

DECISION
OF THE GOVERNMENT OF THE RUSSIAN FEDERATION
NO. 988 OF DECEMBER 21, 2000
ON THE STATE REGISTRATION OF NEW FOODSTUFFS, MATERIALS AND ARTICLES
(with the Amendments and Additions of April 27, 2001)

On the State Registration of New Foodstuffs, Materials and Articles, Perfume and Cosmetic Products, Oral Hygiene Means and Articles, Tobacco Articles, see [Order](#) of the Ministry of Public Health of the Russian Federation No. 89 of March 26, 2001

Pursuant to the [Federal Law](#) on the Quality and Safety of Foodstuffs the Government of the Russian Federation hereby resolves:

[Decision](#) of the Government of the Russian Federation No. 324 of April 27, 2001 amended Item 1 of this Decision

[See the previous text of the Item](#)

1. To institute, effective from January 1, 2002, the state registration of new foodstuffs, materials and articles.

2. To endorse the [Regulations](#) on the State Registration of New Foodstuffs, Materials and Articles and on Keeping a State Register of Foodstuffs, Materials and Articles Permitted for Manufacture on the Territory of the Russian Federation or Import into the Territory of the Russian Federation and Circulation attached hereto.

3. The Ministry of Public Health of the Russian Federation is hereby vested with the duty:

a) of performing the state registration of new foodstuffs, materials and articles (hereinafter referred to as "the state registration of products");

b) of keeping a State Register of Foodstuffs, Materials and Articles Permitted for Manufacture on the Territory of the Russian Federation or Import into the Territory of the Russian Federation and Circulation (hereinafter referred to as "the state register")

The state registration of new foodstuffs of animal origin and the keeping of the state register of such products shall be carried out by the Ministry of Public Health of the Russian Federation jointly with the Ministry of Agriculture of the Russian Federation.

4. It is hereby established that the expenses incurred in performing the state registration of products shall be borne by the applicant. An appropriate payment procedure shall be endorsed by the Ministry of Public Health of the Russian Federation and the Ministry of Agriculture of the Russian Federation in agreement with the Ministry of Finance of the Russian Federation.

5. The Ministry of Public Health of the Russian Federation and the Ministry of Agriculture of the Russian Federation shall:

a) within three months elaborate and endorse a nomenclature of goods subject to state registration, documents governing registration organisation, conduct and payment and also the provision of information on products that have passed state registration, state registration application and certificate forms and anti-counterfeiting protection;

b) institute, in the Year 2001, an information system for keeping a record of the products that have passed state registration.

See [Regulations](#) on the Accreditation of Organisations Pursuing the Activity of Assessing the Compliance of Products, Manufacturing Processes and Services with Established Quality and Safety Standards, endorsed by [Decision](#) of the Government of the Russian Federation No. 514 of July 6, 2001

6. The Ministry of Public Health of the Russian Federation, the Ministry of Agriculture of the Russian Federation and the State Customs Committee of the Russian Federation shall elaborate and endorse, before April 1, 2001, a procedure for interaction in controlling the import of the

products subject to state registration into the territory of the Russian Federation.

Chairman
of the Government
of the Russian Federation

M.Kasyanov

Regulations
on the State Registration of New Foodstuff, Materials
and Articles and on Keeping a State Register of Foodstuffs,
Materials and Articles Permitted for Manufacture on the
Territory of the Russian Federation or Import into the
Territory of the Russian Federation and Circulation
(endorsed by [Decision](#) of the Government
of the Russian Federation No. 988 of December 21, 2000)

On the State Registration of New Foodstuffs, Materials and Articles, Perfume and Cosmetic Products, Oral Hygiene Means and Articles, Tobacco Articles, see [Order](#) of the Ministry of Public Health of the Russian Federation No. 89 of March 26, 2001

1. The present Regulations establish a procedure for organising and conducting the state registration of new foodstuffs, materials and articles and also for keeping the State Register of Foodstuffs, Materials and Articles Permitted for Manufacture on the Territory of the Russian Federation or Import into the Territory of the Russian Federation and Circulation (hereinafter referred to as "the state register").

2. The following shall be subject to state registration: new foodstuffs, materials and articles, perfume and cosmetic products, oral hygiene means and articles and also tobacco articles (hereinafter referred to as "products") listed in the [annex](#) hereto and being in compliance with the nomenclature for such products endorsed by the Ministry of Public Health of the Russian Federation and the Ministry of Agriculture of the Russian Federation.

The term "new products" means products developed and industrially manufactured for the first time on the territory of the Russian Federation (hereinafter referred to as "Russian-made products") and also products imported into the territory of the Russian Federation for the first time, such products not having been on sale in the Russian Federation before (hereinafter referred to as "imported products").

3. The state registration of Russian-made products shall be carried out at the stage of their being prepared for manufacture and that of imported products before their being brought into the territory of the Russian Federation.

4. A product which is subject to state registration but has not undergone such registration shall be prohibited for industrial manufacture and import into the territory of the Russian Federation and circulation.

5. The state registration of products shall be performed as aimed at:

a) revealing the products' properties hazardous for human life and health and also causing a possibility of harm to human health in the course of manufacture, circulation and consumption (use) of the products;

b) assessing the compliance of the products, conditions of its manufacture and circulation with state sanitary-epidemiological and hygiene rules and regulations (hereinafter referred to as "sanitary rules and regulations"), and as concerns animal origin foodstuffs, the conditions of their production and circulation, their compliance with veterinary standards, veterinary-sanitary expert examination rules and regulations (hereinafter referred to as "veterinary rules and regulations");

c) assessing the effectiveness of measures for preventing harmful effects of the products on human health during the manufacture, circulation and consumption (use) thereof and also during the disposal or destruction of poor-quality and hazardous products.

6. The state registration of products shall include the following:

a) an expert examination of the documents presented by the manufacturer (supplier) of products to characterise the properties of the products and the effectiveness of measures to prevent their harmful effect on human health and also confirming the products' and their manufacturing conditions' and circulation's compliance with sanitary and veterinary rules and regulations;

b) an expert examination of the results of the toxicological, hygienic, veterinary and other kinds of research (testing) performed in respect of a product (when necessary), and in as much as a Russian-made product is concerned, also examination of the conditions of its experimental manufacture;

c) the entry of information on a product and the manufacturer (supplier) thereof in the state register;

d) the issuance of a product state registration certificate whereby the product in question is granted a permit for manufacture on the territory of the Russian Federation or for import into the territory of the Russian Federation and circulated.

7. The state registration of products shall be performed by the Ministry of Public Health of the Russian Federation and the institutions of the Russian state sanitary-epidemiological service authorised by the Ministry.

The state registration of new animal origin foodstuffs shall be performed by the Ministry of Public Health of the Russian Federation jointly with the Ministry of Agriculture of the Russian Federation.

8. If necessary, organisations and experts accredited for the purposes of expert examination performance under the procedure established by the Ministry of Public Health of the Russian Federation and the Ministry of Agriculture of the Russian Federation may be recruited under a contract to take part in expert examinations.

9. For the purposes of state registration of products an individual entrepreneur or organisation pursuing the elaboration or import of products (hereinafter referred to as "applicant") shall file the following documents with the Ministry of Public Health of the Russian Federation or the institution of the Russian state sanitary-epidemiological service authorised by the Ministry, and in respect of animal origin foodstuffs, also with the Ministry of Agriculture of the Russian Federation (hereinafter referred to as "registration body"):

a) a state registration application concerning the products, including name and legal address (for an organisation), full name, personal identity document details (for an individual entrepreneur) and product description;

b) the regulatory and/or technical documents endorsed in the established manner (standards, technical conditions, rules, technological instructions, specifications etc.) whereby the industrial manufacture of the Russian-made products is going to be performed or whereby the imported products are manufactured;

c) a statement containing the results of expert examinations;

d) copies of the sanitary-epidemiological statements, state veterinary service statements certifying the compliance of the technical documents whereby the Russian products are going to be industrially manufactured with the provisions of sanitary and veterinary rules and regulations, such copies being attested in the established manner, and in as much as imported products are concerned, copies of documents issued by the authorised bodies of the country of products' origin certifying the products safety for humans;

e) a document confirming that the applicant has made payment for the consideration of the state registration application concerning the products.

10. The documents presented to a registration body shall be accepted against a list of documents, with a copy of the list being forwarded (delivered) to the applicant as bearing an annotation with the date of acceptance.

No other documents shall be demanded from the applicant, except those specified in the present Regulations.

11. A fee of 300 roubles shall be charged for consideration of a state product registration application by a registration body, this amount being entered into the federal budget.

The fee shall not be refundable to the applicant if state registration is refused.

12. A registration body shall consider documents presented thereto within 40 days of the receipt of an application with all the necessary documents attached.

A fee of 1,000 roubles shall be charged for the state registration of products, this amount being entered in the federal budget.

13. Using the results of scrutiny of documents and expert statements a registration body shall make a decision as to the state registration of products and shall issue a certificate of state registration of the established format (hereinafter referred to as "registration certificate") to the applicant.

Information on a product that has undergone state registration shall be entered in the state register.

A registration certificate shall be issued within five days after the applicant's submission of a document confirming that payment has been made for the state registration of products.

14. Registration certificate forms shall be deemed strict accountability documents and they shall be manufactured by a technology ensuring that they are counterfeit-proof.

A copy of a registration certificate shall be kept by the registration body that has issued the certificate.

15. The effective term of a registration certificate shall be established for the whole term of industrial manufacture of Russian-made products or delivery of imported products.

16. The manufacturer (supplier, seller) of a product shall notify consumers of the state registration of product by means of indicating data on the number and date of registration certificate on the label (package, insert sheet), in user's instructions, technical certificate and also in product advertising materials.

17. The manufacturer (supplier) of a product shall be accountable for the compliance of the product with the established quality and safety standards within the whole period of industrial manufacture of a Russian-made product or delivery of an imported product.

18. A product may be refused state registration if:

a) the quality and safety of the product does not comply with the sanitary and/or veterinary rules and regulations and the product is a real hazard to human life and health;

b) no safety standards can be set in keeping with modern scientific levels for the product and conditions of the manufacture and circulation thereof and also no methodology is available for detecting and measuring the hazardous factors of the product in the product proper and in the human environment;

c) effective measures do not exist or cannot be implemented for preventing the product's hazardous effects on human health and the human environment in the manufacture, circulation and consumption (use) thereof.

19. The decision to refuse state registration of a product together with the reasons for such refusal shall be forwarded to the applicant in writing within three days.

20. Products differing from each other in terms of their consumer properties shall not be state-registered under one and the same name, and likewise, a product shall not be state-registered several times under one name or different names.

21. An applicant is entitled to appeal, in accordance with the administrative or judicial procedure, a registration body's decision to refuse state registration.

22. A registration certificate may be suspended by the registration body if the manufacturer (supplier) of product is in breach of the provisions of [Items 17](#) and [18](#) of the present Regulations.

If the said breach cannot be eliminated or if a product's hazardous properties in its industrial manufacture and circulation are discovered which were not known before the registration certificate shall be annulled by the registration body.

A decision to annul a registration certificate together with detailed reasons for the annulment shall be forwarded in writing to the manufacturer (supplier) of a product as binding thereon to terminate the manufacture and sale of the poor-quality and hazardous products, arrange its recall from buyers and/or replacement and the disposal/destruction of such products in accordance with the procedure established under Russian law.

23. The state register shall be kept by the Ministry of Public Health of the Russian Federation (jointly with the Ministry of Agriculture of the Russian Federation if animal origin foodstuffs are concerned).

24. The following details shall be entered in the state register:

a) the name and legal address of an organisation, the full name, personal identity document details of an individual entrepreneur pursuing the elaboration and preparation for manufacture of a Russian-made product;

b) the name, country of origin and legal address of an organisation manufacturing and supplying an imported product;

c) product description and trademark used in the manufacture thereof (if any);

d) information on the regulatory or technical documents applied in the manufacture of the product;

e) a list of the product's hazardous properties including indication of their parameters;

f) information on the safety measures required in the manufacture, circulation and consumption (use) of the product;

g) the number and date of issue of registration certificate;

h) the name and legal address of the registration body that issued the registration certificate.

25. The documents, expert statements, copies of registration certificates submitted for registration purposes shall make up the information stock of the state register and they shall be permanently preserved by a registration body.

26. The Ministry of Public Health of the Russian Federation jointly with the Ministry of Agriculture of the Russian Federation shall publish information on the products that have undergone state registration or been deregistered and shall provide such information to state bodies, natural persons and legal entities on their request.

When said information is being published and provided the standards governing the dissemination of confidential information and copyright shall be observed.

Annex
to the [Regulations](#)
on the State Registration
of New Foodstuffs, Materials and Articles
and Keeping the State Register of Foodstuffs,
Materials and Articles Permitted for Manufacture
on the Territory of the Russian Federation
or Import into the Territory of the Russian Federation
and Circulation

List
of the Foodstuffs, Materials and Articles, Perfume
and Cosmetic Products, Oral Hygiene Means and Articles
and Also Tobacco Articles Subject to State Registration

1. Mineral water (natural table, treatment table and treatment), bottled potable water.

2. Infant food (canned fruits and vegetables, in particular homogenised, canned vegetables, in particular sterilised intended for infants; canned fruits as infant and dietetic food; specialised infant foodstuffs on a dairy basis; cereal, fruit and vegetable, fish, meat-based additional nutrition products; canned fruits and vegetables; pre-school and school child food).

3. Dietetic foods (treatment and prophylactic) (dietetic and diabetic bread and baked products; dietetic and diabetic sweets; dietetic alcohol-free beverages; animal fats, vegetable oils, dietetic margarine products; dietetic canned fruits and vegetables and dietetic canned fruits; canned lunch, canned natural products, canned enriched mushrooms).

4. Meat products (sausages, frankfurters, Paris sausages etc.) enriched with protein and/or other microelements*.

5. Canned meat and meat-vegetable enriched with protein and/or other microelements^{*}.
6. Dairy products enriched with vitamins and/or other microelements.
7. Food additives (organic food acids and derivatives thereof, emulgators, flavours, acidity regulators, foam-suppressers, antioxidants, dyes, taste and flavour enhancers, baking powders, stabilisers, sweeteners, thickeners, complex and combined functional and technological food additives).
8. Biologically active food additives (nutrition additives, parapharmaceutical additives, probiotics).
9. Foodstuffs produced from genetically modified sources.
10. Foodstuffs, in particular foodstuff raw materials^{*}, produced by means of new technologies^{**}.
11. The materials and articles contacting foodstuffs (technological equipment, instruments, devices etc.; dishware and cutlery; materials used to manufacture, pack, store and transport foodstuffs).
12. Perfume and cosmetic products.
13. Oral hygiene means and articles.
14. Tobacco articles including raw materials, auxiliary materials and accessories.

* Registered by the Ministry of Public Health of the Russian Federation jointly with the Ministry of Agriculture of the Russian Federation.

** "New technologies" means technological processes of manufacture, storage, transport and sale of products which have not been used before on the territory of the Russian Federation and also technological processes of manufacture of products from types of raw materials and other components which have not been used before.