

III. Hygienic Requirements for Safety and Nutrition Value of Food Products

3.1. These Sanitary Rules shall establish hygienic requirements for safety of foodstuffs and their ability to satisfy physiological need of a man in major nutrient materials and energy.

3.2. Organoleptic properties of food products shall be defined by such properties as flavour, colour, smell and consistency, specific for each type of product and must meet traditionally established tastes and habits of people. Organoleptic properties of food products shall not be changed during storage, transportation and distribution.

3.3. Foodstuffs shall not have foreign odours, after-tastes, inclusions, differences in colour and consistency incidental to the given type of product.

3.4. Safety of foodstuffs regarding their microbiological and radiological safety as well as with respect to content of chemical contaminants shall be determined by their compliance with hygienic standards provided for by these Sanitary Rules (Annex 1).

3.5. Determination of parameters of safety and nutrition value of food products including biologically active food additives, mixed composition shall be carried out for basic type(s) of raw materials both by the mass fraction and by permissible levels of controlled contaminants.

3.6. Determination of safety parameters of dry, concentrated or diluted food products shall be carried out in terms of original product subject to content of dry substances in the raw and final product.

3.7. Hygienic standards shall apply to potentially hazardous chemical compounds and biological subjects the presence of which in foodstuffs must not exceed permissible levels of their content in the weight specified (volume) of product under examination.

3.8. The content of major chemical contaminants endangering human health shall be monitored in food products.

Hygienic requirements for permissible level of content of toxic elements shall apply to all types of food raw material and foodstuffs.

3.9. Content of mycotoxins - aflatoxin B1, deoxynivalenol (vomitoxin), zearalenone, T-2 toxin, patulin shall be controlled in food raw material and food products of plant origin, aflatoxin M1 – in milk and dairy products. Most dangerous contaminants are: for cereal products - deoxynivalenol; for nuts and oil seeds - aflatoxin B1; for fruit and vegetable derivatives - patulin.

The content of ochratoxin A shall be controlled in food grain and flour-cereal products.
(the paragraph was introduced by Amendments No. 12, approved by Resolution No. 58 of Chief State Sanitary Inspector of the RF dated 10.10.2008)

3.10. Occurrence of mycotoxins in baby food and dietary products shall be excluded.

3.11. Pesticides shall be controlled in all types of food raw material and food products: hexachlorocyclohexane (alpha-, beta-, gamma isomers), DDT and its metabolites. Organomercury pesticides, 2, 4-D acid, its salts and esters shall be controlled in grain and its derivatives. 2, 4-D acid, its salts and esters shall also be controlled in fish and fish derived products.

3.12. Control of food raw material and food products as per the content of residual quantity of pesticides and agrochemicals including fumigants is based on information provided by the product manufacture (supplier) on use of pesticides and agrochemicals during the processes of manufacturing and storage of food products.

3.13. Sanitary and epidemiological examination of food raw material and foodstuffs containing pesticides shall be carried out in compliance with the applicable hygienic standards of pesticide content in the objects of environment.

3.14. Residual quantities of animal growth-promoting substances (including hormonal agents), pharmaceuticals (including antibiotics) used in cattle breeding for fattening up, treatment and prevention of diseases of livestock and fowl shall be controlled in food products of animal origin, including in baby food.

The following feed and medical antibiotics most commonly used in animal breeding and veterinary (Annex 1 of these Sanitary Rules) shall be controlled:

- bacitracin (bacitracin A,B,C, zincbacitracin);
- tetracycline group (tetracycline, oxytetracycline, chlortetracycline –sum of the original substances and their 4-epimers);
- penicillin group (benzylpenicillin, phenoxymethylpenicillin, ampicillin, amoxicillin, penethamate);
- streptomycin;
- laevomycetin (chloramphenicol).

(Clause 3.14 as amended by Amendments and Additions No. 22, approved by Resolution No. 177 of Chief State Sanitary Inspector of the RF dated 27.12.2010)

3.15. Control over the content of animal growth-promoting substances (including hormonal agents), pharmaceuticals (including antibiotics) used in cattle breeding for fattening up treatment and prevention of diseases of livestock and fowl, preparations not specified in Clause 3.14 shall be based on information provided by the product manufacture (supplier) on the preparations used during manufacturing and storage of such products (Annex 21 of these Sanitary Rules).

(Clause 3.15 as amended by Amendments and Additions No. 22, approved by Resolution No. 177 of Chief State Sanitary Inspector of the RF dated 27.12.2010)

3.17. Occurrence of benzopyrene in baby food and dietary products shall be excluded.

3.18. The following shall be controlled in separate food products: the content of nitrogen compounds: histamine – in salmonids and scombrids (including the tuna group); nitrates – in horticulture product; N-nitrosamines – in fish and fish products, meat products and brewer's malt.

Phycotoxins shall be controlled in non-fish products (shell-fish, internal organs of crabs).

(the paragraph was introduced by Amendments No. 12, approved by Resolution No. 58 of Chief State Sanitary Inspector of the RF dated 10.10.2008)

3.19. Indications of oxidative deterioration shall be controlled in fatty products: acid and peroxide value.

3.20. The content of radionuclides shall be controlled in food products.

(as amended by Amendments and Additions No. 2, approved by Resolution No. 41 of Chief State Sanitary Inspector of the RF dated 15.04.2003)

Radiological safety of foodstuffs for Caesium-137 and Strontium-90 shall be determined by their permissible levels of specific activity of radionuclides provided for by these Sanitary Rules. Compliance factor – B shall be used for determining compliance of foodstuffs with criteria of radiological safety, the value of it is calculated using results of measuring specific activity of Caesium-137 and Strontium-90 in a sample:

$B = (A/H) 90\text{Sr} + (A/H) 137\text{Cs}$, where A - is the value of specific activity of 90Sr and 137Cs in a food product (Bq/kg), H - is a permissible level of specific activity for 90Sr and 137Cs in the same product (Bq/kg).

(as amended by Amendments and Additions No. 2, approved by Resolution No. 41 of Chief State Sanitary Inspector of the RF dated 15.04.2003)

Radiological safety of foodstuffs contaminated with other radionuclides shall be determined by sanitary rules that specify radiological safety standards.

3.21. Presence of pathogenic microorganisms and pathogens of parasitic diseases, their toxins causing infectious and parasitic diseases or endangering human and animal health shall be excluded from food products.

3.22. Sanitary and epidemiological examination of meat and meat products, fish, shell fish, molluscs, amphibians, reptiles and products of their processing for the presence of pathogens of parasitic diseases shall be carried out in accordance with sanitary rules for conducting parasitological control and parasitological parameters of safety (Annex 6).

3.23. Presence of pathogens of parasitic diseases in meat and meat products shall not be tolerated: bladder worms (cysticercus), larvae of trichinella and echinococci, cysts of sarcocystis and toxoplasma.

3.24. Presence of living larvae of parasites threatening human health shall not be tolerated in fish, shellfish, molluscs, amphibians, reptiles and products of their processing.

When finding living helminths larvae one should be governed by sanitary rules for parasitic diseases preventive measures.

3.25. Presence of helminths eggs and cysts of enteric pathogens shall not be tolerated in fresh and quick-frozen table greenery, vegetables, fruits and berries.

3.26. Hygienic standards for parasitological safety parameters of drinking water shall be determined in accordance with hygienic standards specified for quality of centralized drinking water supply systems.

3.27. Hygienic standards for microbiological parameters of safety and nutrition value of foodstuff shall include the following groups of microorganisms:

- sanitary-indicative ones, which include: number of mesophilic aerobic and facultative-anaerobic microorganisms (NMAFAnM), Coliform bacteria - coliforms, bacteria of Enterobacteriaceae family, enterococcus;

- opportunistic pathogens, which include: E. coli, S. aureus, Proteus class bacteria, B. cereus and sulfite-reducing clostridia, Vibrio parahaemolyticus;

- pathogenic microorganisms, including salmonella and Listeria monocytogenes, Yersinia class bacteria;

- spoilage microorganisms – yeast and mold fungi, lactic-acid microorganisms;

- starter population microorganisms and probiotic microorganisms (lactic-acid microorganisms, propionate microorganisms, yeast, bifidobacteria, acidophilic bacteria and etc.) – in products with controlled level of biotechnological flora and probiotic products.

3.28. Controlling of microbiological parameters of safety of foodstuff shall be carried out for majority groups of microorganisms under the alternative principle, i.e. the mass of a product is controlled, where coliforms, majority of opportunistic pathogens, as well as pathogenic microorganisms including Salmonella and Listeria monocytogenes shall be excluded. In other cases the standard reflects the number of colony-forming units in 1 g (ml) of the product (CFU/g, ml).

3.29. Criteria of safety of preserved food products (manufacturing sterility) is the absence of microorganisms capable of developing under temperature of storage specified for certain type of canned food and microorganisms and bacterial toxins endangering human health life in preserved food products (Annex 8).

3.30. Biologically active food additives are the source of food, minor, pro- and prebiotic natural (identical to natural) biologically active food substances (components), which provide their intake into a human body while eating or introducing into the composition of food products.

Biologically active substances, food components and products being their sources and used during manufacturing of biologically active food additives must ensure their efficiency and must not negatively affect human health (Annex 5a).

Biologically active substances, food components and products being their sources that pose - according to current research data – a hazard to human life and health when used as a component of biologically active food additives shall not be allowed for use when manufacturing biologically active food additives (Annex 5b).

3.31. The parameters of nutrition value shall be established in food products. Parameters of nutrition value of food products shall be established by a manufacturer (developer of technical documents) on the basis of analytical methods of research and/or with the use of calculating method subject to composition of a food product and data on composition of raw materials.

3.32. Specific foodstuffs as per parameters of nutrition value must comply with requirements of these Sanitary Rules (Annex 2).

3.33. Baby food must comply with physiological conditions of a child with account of his/her age and must be safe for baby health.

3.34. Baby food and its components, foodstuff for pregnant and breast feeding women (hereinafter referred to as the specialized products) must comply with hygienic standards of safety and nutrition value provided for by these Sanitary Rules (Annex 3)

3.35. Foodstuffs shall allow the use of food additives which - according to the data of current research - do not negatively affect human life and health as well as life and health of future generations (Annex 7).

Foodstuffs containing food additives not specified in Annex 7 shall not be allowed for manufacturing, import and distribution in the territory of the Russian Federation. Their recycling or destruction shall be carried out according to the established procedure.

3.36. Application of food additives and permissible levels of their content in food products are governed by sanitary rules for application of food additives.

3.37. It is not allowed to use poultry meat, except chilled, mechanically separated poultry meat, and collagen containing raw material from poultry meat for production of baby food (for all age groups, including organised children groups) dietary food products (curative and preventive), specialized food products for pregnant and nursing women, delicatessen from poultry meat (pastrami, raw smoked and raw cured products).

(Clause 3.37 was introduced by Amendments and Additions No. 9, approved by Resolution No. 30 of Chief State Sanitary Inspector of the RF dated 23.05.2008 as amended by Amendments and Additions No. 21, approved by Resolution No. 145 of Chief State Sanitary Inspector of the RF dated 12.11.2010)

3.38. It is not allowed to use poultry meat, except chilled, for production of chilled natural semi-manufactured products from poultry meat and food products from poultry meat without heat treatment.

(Clause 3.38 as amended by Amendments and Additions No. 21, approved by Resolution No. 145 of Chief State Sanitary Inspector of the RF dated 12.11.2010)

3.39. Control over the content of melamine in milk and milk products is performed if there are reasonable assumptions about the possibility of its presence in the food raw materials. Food safety regarding melamine content shall be determined by its conformity with hygienic standards set by these Sanitary Rules (Annex 1 and Annex 3). Presence of melamine in food products shall not be tolerated.

(Clause 3.39 was introduced by Amendments No. 11, approved by Resolution No. 56 of Chief State Sanitary Inspector of the RF dated 01.10.2008)

3.40. Control over the content of dioxins in food products shall be carried out in cases of deterioration of environmental situation associated with man-made and natural disasters, which lead to formation and penetration of dioxins in the environment; in case there are reasonable assumptions about the possibility of their presence in food raw materials. Food safety regarding dioxin content shall be determined by its conformity with hygienic standards set by these Sanitary Rules (Annex 1 and Annex 3).

(Clause 3.40 was introduced by Amendments No. 12, approved by Resolution No. 58 of Chief State Sanitary Inspector of the RF dated 10.10.2008)

3.41. Food products must not contain melamine (detection limit shall be less than 1 mg/kg). The content of dioxins must not exceed the permissible levels from 0,000001 to 0,00000075 in the respective food groups, according to the requirements of Annex 1. Dioxins are not allowed in all baby food products.

(Clause 3.41 was introduced by Amendment No. 13, approved by Resolution No. 69 of Chief State Sanitary Inspector of the RF dated 11.12.2008)

3.42. When treating fish fillet with the use of food additives water content in it after the taking off of glaze shall not exceed 86 per cent of the fish fillet.

Mass of glaze, applied to the frozen fish, fish products must not exceed 5% of net mass, mass of glaze, applied to shellfish products and products of their processing, must not exceed 7% of net mass, mass of glaze, applied to products produced from other (except shellfish) non-fish products (molluscs, invertebrates, algae), amphibians, reptiles and products of their processing, must not exceed 8% of net mass of the glazed frozen fish products.

(Clause 3.42 as amended by Amendments and Additions No. 22, approved by Resolution No. 177 of Chief State Sanitary Inspector of the RF dated 27.12.2010)