or without their adding;
- ◎ milk fat – milk product with 99.8% weight fraction of fat and with neutral flavour and produced from milk and/or milk products by milk plasma removing;

Technical Regulation on Milk and Milk Products

Basic definitions,

used for the purpose of this Federal Law (Article 4):

- ① cheese is a milk product or milk composite product produced from milk, milk products and/or milk-processing by-products using specific ferments and techniques which coagulate milk proteins with or without milk-cotting ferments, or by acid or thermal-acid methods followed by separation of cheese curd from whey, by its forming, pressing, salting, ageing or without ageing with adding milk ingredients of non-milk components not for the purpose of replacement or without their adding;
- ① ice-cream – fluffy, frozen and consumed in a frozen state sweet milk product, milk composite product or milk containing product;

Technical Regulation on Milk and Milk Products

State surveillance for compliance with the requirements of this Federal Law is carried out by (Article 28):

- ⦿ Federal executive authority performing veterinary control and surveillance (**ROSSELKHOZNADZOR**) and relative executive authorities of the Russian Federation subjects,
- ⦿ Federal executive authority performing control and surveillance in the field of sanitary and epidemiologic welfare of the population, consumer protection (**ROSPOTREBNADZOR**) and relative executive authorities of the Russian Federation subjects.

Technical Regulation on Milk and Milk Products

State surveillance for compliance with the requirements of this Federal Law is carried out by **ROSSELKHOZNADZOR** in relation to production, storing, transporting, marketing and disposal of raw milk, raw cream and milk-processing products of non-commercial production.

Technical Regulation on Milk and Milk Products

State surveillance for compliance with the requirements of this Federal Law is carried out by ROSPOTREBNADZOR in relation to:

- ⦿ production, storing, transporting, marketing and disposal of milk and milk-processing products for human consumption (at the stage of industrial facilities commissioning, periodic checks of meeting the requirements of this Federal Law and harm prevention program by producer (seller, person functioning as a foreign producer),
- ⦿ milk and milk-processing products at the stage of their circulation in case of acknowledgment of actuality of the information on non-compliance of these products with this Federal Law requirements at the production stage.

Technical Regulation on Milk and Milk Products

Requirements to raw milk and milk-processing products are laid down in Chapter 2:

- ⦿ Requirements to raw milk and raw cream safety (Article 5),
- ⦿ Requirements to specific technological processes in production, storing, transporting and disposal of raw milk and raw cream (Article 6),
- ⦿ Requirements to milk-processing products (Article 7).

Technical Regulation on Milk and Milk Products

Requirements to raw milk and raw cream safety
(Article 5):

1. Conditions of obtaining milk from farm animals, transporting, marketing and disposal of raw milk and raw cream, milk products of non-commercial production are to comply with the requirements of the veterinary legislation of the Russian Federation.
2. Raw milk should be derived from healthy farm animals in the territory free from infectious and other diseases common for humans and animals.

Technical Regulation on Milk and Milk Products

Veterinary Certificate requirements

- ⦿ Exported milk and milk products are derived from healthy animals from farms which are officially free from animal infectious diseases and produced at milk processing plants authorized for export and supervised by the EU competent veterinary service.
- ⦿ Milk and milk products are produced and shipped from farms and administrative territories which are officially free from animal infectious diseases including:
 - ⦿ FMD, rinderpest, contagious bovine pleuropneumonia, vesicular stomatitis during the last 12 months in the territory of the country;
 - ⦿ Bovine brucellosis, leucosis, tuberculosis, paratuberculosis during the last 12 months in the territory of the farm;
 - ⦿ Caprine and ovine brucellosis during the last 2 years in the territory of the farm;
 - ⦿ Caprine and ovine pox during the last 6 months in the territory of the farm.

Technical Regulation on Milk and Milk Products

Requirements to raw milk and raw cream safety (Article 5):

3. It is not allowed to consume raw milk derived during the first seven days after calving and during five days before drying off (before calving) and/or from diseased or quarantined animals.
4. Producer must ensure raw milk safety, namely the absence of inhibitive, detergent, disinfectant and neutralizing substance residuals, animal growth promoting substances (including hormones), veterinary drugs (including antibiotics) used for cattle fattening, treatment and disease prevention in animal production.

Technical Regulation on Milk and Milk Products

Requirements to raw milk and raw cream safety (Article 5):

5. Milk derived from different species of farm animals except cow milk should comply with the parameters, specified standards, regulatory documents of federal executive authorities, code of practice and/or technical documents.
6. Weight fraction of dry fat-free substances in cow raw milk should be not less than 8.2 %. Density of cow milk in which fat weight fraction is 3.5% should be not less than 1,027 kilograms per cubic meter at 20 C or not less than the equivalent parameter for milk with another fat weight fraction.

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7. Chemical and radiological safety parameters of cow raw milk and raw cream must not exceed the Federal Law specified admissible level:

Potentially dangerous substances	Admissible levels mg/kg (l) not more
Toxic chemicals	
Lead	0.1
Arsenic	0.05
Cadmium	0.03
Mercury	0.005
Mycotoxins (Aflatoxin M1)	0.0005
Antibiotics (chloramphenicol), tetracyclines, streptomycin, penicillin)	Not admissible
Inhibitive substances	Not admissible
Pesticides (in terms of fat): hexachlorocyclohexane (alpha-, beta-, gamma-isomers)	0.05 (1.25 for cream)
DDT and its metabolites	0.05 (1.0 for cream)
Radionuclides	
Cesium-137	100 Bq/l
Strontium-90	25 Bq/l

Technical Regulation on Milk and Milk Products

Under the Technical Regulation the grading into 3 grades of milk (premium, first and second) was introduced instead of 4 grades of raw milk which were used in accordance with GOST P 52054-2003 (premium, first, second and non-grade).

Milk which was classified as non-grade according to GOST P 52054-2003 is not allowed to be processed in accordance with the Technical Regulation

Technical Regulation for Milk and Milk Products

8. Parameters of microbiological safety and content of somatic cells of cow raw milk and raw cream should not exceed admissible level laid down in the Federal Law.

Products	QMAFAnM, CFU/cm ³ (g), not more	Product mass (g, cm ³), in which the following is not allowed		Content of somatic cells
		Coliforms	Pathogenic microorganism s	
RAW MILK				
Premium quality	100,000	-	25	200,000
First quality	500,000	-	25	1,000,000
Second-class quality	4,000,000	-	25	1,000,000
RAW CREAM				
Premium quality	500,000	-	-	-
First quality	4,000,000	-	-	-

Requirements for safety of raw milk of the Russian Federation and European Union

Parameters of safety	Requirements of the Russian Federation		Requirements of the European Union
Total bacterial count (CFU/cm³), not more	Premium quality	100,000	100,000
	First quality	500,000	
	Second-class quality	4,000,000	
Admissible level of somatic cells (cm³), not more	Premium quality	200,000	400,000
	First quality	1,000,000	
	Second-class quality	1,000,000	
Radionuclids: Cesium-137 Stroncium-90	100 Bq/kg 25 Bq/kg		370 Bq/kg -

Intervals of control of microbiological safety parameters of raw milk

	Russian Federation	European Union
Intervals of raw milk testing	According to industrial control	Microbiological parameters : 2 times a month, parameter of somatic cells: 1 times a month
Microbiological parameters (m/p)	Absolute value of m/p is determined	Relative value of m/p is determined*

* Geometrical mean over the last two months (for the parameter of total bacterial count) and over the last three months (for the parameter of somatic cells).

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Requirements for the safety of raw milk and raw cream
(Article 5, p. 7):

Additional requirements may be imposed on raw milk used for production of food with definite consumer properties.

It refers to:

- ⦿ production of baby-food based on milk,
- ⦿ production of sterilized milk, including concentrated milk or condensed milk,
- ⦿ production of cheese,
- ⦿ production of dietary foods.

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Raw milk from farm animals, intended for the production of baby-food based on milk, should also comply with the following requirements (Article 5, p.7, pp. 1):

- a) parameter of purity not lower than of the first group, parameter of heat resistance according to alcohol test not lower than of the third group according to the requirements of the national standard;
- b) number of colonies of mesophilic aerobic microorganisms and facultative anaerobic microorganisms does not exceed admissible level, established for raw milk of premium quality and raw milk of first quality according to Annex 2 of the present Federal Law;

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Raw milk from farm animals, intended for the production of baby-food based on milk, should comply with the requirements of Article 5 and the following requirements (Article 5, p.7, pp. 1):

- c) number of somatic cells does not exceed admissible level, established for raw milk of premium quality according to Annex 2 of the present Federal Law;
- d) storage and transportation of raw milk, intended for the production of baby-food based on milk is performed in separate containers in compliance with requirements laid down in Article 6 of the present Federal Law;
- e) use of raw milk, identification parameters of which do not match with the species of farm animals from which the milk was obtained, and (or) safety parameters of which do not comply with the requirements of the present Federal Law, is not allowed.

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Raw cow milk intended for the production of sterilized milk, including concentrated milk or condensed milk, should comply with the requirements of Article 5 and parameter of heat resistance according to alcohol test not lower than of the third group according to the requirements of the national standard (Article 5, p.7, pp 2).

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Raw cow milk intended for the production of cheese, should comply with the requirements of Article 5, and the following requirements (Article 5, p.7, pp.3):

- a) rennet-fermentation sample of Class I and II;
- b) bacterial number according to reductase test of Class I and II according to the requirements of national standard, number of colonies of mesophilic aerobic microorganisms and facultative anaerobic microorganisms is not more than 1×10^6 of colony-forming units in cm^3 ;

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Raw cow milk intended for the production of cheese, should comply with the requirements of Article 5, and the following requirements (Article 5, p.7, pp.3)

- c) number of spores of mesophilic anaerobic lactate-fermenting butyrate microorganisms is as follows:
 - for cheese with low temperature of curd scalding not more than 13,000 spores in dm^3 ;
 - for cheese with high temperature of curd scalding not more than 2,500 spores in dm^3 ;
- d) Turner degree (acidity) not more than 19;
- e) weight fraction of protein not less than 2.8 %.

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Raw cow milk intended for the production of dietary foods, should comply with the requirements of Article 5, and the following requirements (Article 5, p.7, pp.4):

a) number of colonies of mesophilic aerobic microorganisms and facultative anaerobic microorganisms is not more than 5×10^5 of colony-forming units in cm^3 ;

b) number of somatic cells is not more than 5×10^5 in cm^3 ;

c) parameter of heat resistance according to alcohol test not lower than of the third group according to the requirements of the national standard.

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Requirements for the special operating procedures during production, storage, transportation and disposal of raw milk and raw cream (Article 6).

Raw milk after milking farm animals should be purified and chilled to $4^{\circ}\text{C}\pm 2^{\circ}\text{C}$ within 2 hours.

	Raw milk	Raw cream
Storage temperature	$4^{\circ}\text{C}\pm 2^{\circ}\text{C}$	Not higher than 8°C
Storage period taking into account time of transportation	Not more than 24 hours	Not more than 36 hours

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Requirements to production and special technological processes for production and (or) sale of milk-processing products are set forth in Chapter 3:

- ⦿ General requirements to production of milk-processing products (Article 8),
- ⦿ Concepts of processes for production of milk-processing products and requirements to processes associated with obligatory requirements to raw milk and products of its processing (Article 9),
- ⦿ Requirements to arrangement of washing and disinfection of production facilities and equipment (Article 10).

Technical regulation on milk and milk products

Confirmation of conformity of milk and milk-processing products with requirements of the Federal Law (Chapter 11)

Milk and milk-processing products, sold in the territory of the Russian Federation, are subject to obligatory confirmation of conformity with requirements of the Federal Law in a form of the declaration on conformity or obligatory certification according to schemes approved by the Federal Law (Articles 29, 30, 31).

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In case of any scheme of declaration of conformity of milk or milk-processing products an applicant prepares a set of documents including (Article 31, p.7, sp. 3):

- ◎ international standard or detailed description of these products with the indication of their main properties, storage conditions, shelf-lives (*for foreign manufacturers*), used on a voluntary basis for the aim of providing the conformity with requirements of the Federal Law;

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- ① veterinary licenses or certificates of an approved form for confirmation of the conformity of raw milk or raw cream with requirements of the Federal Law.
- ② protocols for testing milk samples or milk-processing products, carried out in a certified testing laboratory, for confirmation of the conformity of these products with requirements of the Federal Law (Article 31, p.7, sp. 4),

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Requirements of international standards (Article 38).

Requirements of international standards in reference to milk and milk-processing products, production processes, storage, transportation, sale and disposal are implemented according to the procedure approved by Laws of the Russian Federation on technical regulation and on the basis of the International Agreement of the Russian Federation.

International Agreements (Article 40).

If the International Agreement of the Russian Federation, ratified according to the procedure, approved by Laws of the Russian Federation, have other rules than those, provided by the Federal Law, then rules of the International Agreement of the Russian Federation are applied.

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Liability of this Federal Law requirements infringement

- ⦿ In case of infringement of this Federal Law requirements manufacturer (seller, person functioning as a foreign producer under the contract as related to ensuring the compliance of delivered products with this Federal Law requirements) bears liability as provided by the Russian Federation legislation.
- ⦿ Removal of defects of milk-processing products, their delivery to the place where such defects are removed and their return to consumers, disposal of milk-processing products of poor-quality and those that do not comply with this Federal Law requirements are performed by manufacturer (seller, person functioning as a foreign producer under the contract, as related to ensuring the compliance of delivered products with this Federal Law requirements) at his/her expense.