

DECISION
OF THE GOVERNMENT OF THE RUSSIAN FEDERATION
NO. 262 OF APRIL 4, 2001
ON STATE REGISTRATION OF CERTAIN TYPES OF PRODUCTS WHICH CAN
BE DANGEROUS TO MAN, AND ALSO OF CERTAIN TYPES OF PRODUCTS WHICH
ARE IMPORTED TO THE TERRITORY OF THE RUSSIAN FEDERATION
FOR THE FIRST TIME
(with Amendments and Addenda of July 5, 2001)

Under the [Federal Law](#) on Licensing of Sanitary and Epidemiological Well-Being of the Population (Collected Acts of the Russian Federation No. 14, Item 1650, 1999) the Government of the Russian Federation hereby resolves:

[Decision](#) of the Government of the Russian Federation No. 499 of July 5, 2001 amended Item 1 of this Decision

1. To introduce as of January 1, 2002 the state registration of certain types of products defined by the present decision which can be dangerous to man and also of other kinds of products which are imported to the territory of the Russian Federation for the first time.

2. To approve the enclosed [Regulations](#) on State Registration of Certain Types of Products Which Can Be Dangerous to Man, and Also of Certain Types of Products Which Are Imported to the Territory of the Russian Federation for the First Time.

3. To entrust the Ministry of Public Health of the Russian Federation with the implementation of the state registration and keeping the state register of certain types of products defined in Item 1 of the present Decision.

4. The Ministry of Public Health of the Russian Federation shall:

- within 3 months approve the nomenclature of certain types of products subject to state registration in accordance with the present Decision;

[Order](#) of the Ministry of Public Health of the Russian Federation No. 324 of August 15, 2001 endorsed the [Nomenclature](#) of Specific Types of Products Potentially Hazardous for the Human Being and Also of Specific Types of Products Brought into the Territory of the Russian Federation for the First Time

- ensure the maintenance of an automated information system designed to keep records on certain types of products which have passed the state registration.

5. The Ministry of Public Health of the Russian Federation and the State Customs Committee of the Russian Federation shall draft the mode of interaction in the course of state monitoring of safety and quality of certain types of products subject to state registration in accordance with the present Decision.

Chairman of the Government
of the Russian Federation

M.Kasyanov

Regulations
on State Registration of Certain Types
of Products Which Can Be Dangerous to Man, and Also of
Certain Types of Products Which Are Imported to
the Territory of the Russian Federation for the First Time
(Endorsed by [Decision](#) of the Government of the Russian
Federation No. 262 of April 4, 2001)

See also the [Procedure](#) for effecting the state registration of specific types of products potentially

hazardous for the human being and also of specific types of products brought into the territory of the Russian Federation for the first time, endorsed by Order of the Ministry of Public Health of the Russian Federation No. 324 of August 15, 2001

1. The present Regulation lays down the procedure for state registration and keeping the state register of certain types of products which can be dangerous to man, and also of certain types of products which are imported to the territory of the Russian Federation for the first time (further, the state register).

2. Subject to state registration shall be certain types of products according to the enclosure which can be dangerous to man, and also of certain types of products which are imported to the territory of the Russian Federation for the first time (further, the products). Nomenclature of said products is approved by the Ministry of Public Health of the Russian Federation.

3. The products will be permitted for manufacture, transportation, purchase, storage, marketing, use (application) following their state registration.

4. Products which can be dangerous to man shall undergo state registration on its stage of preparation for production on the territory of the Russian Federation (hereafter referred to as the Russian products), while products imported to the territory of the Russian Federation and which had not been marketed on the territory of the Russian Federation (hereafter referred to as imported products) - prior to their importation to the territory of the Russian Federation.

5. The state registration is conducted by the Ministry of Public Health of the Russian Federation and by bodies of the State Sanitary and Epidemiological Service of the Russian Federation authorized by the former.

6. The state registration of products is aimed at ensuring the sanitary and epidemiological well-being of the population on the basis of:

- a) results of evaluation of how dangerous the products are to man and the habitat;
- b) establishment of hygienic and other standards for content of substances, individual components of the products in the habitat;
- c) development of protective measures, including the conditions for disposal and destruction of low-quality products and those posing hazard to human health, for preventing its harmful effect on man and the habitat.

7. The degree of hazardous effect the products have on man and the habitat is determined on the basis of analysis of documents presented by the manufacturer (supplier) of the products and also by results of research (tests) and expertise performed as the case may be by duly certified bodies and institutions of the State Sanitary and Epidemiological Service of the Russian Federation and by experts. Research (tests) and expertise are performed on contractual basis.

8. To obtain the state registration of products an individual entrepreneur or an organization engaged in the development and/or preparation for production of Russian products or deliveries of imported products (hereafter referred to as "the applicant") shall submit to the Ministry of Public Health of the Russian Federation and bodies of the State Sanitary and Epidemiological Service of the Russian Federation authorized by the latter (hereafter referred to as "the registrar") the following documents:

- a) an application for state registration of the products stating the product name, its own name and legal address (for an organization), the surname, name, middle name, passport data (for an individual entrepreneur);
- b) duly approved regulatory documents and/or technical documents (standards, specifications, procedures, process manuals, etc.) to be used in the industrial manufacturing of Russian products or manufacturing of imported products;
- c) sanitary and epidemiological opinion whether the technical documents to be used in the industrial manufacturing of Russian products in fact meet the sanitary rules, and as regards imported products - copies of documents issued by authorized bodies of country of origin of the products that confirm they are safe to man;
- d) conclusions on results of completed research, tests, examinations;
- e) duly registered safety certificate of a substance (material) involved in the manufacturing of

the products.

9. Documents submitted to the registrar shall be accepted under an inventory list thereof, a copy of the list with a note on the documents acceptance date is sent or handed over to the applicant.

It is prohibited to demand that the contender for license provides other documents not required under this Regulation.

10. The registrar shall examine the documents submitted for state registration within 40 days upon receipt of the application with all the necessary documents.

11. On the basis of examination of the submitted documents and expert opinions the registrar decides on the state registration of the products and issues to the applicant the standard state registration certificate (hereafter referred to as the registration certificate).

A pay of 300 roubles shall be charged for consideration of a state registration application by the registrar which will be remitted to the federal budget.

A fee of 1,000 roubles remittable to the federal budget shall be charged for performance of the state registration.

The registration certificate shall be issued within 5 days upon decision to grant state registration of the products.

Registration certificate forms are strict accountability documents and they are produced under a technology ensuring their protection against forgery.

A copy of the registration certificate shall be kept in a issuing registrar.

12. The registration certificate shall be valid for the entire period of industrial production of Russian products or deliveries of imported products.

13. The manufacturer (supplier) of the products must provide consumers with information on the state registration of products by stating the number and date of registration certificate issue on the label (packing, insert slip), in the user's manual, in the technical certificate and in the advertisement of the products.

14. The manufacturer (supplier) of the products is responsible for the products' compliance with the effective quality and safety standards over the entire period of industrial production of Russian products or deliveries of imported products.

15. State registration of products may be denied in the following cases:

a) the quality and safety standard of the products do not meet the sanitary rules and pose life and health hazard to man;

b) safety requirements at the modern state of science have not been developed as regards the products and its manufacturing conditions, there are no methods to determine and measure dangerous effects of such products available in the products and in the human habitat;

c) effective measures are not available or can not be implemented to protect against harmful effects of the products on human health in the course of manufacturing, use (application) of such products.

16. The justified decision to deny the state registration of products shall be brought to the notice of the applicant in writing within 3 days.

17. It is not permitted to grant state registration under the same name to products with different consumer properties and also multiple state registration to the same kind of products under a single or different names.

18. The applicant may appeal the registrar's decision to deny the state registration of products in administrative procedure or to a court of law.

19. The registrar may suspend the operation of the state registration of products if producer (supplier) of the products breaches the requirements of [Items 14](#) and [15](#) of the present Regulations.

Registration certificate is annulled by the registrar if such violations can not be eliminated or if are discovered earlier unknown harmful properties of the products in the course of their manufacturing, use (application).

The written decision to annul the registration certificate with a detailed explanation shall be brought to the notice of the products manufacturer (supplier) which on the basis of such decision must stop the production and marketing of the low quality and hazardous products provide

conditions for collecting such products being turned in by consumers and/or replacement of such and also arrange for the disposal or destruction of such products in the procedure laid down by legislation of the Russian Federation.

20. Information about state registration of the products are entered in the state register maintained by the Ministry of Public Health of the Russian Federation.

21. The following data are included in the state register:

a) name and legal address of the organization, the surname, name, middle name, passport data (for an individual entrepreneur)

which develop Russian products and prepare such for the production;

b) name and legal address of manufacturer and supplier organization of imported products;

c) name of the products and trade mark under which it is produced (if available);

d) information about regulatory or technical documents according to which the products are manufactured;

e) list hazardous properties of the products, including their parameters;

f) information on safety measures which must be complied with in the course of manufacture, transportation, storage, sale and use of the products;

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

h) name and legal address of the registrar which had issued the registration certificate.

22. Documents, expert opinions, copies of registration certificates make up the data pool of the state register and shall be subject to permanent storage in the registrar.

23. The Ministry of Public Health of the Russian Federation shall publish information about products which have passed the state registration, about suspension of registration certificate by the registration body, its cancellation, removal of products from the state register and the former shall also furnish said information to interested state bodies and legal entities and natural persons according to their requests.

When said information is published and furnished provisions shall be complied with that limits the dissemination of confidential information and protect copyrights.

**Annex to
the Regulations on State Registration
of Certain Types of Products Which Can
Be Dangerous to Man, and Also of Certain
Types of Products Which Are Imported to
the Territory of the Russian Federation
for the First Time**

**List of
Certain Kinds of Products Subject to State Registration**

Product type description	Code of OKP classes * 005-93
1. Materials, equipment, devices and other technical means for treatment of water designed for application in supply of technical and potable water	out of 42
2. Disinfectants, disinsection and derating means for application in households, medical and sanitary institutions and at other facilities to help ensure safe and healthy environ-	out of 23, 93

ment for people (apart from those with veterenary applications)	
3. Household chemical goods	out of 23

* OKP - stands for the All-Russia Classification of Products, effective July 1, 1994.