

**ORDER**  
**OF THE MINISTRY OF PUBLIC HEALTH OF THE RUSSIAN FEDERATION**  
**NO. 217 OF JULY 20, 1998**  
**ON HYGIENIC ASSESSMENT OF PRODUCTION, DELIVERY**  
**AND REALIZATION OF PRODUCTS AND GOODS**  
**(with Amendments and Addenda of September 2, 1999, October 27, 2000)**

*Order of the Ministry of Health of the Russian Federation No. 325 of August 15, 2001 abolished this Order*

*For the Procedure of Implementation of this Order, see [Letter](#) of the State Committee for Sanitary-Epidemiology Supervision of the Russian Federation No. 1100/2652-98-111 of November 17, 1998*

*In pursuance of this Order, the State Customs Committee of the Russian Federation issued [Letter](#) No.21-15/26400 of December 17, 1998*

With the aim of enhancing the efficiency of activities aimed at protection of life and health of the population, to bring the system of hygienic assessment of products, goods and production facilities into accord with the prevailing laws of the Russian Federation, to bring the said procedure into compliance with international requirements, being guided by [Law](#) of the Russian Federation on Sanitary-Epidemiology Safety of the Population No. 1034-1 \* of April 19, 1991, the [Law](#) of the Russian Federation on the Protection of Consumers (as amended by the [Federal Law](#) on Amending the Law of the Russian Federation on the Protection of Consumers, the RSFSR Code on Administrative Offences No. 2-FZ \*\* of January 9, 1996) and also the [Regulations](#) on the Ministry of Public Health of the Russian Federation, approved by [Decision](#) of the Government of the Russian Federation on Approval of Regulations on the Ministry of Public Health of the Russian Federation No. 659 \*\*\* of June 3, 1997, it is hereby ordered as follows:

**1.** To approve:

**1.1.** Regulations on Effecting Hygienic Assessment of Products, Goods and Production Facilities ([Appendix No.1](#))

**1.2.** Form of hygienic statement for products and goods ([Appendix No.3](#))

**1.3.** Form of hygienic statement for production facility ([Appendix No.4](#))

**2.** To establish that:

**2.1.** The issuance of a hygienic statement shall be effected by the Department of State Sanitary and Epidemiology Supervision of the Ministry of Public Health of the Russian Federation, centres of state sanitary and epidemiology supervision in the subjects of the Russian Federation, centres of state sanitary and epidemiology supervision in the regions for transport, the Federal centre of state sanitary and epidemiology supervision of the Ministry of Public Health of the Russian Federation, centres of state sanitary and epidemiology supervision of the Federal Department of Medical-Biological under the Ministry of Public Health of the Russian Federation, for production, delivery and realization of products and goods, in accordance with the Regulations on Effecting the Hygienic Assessment of Products, Goods and Production Facilities ([Appendix No.1](#)) and the List of Products and Goods Subject to Hygienic Assessment ([Appendix No.2](#)).

**2.2.** The organizational-technical activities associated with hygienic assessment of products, goods and production facilities and the issuance of hygienic statements at the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation shall be undertaken by the Center of Sanitary and Epidemiology Standardization, Hygienic Certification and Expertise of the Ministry of Public Health of the Russian Federation.

**2.3.** The making and distribution of forms of hygienic statements possessing specified degrees of protection shall be effected by the Center of Sanitary and Epidemiology Standardization and Hygienic Certification and Expertise of the Ministry of Public Health of Russia.

**2.4.** The formation and keeping of the register of hygienic statements for products and goods

shall be the responsibility of the Center of Sanitary and Epidemiology Standardization and Hygienic Certification and Expertise of the Ministry of Public Health of Russia.

**2.5.** The Department of State Sanitary and Epidemiology Supervision of the Ministry of Public Health of Russia shall carry out hygienic assessment of socially important, potentially hazardous types of products and goods as per the List ([Appendix No.5](#)).

**3.** The hygienic certificates issued earlier shall be valid until expiration of their effectiveness.

*For terminating the issuance of hygienic certificates, see [Letter of the Ministry of Public Health of Russia No.1100/2026-98-02 of August 28, 1998](#)*

**4.** The products exposed to the procedure of hygienic assessment shall, if so is desired by the producer (seller, supplier), bear a logo confirming that the given products have passed hygienic assessment ([Appendix No. 6](#)).

**5.** Head physicians of the centers of state sanitary and epidemiology supervision in the subjects of the Russian Federation and head physicians of such centers in the regions for transport, heads of other organizations specified under [Item 2.1](#). shall be required:

**5.1.** To provide for the conduct of hygienic assessment of products, goods and production facilities in keeping with the [Regulations](#) approved by this Order.

**5.2.** To ensure that the population, bodies of authority and local administration are kept at all times informed of the results of supervision over quality of products and goods liable to hygienic assessment and provide for compliance with the current sanitary legislation at all stages of their production, storage and realization.

**6.** The first deputy Minister - Head State Sanitary Physician of the Russian Federation shall be required:

**6.1.** To submit proposals on the membership of Councils of experts whose services may be engaged by the Center of Sanitary-Epidemiology Standardization and Hygienic Certification and Expertise of the Ministry of Public Health of Russia to effect hygienic assessment of products, goods, production facilities.

**6.2.** To approve a list of leading testing centers (laboratories) under research institutes and centers of the Ministry of Public Health of Russia and the Russian Academy of Medical Science.

*See [Appendix No. 2 to the List of Overhead Testing Centers \(Laboratories\) under research institutes and centers of the Ministry of Public Health of Russia and the Russian Academy of Medical Science approved by the State Committee for Sanitary-Epidemiology Supervision of the Russian Federation on March 7, 1999](#)*

**7.** To invalidate [Decision](#) of the State Committee for Sanitary-Epidemiology Supervision of the Russian Federation No.1 of January 5, 1993 On the Procedure for Issuance of Hygienic Certificates for Products (registered with the Ministry of Justice of the Russian Federation No.118 of January 18, 1993).

**8.** Control over execution of this order shall be entrusted to the first deputy Minister - Head state Sanitary Physician of the Russian Federation G.G.Onischenko.

**10.** This order shall take effect upon expiration of 10 days after its official publication.

Minister

O.V.Rutkovsky

Registered by the Ministry of Justice of the Russian Federation on August 7, 1998

Registration No. 1587

[Appendix No. 1. Regulations on Conducting the Hygienic Assessment of Products, Goods and Production Facilities](#)

[Appendix No. 2. List of Products and Goods Liable to Hygienic Assessment](#)

[Appendix No. 3. Hygienic statement for Products and Goods](#)

Appendix No. 4. Hygienic statement for Production Facility

Appendix No. 5. List of Socially Important Potentially Hazardous Products and Goods Subject to Hygienic Assessment at the Department of State Sanitary Epidemiology Supervision of the Ministry of Public Health of the Russian Federation

Appendix No. 6. Sample of logo confirming that products passed hygienic assessment

## Appendix No.1

### Regulations on Conducting the Hygienic Assessment of Products and Goods and also Production Facilities (approved by Order of the Ministry of Health of the Russian Federation No. 217 of July 20, 1998)

*Procedure for Conduct of a Sanitary-and-Epidemiological Expert Examination of Products, approved by Order of the Ministry of Health of the Russian Federation No. 325 of August 15, 2001 is effective now*

#### I. General Provisions

II. Procedure of Conducting Hygienic assessment of Products and Goods

III. Procedure of Conducting Hygienic assessment of Production Facilities

#### I. General Provisions

1. This document lays down general requirements to the procedure of effecting hygienic assessment of products, goods and production facilities.

2. The hygienic assessment of products, goods and production facilities is a special procedure effected by bodies and agencies of the state sanitary and epidemiology service to assess potential hazards posed by products and goods to the health of the population which provides for the undertaking of special sanitary-epidemiology investigations and experts' examination, issuance of a hygienic statement in the prescribed format and putting it on the register. The hygienic assessment shall determine permissible areas and conditions of application of products and goods, introduce, if necessary, extra requirements to processes of production, storage, transportation, operation (application) and utilization of products and goods to ensure their safety to man.

*On the procedure for the hygienic assessment of medical products for the purposes of their registration in the Russian Federation see the Instruction, approved by the Ministry of Public Health of the Russian Federation of January 14, 2000*

3. Following the hygienic assessment there shall be issued a statement of a specified pattern (hereinafter referred to as a "statement") which serves as a confirmation of compliance of products and goods with the stipulated requirements of sanitary legislation.

4. The products and goods shall be allowed for production, application and realization after undergoing hygienic assessment and given a statement of a specified pattern.

5. The organization of laboratory and instrument-assisted investigations of products and goods according to hygienically important indicators and also the conduct of hygienic assessment shall be effected on the basis of concluded contracts.

6. The work of hygienic assessment, issuance of statements, hygienic assessment of a production facility, and putting said statements on the register shall be based on a contract made between the applicant and the center of state sanitary-epidemiology supervision or another duly

authorized agency.

7. The work of hygienic assessment of a production facility shall be effected by bodies and agencies of the State Sanitary-Epidemiology Service under a contract made with the organization launching the production of the given products.

8. In conducting hygienic assessment of products, goods and production facilities, these shall be subject to requirements laid down by applicable legislation.

9. The decision as to the safety of products, goods and specific products in the hygienic assessment of production facility shall be taken on the basis of examination of presented documents and results of tests. In the event of complete compliance of presented data with the requirements of sanitary legislation, the center of state sanitary epidemiology supervision or another duly authorized agency shall prepare a [statement](#) of a stipulated pattern. The statement shall be signed by the head state sanitary physician of the Russian Federation or his deputies, head state sanitary physicians for the subjects of the Russian Federation, cities, regions at transport or their deputies.

10. In case of non-compliance of presented data with the requirements of sanitary legislation, the center of state sanitary epidemiology supervision or another duly authorized agency shall take a decision to refuse the statement the fact of which shall be duly notified to the applicant giving respective reasons in writing. If the applicant does not agree to the decision taken to refuse the statement, it shall have the right to file an appeal to the Appeals Council under the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation.

11. The products that were subjected to hygienic assessment may bear, if so desired by the manufacturer (seller, supplier), a logo confirming that the given products have passed the hygienic assessment.

12. The copies of hygienic [statements](#) issued by the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation, centers of state sanitary-epidemiology supervision in the subjects of the Russian Federation and also center of state sanitary-epidemiology supervision in the regions at transport, the Federal center of state sanitary-epidemiology supervision of the Ministry of Public Health of the Russian Federation, centers of state sanitary-epidemiology supervision of federal management of medical-biological and extreme problems under the Ministry of Public Health of the Russian Federation shall possess specified degrees of protection.

## **II. Procedure of Conducting Hygienic Assessment of Products and Goods**

1. The Hygienic assessment of Products and Goods shall comprise as follows:

- taking and registration of application for conducting hygienic assessment of products and goods;
- assessment of volume and cost of work, signing a contract with the applicant for carrying out operations of hygienic assessment;
- examination of presented documentation and samples of products;
- taking a decision on the basis of results of hygienic assessment of products and goods;
- execution and issuance of hygienic statement and putting it on the register of [hygienic statements](#) on products and goods that passed hygienic assessment.

2. For the purpose of hygienic assessment and issuance of a statement of a prescribed pattern, the applicant (legal entity or individual) shall submit to a body or agency of the state sanitary-epidemiology service an application enclosing the following documents.

For domestic products:

- statutory or technical documentation on products, specifications, technological instructions, composition of products, etc.;
- brief description of the method and area of application of products, goods;
- protocols of testing products, goods (if available);
- other documents confirming safety of products;
- samples of products (goods) required for hygienic assessment.

For imported products:

- document of the manufacturing company confirming the quality of products (goods);
- safety certificate of the manufacturing country issued by bodies duly authorized thereto and/or the certificate (confirmation) of the manufacturing company, other materials obtained in the manufacturing country that confirm the safety of products, goods;
- protocols of the testing of products, goods (if available);
- samples of products, goods in the quantity necessary for hygienic assessment;
- specifications for the manufacture of products (goods) indicating conditions of application (utilization) and other statutory and technical documents on the composition and conditions of application.

**3.** The documents of the manufacturing country (supplier) shall be presented to agencies of the state sanitary-epidemiology service with their translation into Russian to be duly certified in the established manner.

**4.** The period of conducting hygienic assessment shall be fixed depending on the type and volume of investigations of a specific type of product, goods; it may not, however, exceed two months. In case of newly developed domestic products and also if it is required to carry out additional testing, the period of hygienic assessment may be extended up to three months.

**5.** The issuance of **statement** shall be made:

**5.1.** For any specific type of products indicating the range of products in case of hygienic assessment of production facility.

**5.2.** For an individual unit within the range:

- when starting manufacture of products (given the availability of duly approved statutory or technical documentation (Gost, Ost, specifications, technological instructions);
- in case of any alterations made in the composition, completeness, technological process of production, norm-setting and technical documentation on products, goods, design;
- when making contracts (agreements) for purchase of products abroad;
- upon expiration of validity of an earlier given statement;
- for trial consignment of products;
- for consignment of imported products arriving into the territory of the Russian Federation, in the absence of statements for to-be-imported products of a specific manufacturer under specific statutory or technical documentation.

**6.** The statement for domestic products shall be given upon obligatory assessment of manufacturing conditions that determine its safety.

**7.** The obtaining of approvals for norm-setting and technical documentation with the agencies of the state sanitary-epidemiology service shall be effected depending on the results of the hygienic assessment to be followed by issuance of a **statement** for manufactured products.

**8.** The validity of the statement shall be such as prescribed by a body or agency of the state sanitary-epidemiology service issuing hygienic statement depending on the potential hazard of this or that product or good, proceeding from the data describing sanitary, hygienic and epidemiological significance of products and goods, and peculiarities of its manufacture and shall be fixed as follows:

- for any type of product (including imported ones) - 5 years maximum.
- for trial consignment of products - one year maximum.
- for consignment of imported products arriving into the territory of the Russian Federation (in the absence of a hygienic statement for a specific type of product of a specific manufacturer issued at the stage of making a delivery contract) - for a term not exceeding the term of worthiness of specified products.

**9.** The hygienic assessment of products listed in Appendix No.5 to Order of the Ministry of Public Health of the Russian Federation No.217 of July 20, 1998 shall be effected at the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation.

**10.** The laboratory and instrument-assisted investigations and measurements, operations of expertise necessary to carry out hygienic assessment of products and goods at the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation shall be carried out by higher testing centers (laboratories) under research institutes and centers of

the Ministry of Public Health of the Russian Federation and the Russian Academy of Medicine. The list of said testing centers shall be approved by the Head State Sanitary physician of the Russian Federation.

### **III. Procedure of Conducting Hygienic Assessment of Production Facilities**

1. The hygienic assessment of a production facility with the aim of giving a [hygienic statement](#) for any specific type of products to be made shall be effected on a voluntary basis upon the application of the manufacturer and shall not exclude sanitary supervision to be exercised on a planned basis by bodies and agencies of the state sanitary epidemiology service.

2. The hygienic assessment of production facility manufacturing domestic products shall be effected at the stage of launching the production.

3. The hygienic assessment of a production facility of domestic products and also that of imported products located in the territory of the Russian Federation shall be conducted by the Department of the State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation, centers of state sanitary-epidemiology supervision in the subjects of the Russian Federation and also centers of state sanitary-epidemiology supervision in the regions for transport, the Federal center of state sanitary-epidemiology supervision of the Ministry of Public Health of the Russian Federation, centers of state sanitary-epidemiology supervision of federal management of medical-biological and extreme problems under the Ministry of Public Health of the Russian Federation.

4. The hygienic assessment of production facilities located in the territory of the Russian Federation must be accompanied with the assessing of the conditions of work and hygienic requirements to environmental conservation.

5. The hygienic assessment of production facilities located outside the Russian Federation that supply their products to the territory of the Russian Federation shall be carried out by the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation.

6. The [hygienic statement](#) shall be given by a specific manufacturing organization. It shall describe the type of manufactured products (for foreign manufacturers, exported into the Russian Federation) and also the range of products manufactured at the time of conducting the hygienic assessment.

7. The manufacturer shall, in case of alteration (expansion) of the range of products or production technology, obtain approvals for the same from the agency that issued the hygienic statement without repeating the hygienic assessment. Moreover, the hygienic statement for the production facility shall be given as is envisaged under Appendix No.3 to Order of the Ministry of Public Health of the Russian Federation No.217 of July 20, 1998.

8. The hygienic assessment of a production facility shall comprise of:

- the acceptance and registration of the application for conducting hygienic assessment of production facility;
- assessment of volume and cost of work, making a contract with the applicant for carrying out the work of registration of the production facility;
- examination of presented documentation and samples of products;
- conducting hygienic assessment of a production facility of applying organization;
- taking decision on the basis of results of the hygienic assessment of the production facility;
- execution and issuance of a [hygienic statement](#) and putting it on the register of production facilities that passed hygienic assessment.

9. The hygienic assessment shall be conducted directly at the applying organization's premises.

10. For the purpose of hygienic assessment and issuance of a hygienic statement, the applicant (legal entity or individual) shall submit to the body or agency of state sanitary-epidemiology service an application of a specified pattern enclosing the following documents.

- a brief description of production facility, technological processes indicating statutory

requirements to the safety of products set by the manufacturing country (for production facilities of imported products and production facilities located abroad), the range of manufactured products, the organization of laboratory control;

- introduction at the enterprise to the system of inspection of production critical points;
- norm-setting or technical documentation for manufactured products;
- certificates or other documents of the manufacturing country confirming the safety of the products;
- other documents of the manufacturer confirming the compliance of production facility with hygienic requirements;
- list of the to-be-presented documents may be updated and extended with respect to specific types of products and manufacturing enterprises.

**11.** The documents of the manufacturing country (supplier) shall be submitted to the bodies and agencies of state sanitary-epidemiology service together with a translation into Russian duly certified in the established manner.

**12.** The types of products manufactured at the production facility that passed hygienic assessment and were put on the Register shall not be subject to further hygienic assessment.

**13.** When deciding about the possibility of hygienic assessment of production facilities located in the territory of the Russian Federation, it is necessary to consider the following:

- the availability at the enterprise of conditions necessary for manufacture of the given type and quantity of products;
- the eventual unfavourable impact of the operation of enterprise upon the living conditions of the population;
- the state of working conditions of workers employed at enterprise;
- organization of production control at the enterprise over the quality of initial feedstock, the technology of production and indicators of safety of end products;
- whether various production premises are appropriate to production technology.

**14.** The production of any type of products at a specific manufacturing organization requires the obtainment of approvals for norm-setting or technical documentation for the whole range of manufactured products from bodies and agencies of the state sanitary-epidemiology service in the prescribed manner.

**15.** When inspecting a manufacturing organization located outside the Russian Federation that supplies products into the territory of the Russian Federation, the following shall be subject to assessment, viz.:

- the availability at the manufacturing organization of conditions necessary for the manufacture of the given type of products;
- the exercising of production control over the quality of initial feedstock, production technology and indicators of safety of end products;
- compliance of the manufactured products with the requirements of sanitary rules and norms in force in the territory of the Russian Federation.

**16.** The [hygienic statement for a production](#) facility shall be given for a maximum period of 5 years. Said period may be reduced in case of violation of the conditions specified as obligatory for giving such statement.

## **Appendix No. 2**

### **List of Types of Products and Goods Subject to Hygienic Assessment (Approved by [Order](#) of the Ministry of Public Health of the Russian Federation No. 217 of July 20, 1998) (with the Amendments and Addenda of September 2, 1999)**

*See [List](#) of Products subject to a sanitary-and-epidemiological expert examination, approved by [Order](#) of the Ministry of Health of the Russian Federation No. 325 of August 15, 2001*

1. Edible feedstock, food products, food supplements, biologically active supplements, conserving agents, materials and items made therefrom that come into contact with food products.

*For the procedure of hygienic assessment and registration of food products obtained from genetically modified sources, see [Decision](#) of the Head State Sanitary Physician of the Russian Federation No. 7 of April 6, 1999*

2. Children's goods: games and toys, clothes (including bed linen), footwear, teaching aids, stationery, furniture, prams, satchels, man-made polymeric and synthetic fibres for manufacture of children's goods.

3. Materials, equipment and substances used in domestic and portable water supply systems.

4. Perfumery and cosmetics, dentifrice.

5. Chemicals and petrochemicals of production purposes, domestic chemical goods.

6. Polymeric and synthetic materials applied in building construction, for transport, for making furniture and other household items; chemical thread and fibres, textiles, sewn and knitted materials containing chemical fibre and textile auxiliary substances; man-made and synthetic skins and textile materials for footwear.

7. Products of machine-building and instrument-making of production, medical and domestic purposes.

*By [Order](#) of the Ministry of Public Health of the Russian Federation No. 339 of September 2, 1999, Item 8 of this List was amended*

8. Publishers' products: teaching books, aids, didactic matter for general education, secondary schools and higher educational establishments, books and magazines for children and teenagers.

9. Articles of natural feedstock subjected during production to treatment (dying, impregnation, exposure to ionizing radiation, etc.)

10. Materials for articles coming into contact with man's skin.

11. Products and articles that are a source of ionizing radiation, including generating radiation and also articles and goods containing radioactive substances.

12. Building raw material and materials subject under hygienic norms to regulation of the content of radioactive substances, including production waste intended for re-processing and utilization in the national economy and metal scrap.

13. Mobile transport vehicles and products of transport purposes.

*[Order](#) of the Ministry of Public Health of the Russian Federation No. 381 of October 27, 2000 abolished Appendix 3 to this Order and approved the new [forms](#) of Sanitary-Epidemiological Statement*

### Appendix No. 3

~~(name and essentials of agency)~~

~~Hygienic statement for products and goods  
(approved by [Order](#) of the Ministry of Public Health of  
the Russian Federation No.217 of July 20, 1998)~~

~~No. \_\_\_\_\_ dated \_\_\_\_\_~~

~~The products \_\_\_\_\_~~

~~\_\_\_\_\_~~

~~(name)~~



~~are allowed for production, supply, realization, application in the territory of the Russian Federation (delete where necessary).~~

~~Organization-developer of norm-setting documentation~~

~~Manufacturing organization~~

~~Recipient of hygienic statement~~

~~Norm-setting and technological documentation:~~

~~Protocols of investigations~~

~~(name of agency that conducted investigations)~~

~~Essential requisites of products:~~

~~Hygienic Characteristics of Products~~

~~Substances \_\_\_\_\_ Hygienic~~

~~Indicators (factors) \_\_\_\_\_ norm~~

~~(Sanpin, MDU, PDK, etc.)~~

~~Area of application:~~

~~Requisite conditions of application, storage, transportation and safety measures:~~

~~Information to be given on the label:~~

~~This statement is valid until:~~

~~Head state sanitary \_\_\_\_\_ Full name, signature  
physician (deputy head state~~

~~sanitary physician) \_\_\_\_\_ Seal~~

*Order of the Ministry of Public Health of the Russian Federation No. 381 of October 27, 2000 abolished Appendix 4 to this Order and approved the new forms of Sanitary-Epidemiological Statement*

## Appendix No. 4

Ministry of Public Health of the Russian Federation

Hygienic statement for Production Facility  
(approved by Order of the Ministry of Public Health of  
the Russian Federation No.217 of July 20, 1998)

dated " \_\_\_\_ " \_\_\_\_\_ 19 \_\_\_\_ No. \_\_\_\_\_

Issued \_\_\_\_\_  
(name of enterprise, workshop, section)

Type/s of manufactured products \_\_\_\_\_

Nomenclature of manufactured products	No., name of norm setting or technical document governing the manufacture of products	Description of sanitary norms and rules or other norm
---------------------------------------	---	---

		setting document
		duly coordinated
		with the state
		sanitary
		epidemiology
		service for the
		products to
		comply with

During production, it is required to observe the following conditions and safety measures:

The production control over product quality and safety shall provide for:

The validity of this statement is fixed until " \_\_\_\_ " \_\_\_\_ 19  
Statement issued by

(name of agency of the State Sanitary Epidemiology Service)

Head state sanitary	_____
physician (deputy head state	Full name, signature
sanitary physician)	Seal

## Appendix No. 5

**List**  
**of Socially Important, Potentially Hazardous Types of Products and Goods Subject to Hygienic Assessment at the Department of State Sanitary-Epidemiology Supervision of the Ministry of Public Health of the Russian Federation**  
**(Approved by Order of the Ministry of Public Health of the Russian Federation No. 217 of July 20, 1998)**

*See Products subject to the sanitary-and-epidemiological expert examination with the Department of the State Sanitary-and-Epidemiological Inspection of the Ministry of Health of Russia, approved by Order of the Ministry of Health of the Russian Federation No. 325 of August 15, 2001*

1. Food products <sup>\*</sup>:
  - 1.1. Special-purpose food products for children, including components for their production;
  - 1.2. Food supplements (aromatizers, conserving agents, stabilizers, looseners);
  - 1.3. Food products and edible feedstock made of the latest (non-traditional) types of feedstock and those obtained after latest technologies;
  - 1.4. Products intended for medicinal and disease-preventive diets.
2. Children's goods:
  - 2.1. Materials used in the production of goods for newly-born babies and children of the first year of age;

*Under Letter of the Department of the State Sanitary-Epidemiology Supervision of the Ministry of the Russian Federation No.03-16/31-05 of February 12, 1999, in the absence of hygienic statement for materials specified under Item 2.1. hereof, hygienic assessment at the Department of State Sanitary-Epidemiology Supervision shall apply to the article itself*

- 2.2. Perfumery and cosmetics for children;
- 2.3. Teaching aids, text-books, didactic matter;
- 3. Dyes, finishing, anti-shrinking, water-repellent agents, plasticizers.
- 4. Products of domestic application:
  - 4.1. Reagents used for treatment of portable water;
  - 4.2. Domestic devices intended for additional treatment of drinking water;
  - 4.3. Perfumery and cosmetics and dentifrice containing biologically active components, ether oils, aromatizers, conserving agents, dyes, photoprotective and fluorine containing compounds, skin protective means of domestic purpose. Newest and non-traditional types of feedstock used in perfumery and cosmetics and dentifrice.
- 5. The products intended for application in industry:
  - 5.1. Means of individual protection including ointments, pastes, and creams used in industry.
  - 5.2. Equipment, units for collective protection, materials to manufacture ventilation systems.
  - 5.3. Rubbish burners.
- 6. Medical equipment, instruments and hygienic means:
  - 6.1. Physiotherapeutic, diagnosis and medical equipment.
- 7. Products containing sources of ionizing radiation, including generating generation, intended for mass-scale production or application of the newest technologies. Production wastes containing natural or man-made radionuclides used as building materials, fertilizers or for other purposes.
- 8. Antenna-feeder systems of radio-relaying stations, radar stations (including those of space tracking), outdoor switchgear of high and ultra-high voltage substations, satellite systems of communication.

---

\* With due regard for the procedure of interaction of the State Standards Committee of Russia and the State Sanitary-Epidemiology Service of the Russian Federation when effecting certification within the system of Gost R and hygienic assessment of food products of April 30, 1998

## Appendix No. 6

**Sample of logo  
confirming that products passed hygienic assessment  
(Approved by [Order](#) of the Ministry of Public Health of  
the Russian Federation No. 217 of July 20, 1998)**

*Since the technical facilities do not make it possible to reproduce the example of marking given in the original of the document, it is not given in the Database*

---

\* Vedomosty Verkhovnogo Soveta RSFSR, 1991, No. 20, item 641

\*\* Sobranie Zakonodatelstva Rossiskoy Federatsii No. 3, 1996, item 140

\*\*\* Sobranie Zakonodatelstva Rossiskoy Federatsii No. 23, 1997, item 2691