

CONTROL METHODS.

BIOLOGY AND MICROBIOLOGICAL.

SANITARY-EPIDEMIOLOGICAL ASSESSMENT OF TERMS reasons CONSUMPTION AND FITNESS FOR STORAGE OF FOOD

METHODOLOGY

CHIEF STATE SANITARY PHYSICIAN FR

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APPROVES

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Methodological guidelines are prepared taking into account comments and suggestions of experts of the State Sanitary-Epidemiological Surveillance of Moscow, Moscow Oblast, Leningrad and Rostowski.

2. Approved by the Chief State Sanitary Doctor of the Russian Federation 6 March 2004 and validated on 20 June 2004

3. Are introduced in place of the standard MYK 4.2.727-99 "Evaluation of hygienic terms of suitability for consumption of food products", approved 04 and validated by the Chief State Sanitary Doctor of the Russian Federation 21.01.99.

1. Scope

1.1. These guidelines are intended for Methodical authorities and institutions of the State Sanitary and Epidemiological Service of the Russian Federation (hereinafter the outpouring of Russia) and for other organizations that have received under the applicable law to carry out policy research and analysis of food products, from individual entrepreneurs and legal persons, whose activities are implemented in the production, marketing of food products and to develop normative and technical documentation.

1.2. These guidelines specify the order Methodical and methodology for making sanitary-epidemiological assessment to justify the shelf-life dates and storage conditions of food products.

2. Source of normative

- 2.1. Federal Law "On sanitary-epidemiological safety of population" of 30 March 1999, No. 52-Φ3.
- 2.2. Federal Law "On quality and safety of food products" of 2 January 2000, No. 29-Φ3.
- 2.3. Order of the State Sanitary and Epidemiological Service of the Russian Federation, approved by Resolution of the Government of the Russian Federation of 24 July 2000 No. 554
- 2.4. Law of the Russian Federation dated 02.07.92 No. 2300-1 "On protection of consumer rights."

2.5. Resolution of the Government of the Russian Federation of 21 December 2000 No. 987 "On state supervision and control of quality assurance and food safety."

2.6. Resolution of the Government of the Russian Federation of 21 December 2000 No. 988 "On state registration of new food products, materials and products."

2.7. Normatyvy regulations and sanitary and epidemiological 2.3.2.1078-01 "Hygienic requirements for safety and nutritional value of food products."

2.8. Normatyvy regulations and sanitary and epidemiological 2.3.2.1153-02 "Hygienic requirements for safety and nutritional value of food products. Supplement No. 1 to the norm of the Rules and sanitary-epidemiological 2.3.2.1078-01."

2.9. Normatyvy regulations and sanitary and epidemiological 2.3.2.1280-03 "Hygienic requirements for safety and nutritional value of food products. Completions No. 2 and amendments to the Rules and sanitary-epidemiological norm 2.3.2.1078-01."

2.10. Normatyvy regulations and sanitary and epidemiological 2.3.2.1324-03 "Hygienic requirements concerning time limits shelf-life and storage conditions of food products."

2.11. Normatyvy regulations and sanitary and epidemiological 2.3.2.1293-03 "Hygiene requirements for the use of food additives."

2.12. Standard state 2.3.3.972-00 "acceptable limit emissions of chemicals from materials in contact with food products."

3. General Provisions

3.1. Expiry dates and storage conditions of consumption of food products are determined by the manufacturer of food products or by the unit, developing a normative and technical documentation in accordance with the requirements of hygiene and safety and nutritional value of food products and are entered into the normative and technical documentation in accordance with current policy.

3.2. Sanitary-epidemiological assessment to justify the shelf-life dates and storage conditions of food products is carried out to confirm the compliance of products with the hygiene requirements laid down during these periods and to prevent any harmful effects on human health and the environment.

3.3. The sanitary-epidemiological studies to justify the shelf-life dates and storage conditions of food products are conducted by authorized bodies and institutions and Sanepidu Russia Scientific-Research Institutes of the Ministry of Health of the Russian Federation and Russian Academy of Medical Sciences, accredited in accordance with current policy.

3.4. Expert Sanitary-Epidemiological term of validity of food products, manufactured in accordance with the normative documents (technical regulations, standards and GOST GOST R), is carried out based on the results of extensive research by the manufacturing industry research institutions with the participation of eligible individuals Sanepidu Russia and Institutes of research Ministry of Health of the Russian Federation and Russian Academy of Medical Sciences, accredited in accordance with current policy, drawing up the proposals with the following sanitary-epidemiological conditions for the production of concrete producers in accordance with plant-based manufacturer.

3.5. Sanitary-Epidemiological Conclusion o possible to determine the shelf-life dates for perishable food products, manufactured in accordance with new technologies and / or new types of raw materials, food products for children, dietetic (therapeutic or prophylactic), including canned, obtained from genetically modified food sources issued by an authorized federal body Sanepidu Russia. For other types of applications o possible to determine the shelf-life dates are issued by local authorities and institutions of the Russian Federation Sanepidu competent siedzibom plants-producers.

3.6. When you make changes to the technical documentation and / or operative to products which do not relate to changes in recipes, production techniques, storage conditions and time limits shelf-life products is not required to carry out sanitary-epidemiological expertise for pre-determined shelf-life dates for these products.

3.7. These guidelines do not specify the order Methodical sanitary-epidemiological assessment to justify the shelf-life dates and bottled water and mineral water, soreness bacteria, starter cultures, biologically active food additives, preparations of the enzymes for the food industry.

3.8. It is not permissible to carry out sanitary-epidemiological studies on the grounds of validity dates of food products, manufactured in accordance with the normative and technical documents, if the expiry dates do not exceed the time limits established for similar types of products listed in Annex 1 sanitary standards "Hygiene requirements for shelf-life dates and storage conditions of food products "
(para. 2.10).

3.9. The sanitary-epidemiological studies to justify the shelf-life dates are conducted in accordance with the current policy of using control methods regulated rates.

3.10. When production of products with which the sanitary-epidemiological terms of suitability for consumption was carried out according to the operative or technical documentation in accordance with the agreed order, the tests are carried out as follows - one lot is not less than 3 times within a fixed period of shelf-life - at the beginning of storage, at the time of the end of the shelf, and after a certain length of time, calculated in accordance with the relevant reserve ratio.

4. Methodological principles of sanitary-epidemiological studies to justify the shelf-life periods of food products.

4.1. The basis of sanitary-epidemiological grounds terms of suitability for consumption of food is to carry out microbiological tests, sanitary and chemical evaluation of the organoleptic tests of products in the storage temperature, provided the normative documentation and / or technical assistance.

4.2. Dates of research products should last longer than the prescribed date for consumption, contained in the draft normative and technical documentation on time, determined by the so-called. reserve ratio.

4.2.1. Reserve ratio for perishable products is:

- At the shelf-life to 7 days inclusive - 1.5;
- At the shelf-life of 30 days inclusive - 1.3;
- The period of usefulness of more than 30 days - 1.2.

4.2.2. Reserve ratio for products that are not quickly perishable is 1.15.

4.2.3. Reserve ratio for perishable products intended for infants and children under 3 years, therapeutic and prophylactic products is 2

4.2.4. Reserve ratio for products that do not spoil quickly is 1.5.

4.3. Principle of increase of storage temperature.

Principle of increase of temperature to take account of any interruptions or breaches the supply chain of chilled product to consumers and the ensuing activation of the possible microbial resistance to low temperatures. At the same time is taken into account the fact that the multiplication of pathogenic and conditionally-pathogenic bacteria resistant to low temperatures (eg, the type of bacteria *Yersinia*, *Listeria*) is needed longer time than the multiplication of mesophilic germs that cause food poisoning and intestinal infections.

In addition to the detection of microbial instability in perishable products, this principle is used for early registration processes, oxidation of fatty ingredients.

4.3.1. Carrying out checks at a temperature exceeding the temperature of the operative or technical documentation for 50% (increase) is essential for perishable food products that passed in the manufacture of heat treatment at temperatures below 80°C, and / or were produced using manual operations. For example, for chilled products, which should be stored at $(4 \pm 2)^\circ$, the tests are carried out at $(9 \pm 1)^\circ$; for frozen products - with a minus $(18 \pm 1)^\circ$ and minus $(12 \pm 1)^\circ$.

4.3.2. The temperature increased (increase) are conducting research into one of three batches of food products subject to testing.

4.3.3. Products containing food additives for preservative action, produced using a temperature over 80 ° C, pasteurized UHT milk, flour products, no cream, made with the use of cream and vegetable fat, high-fat products, with high content of fatty acids with a pH below 4.5, chilled or semi-frozen meat, poultry, fish, canned products are tested without the use of control tests with increased temperature.

4.4. For some food products (for example, vegetable oils) is acceptable grounds for defining time periods shelf on the basis of validated test methods express, carried out in laboratories and institutions, accredited in accordance with current policy, entitled to carry out such tests, while carrying out these tests in units of the relevant premises Sanepidu plant-manufacturer.

Determination of shelf-life periods of vegetable oils is carried out in accordance with the "Guidelines for methodological validity of the accelerated timing of food of vegetable oils", as approved by the Deputy Chief State Sanitary Doctor FR, No 1100/2261-98-115 dated 23.09.98.

4.5. Evaluation of sanitary-epidemiological grounds dates shelf of canned products is made on the basis of the modes provided by the manufacturer of sterilization, developed and scientifically justified and based on the results of preliminary studies concerning the determination of predictable time limits shelf life.

5. Organization of sanitary-epidemiological studies on the assessment of the justification terms of suitability for consumption of food

5.1. In order to carry out sanitary-epidemiological expertise dates shelf food manufacturer or organization developing a product gives the following documents:

- Technological justification for determining the suitability of the product prolongation date;
- Documentation of normative and / or technical or design documentation and technological instructions (rules), recipes, developed and prepared to be arranged in accordance with applicable policy;
- Confirmation (approval) of the organization to draft normative documentation or technical expertise to carry out sanitary-epidemiological terms of suitability for consumption of products produced by the manufacturer, which is not the owner of the file;
- The results of sanitary-epidemiological trials of products to confirm the suitability of the planned dates for human consumption;
- The application of sanitary-epidemiological met by an adequate sanitary facilities;
- Sanitary-epidemiological conclusions concerning the use of raw materials, food ingredients, food additives, coatings, Packing materials, which may affect the shelf-life periods of the finished product, or certified in accordance with the applicable order copies of these documents.

5.2. Sanitary-Epidemiological studies justify the shelf-life dates and storage conditions of food products are conducted in accordance with the research programs developed by authorized institutions (in accordance with paragraphs. 3.3) on the basis of a dossier for a specific type (type) of food products in accordance with paragraph. 5.1 and Annex 1 (periodicity of control) and 2 (defined list of indicators) to these methodological guidelines.

5.3. The test program should include:

5.3.1. Controlled list of indicators for each type (type) of food products:

- Sanitary and microbiological (mandatory safety indicators provided by the rules and normatywy sanitary-epidemiological 2.3.2.1078-01 "Hygiene requirements for the safety and nutritional value of food products", the parameters characterizing the stability of the product during storage);
- Sanitary-chemical (selected for periodic inspection of the product composition, the physico-chemical parameters, storage conditions, to assess the possible migration of chemicals from packaging materials);
- Organoleptic characteristics;
- Indicators of nutritional value, characterizing behavior of the product during storage.

5.3.2. Methods for determining the rates controlled (in accordance with Annex 3).

5.3.3. Schedule and order of sample products tested. In developing a program is allowed grouping the types of products manufactured by the same normative and technical documentation, single according to the recipe and manufacturing technologies. Obtained in the sanitary-epidemiological study results include the whole group of products.

5.3.4. Diagram of testing (duration, number of control points).

5.3.5. Number of attempts required to perform all planned tests in accordance with the period of their duration and the number of points checked (it is determined in accordance with paragraphs. 5.3.1 and 5.3.4).

One copy of the program is transmitted to the unit, which carries out research, and the second - the principal.

6. Selection tests and periodical tests

6.1. For research are made available to test products in immediate packing, selected in the plant-manufacturer in accordance with the testing program by point. 5.3.

6.2. Samples for testing are selected no less than 3 different dates of production (production batch).

6.3. Number of selected samples should provide for carrying out all planned testing in accordance with the period of their duration and the number of checkpoints at the program. At every point should be provided for the number of trials required to prepare an average sample (for small devices - not less than 3 units of packaging, for large (over 500 g) - not less than 2 units package).

6.4. To provide samples for the organization, the test should be conducted in accordance with the normative documents concerning the methods of sampling for a product group or in accordance with the normative and technical documentation for the product.

6.5. Periodicity of selected research trials should be calculated taking into account the duration of the intended shelf life and product specific and should not be less than 3 times the test periods of 30 days, 4 times - at times the test more than 60 days (after manufacture, the middle shelf for consumption at the end of a predictable period of usefulness, at the end of the period of the reserve ratio). Recommended periodicity of testing schemes are given in Annex 1

6.6. During the tests should be provided for the storage conditions of temperature tests in accordance with the normative and technical documentation, and the principle of increasing temperature.

6.7. The temperature inside the cooling of the containers stored in the middle of trying to be monitored daily by thermometry by the responsible person or by automatic means of recording temperature.

6.8. In case of detection of the first checkpoint, tested samples of non-compliance with the requirements set out in normative documents according to microbiological indicators, sanitary-chemical and organoleptic characteristics, are dropped from further investigations.

7. Details of testing sanitary-microbiological

7.1. List of microbiological indicators examined include both mandatory safety indicators, adjustable for a product group by the rules and standards of fire safety and more - to obtain detailed characteristics of the sanitary and microbiological confirmation of the stability of the product during storage

(lists of indicators for the basic food groups are given in Annex No. 2).

7.2. For food products of animal origin from the date of the shelf-life of 10 or more days (milk and milk products, meat and poultry, fish products) and for vegetable dishes with raw vegetables for food products intended for infants, pregnant women and nursing mothers, for the presence of the bacterium *Listeria monocytogenes*

Shall be 25 g (50, 100 g) not to me twice in the screening process - after the manufacture and end date.

7.3. The products, containing living microflora or technology-enriched probiotics (mlekovymi, propiono-acid bacteria, bifidobakteriami, yeast and others.) Is a controlled amount of microflora throughout the study. If you need to be controlled by the composition of microflora species.

With this control the content of lactic acid and probiotic bacteria in products whose shelf-life period is 2 weeks or less, is implemented with a frequency not less that 1 time for 5 days for products with longer shelf-life control is implemented during the first 2 weeks of storage -- 1 time for 5 days, then - every 3 days.

7.4. Studies of the absence of conditionally-pathogenic microorganisms (mold coli, *S.aureus*, sulphite-reducing Clostridia) should be carried out in the expanded field: the seed of 2 - 3 product weight - weight, according to the standards and naważkach, exceeding the norm by one order, for example, the standard forms coli in the absence of 0.1 g sow 1.0, 0.1 g of the product.

7.5. For the types of food products in which the absence of forms coli, *S.aureus*, sulphite-reducing Clostridia is determined in 1 g of the product, sow 1.0 and 0.1 g of the product in order to detect microorganisms in the last control points of the study.

7.6. Mandatory is studied the dynamics of the microbial spoilage indicators, namely:

- Yeasts and molds - in all products tested (except the semi-frozen raw meat, fish, poultry without Coating), yeast are not defined in articles with dough;
- Proteus bacteria family - in refrigerated semi-finished garmazerii meat, fish, chicken dishes, catering for posiewie 1.0, 0.1 g of the product.

7.7. Additionally, are examined:

- Micro products - the products of meat and poultry, packaged with the limited access of oxygen;
- Pseudomonas bacteria family - semi-finished products in refrigerated meat, fish, poultry, fatty products, and maslach with reduced fat content.

8. Investigate the physical-chemical, sanitary-chemical and organoleptic evaluation

8.1. Assessment of organoleptic properties of food products is carried out in accordance with the requirements of techne-date records for a specific type of product.

Research patterns of respondents tasting products are carried by 5-phase system at the same time the percentage of coded patterns of the product at the end of a predictable shelf life (in the case of positive results of laboratory tests) and similar products immediately after production. At the same time are evaluated:

External appearance, texture, color, taste, smell and other characteristics.

To ensure that the results of statistical reasons the number of independent participants in the tasting, not informed of the codes of practice should be not less than 7

8.2. In assessing the sanitary-epidemiological findings are incorporated into the Commission's assessment of tasting conducted by a competent official body of the manufacturer or organization to draft normative documents and / or technical assistance.

8.3. Study of indicators of oil deterioration as a result of oxidation (the number of oxidative, acid number) is carried out not less than 3 times within the shelf life - at the beginning of storage, at the end of the declared period of suitability and reserve end of the period, which coincides with the end of the study:

- In food products with natural weight of oil 5% or more - in terms of suitability for consumption of 45 days and more;
- In food products, manufactured using only vegetable oils (except palm), with 10% fat by weight and more - in terms of suitability for consumption of 10 days and more;
- In food products, manufactured using animal fats or mixtures of animal fats and vegetable oils, including palm fat by weight with 10% or more - in terms of suitability for consumption of 30 days and more;
- In food products containing polyunsaturated fatty acids, including nuts and products containing nuts - in terms of suitability for 30 days and more.

8.4. Study the contents of N-nitrosamines in meat products, fish and other finished products manufactured with the addition of nitrite and / or potassium nitrate and sodium is carried out not less than 3 times within the shelf-life at the beginning of storage, at the end of the declared period of suitability and finally period reserve which coincides with the end of the study.

8.5. Study the contents of histamine and biogenic amine in the finished products - no less than 3 times no less than 3 times within the shelf-life at the beginning of storage, at the end of the declared period of suitability and reserve end of the period, which coincides with the end of the study.

8.6. The food products fortified with vitamins, in products which are their major source, as well as in food products for children, frozen products, which contain vitamins is placed on the label, it is necessary to carry out state control of their behavior in accordance with reglamentowanymi levels of these vitamins or Comparative control of the initial content of these vitamins (for frozen products).

8.7. Additionally, the necessity test is performed to determine the content of salt and moisture, pH, acidity titration are labeled (in those cases where these factors affect the safety, preserve the nutritional value and organoleptic characteristics of products). It is possible to carry out tests to determine other indicators of the physico-chemical, sanitary, chemical, biochemical, mikrostrukturalne depending on the specific product or its storage conditions (water activity A_w , indicators of nutritional value, mycotoxin content;

weight placed on the participation of preservatives, acidity regulators, fatty acid composition and ratio of polyunsaturated and saturated fatty acids and others).

Additional studies should be included in an appropriate research program.

9. The order of testing products, canned

In order to justify the timing of the shelf-life products including the following tests are carried out.

9.1. The development of scientifically based methods of sterilization of the product in case of necessity - their presentation to the evaluation of experts and the arrangements for specialized research institutions, with a license to conduct such research.

9.2. Evaluation of sanitary-epidemiological used in the production of such products including raw materials by microbial indicators in accordance with the Instruction on the procedure of control of sanitary-technical canning factories, warehouses, retail trade and catering enterprises (zatw. No. 01-19/9 -11), no fewer than three different batches.

9.3. Determination of resistance to the use of packaging used for sterilization methods.

9.4. Production of trial batches of canned according to the approved method of sterilization. Are used for the test sample of not less than three lots of canned one range, the same kind of container with the same coating the inner surface with lots of different materials.

9.5. Number of samples in each batch should ensure that tests throughout the study period, which should be 1.15 times higher in the anticipated shelf-life. The periodicity of testing of samples - not less than 5 times (in the case of the survey to 2.5 years).

9.6. Periodic testing of canned products during storage are carried out according to the following indicators:

- Microbiological indicators (conformity with the requirements of industrial sterility for a group canned);
- Organoleptic indicators of the product;
- Physical and chemical indicators;
- Assessment of the internal and external surfaces of the packaging;

- Content of toxic elements, N-nitrozaminów (for canning with the addition of nitrite) in the product.

9.7. Studies of preserved products during storage are addressed in the case of detection of any of the following deviations:

- Non-compliance with the requirements of experimental trials of industrial sterility for group preserves;

- Reduction of indicators of organoleptic, physico-chemical properties in comparison with established normative documentation and / or the original characteristics of the product;

- Creation of defects on the inner surface of the packaging;

- Increased migration of toxic elements of the packaging material to product.

9.8. Evaluation of sanitary-epidemiological reasons shelf life of canned products based on the results of confirmatory behavior indicators of organoleptic, physico-chemical properties and safety of canned during the entire period of testing.

10. Evaluation of results and decision

10.1. After completion of the study samples of food products in accordance with the program is carried out sanitary-epidemiological evaluation of the results obtained to justify the shelf-life periods.

10.2. The primary criterion for positive evaluation of sanitary-epidemiological reasons shelf life of products is the lack of a negative growth of all the indicators examined in accordance with the testing program (microbiological, physico-chemical and organoleptic) in samples from all surveyed lots (not less than 3), the following criteria :

- Incompatibility standardized microbiological indicators with the values set in the dossier considered enacting at any control point;

- Detection of the bacterium *Listeria monocytogenes* in 25 g (50, 100 g) of the product at any checkpoint during the test for testing in accordance with paragraph. 7.2;

- Increase the number of factors that cause spoilage (yeast and mold), more than twice the equation of the original starting level;

- Detection of microorganisms in dairy products, packaged with the reduction of oxygen in excess of established levels for these products КМАФАИМ;

- Reduce the content of probiotic microflora and / or acid products with a content below the level of regulated or declared;

- Detection of bacteria *Proteus*: a) in samples of the products, standardized according to this index - in the case of non-compliance with the norm, б) in trials in which the test is carried out in accordance with Annex 2, - in the case of detection of 0.1 g of the product (in 1.0 g of the product for children, a therapeutic or preventive action);

- Detection of other factors that cause spoilage (bacteria genus *Pseudomonas* and others) in 0.1 g of finished products, carrying out the tests in accordance with Annex 2;