

FEDERAL ACT OF THE RUSSIAN FEDERATION ON STATE REGULATION OF GENETIC ENGINEERING ACTIVITY

Adopted by the State Duma on 5 June 1996

Article 1. Scope of this Federal Act

This Federal Act establishes regulations governing relations in the spheres of the utilization of nature, protection of the environment and assurance of environmental safety arising in connection with the conduct of genetic engineering activity. The Act is not applicable to procedures for the conduct of genetic engineering activity or to the application of genetic engineering techniques to human beings or to tissues or cells in the human organism.

Article 2. Key concepts

The key concepts employed in this Act are defined as follows:

Genetic engineering: all procedures, methods and technologies, including technologies for obtaining recombinant ribonucleic and deoxyribonucleic acids, designed to remove genes from an organism, perform manipulations on genes and introduce them into other organisms;

Genetic engineering activity: activity undertaken by means of genetic engineering methods and genetically modified organisms;

Genetically modified organism: one or more organisms in the form of any acellular, monocellular or multicellular entities which are capable of multiplication or transmission of genetic material, are distinct from natural organisms, are obtained by means of genetic engineering methods and contain genetically engineered material, including genes, or fragments or combinations of genes;

Release of genetically modified organisms into the environment: the commission or omission of any action resulting in the introduction of genetically modified organisms into the environment;

Biological protection: the creation and application in genetic engineering of combinations of biological material which have no harmful effects for human beings or for the environment and whose properties preclude the undesirable survival of genetically modified organisms in the environment and the transmission by such organisms of genetic information;

Physical protection: the creation and application of special technical means and methods to prevent the escape of genetically modified organisms into the environment and (or) the transmission by such organisms of genetic information;

Closed system: a system for conducting genetic engineering activity in which an organism is genetically modified or in which genetically modified organisms are manipulated, cultivated, stored, utilized, transported, destroyed or disposed of under conditions involving physical, chemical or biological barriers or combinations of such barriers designed to prevent contact between the genetically modified organism on the one hand and the public and the environment on the other;

Open system: a system of conducting genetic engineering activity which permits contact between genetically modified organisms on the one hand and the public and the environment on the other in cases where such organisms are intentionally released into the environment, where they are used for medical purposes or in foodstuffs, where they are exported or imported, or where they are used in connection with technology transfer;

Transgenic organisms: animals, plants, micro-organisms or viruses whose genetic programme has been altered by means of genetic engineering techniques.

Article 3. Legislation of the Russian Federation in the field of genetic engineering activity

The legislation of the Russian Federation in the field of genetic engineering activity consists of this Federal Act, other federal acts and regulatory legal acts of the Russian Federation, and also the laws and other regulatory legal acts of subjects of the Russian Federation.

Article 4. Purposes of State regulation in the field of genetic engineering activity

State regulation in this field has the following purposes:

- To establish the main areas of activity of federal organs of State power, of the organs of State power of subjects of the Russian Federation, of the organs of local self-government, and of corporations and citizens (individuals) in the field of genetic engineering activity;
- To establish the main provisions of the legal regime governing relations arising in the field of genetic engineering activity;

- To define a mechanism to ensure public safety and environmental protection in respect of genetic engineering activity and the application of its results;
- To establish the legal bases of international cooperation undertaken by the Russian Federation in the field of genetic engineering activity;
- To create the necessary conditions for the development of priority areas of genetic engineering activity.

In order to achieve these objectives federal and regional programmes shall be undertaken in connection with the development of genetic engineering activity.

Article 5. Main aims of State regulation in the field of genetic engineering activity

The main aims of State regulation in the field of genetic engineering activity are to:

- Raise living standards and protect human health;
- Protect and restore the environment, and preserve biodiversity;
- Improve the efficiency of agriculture;
- Improve the efficiency of the primary production and processing industries;
- Preserve and improve the pool of key personnel in the field of genetic engineering activity, improve their level of expertise and promote higher standards of training for specialists engaged in such activity.

Genetic engineering activity shall be based on the following principles:

- The safety of the public (individuals) and of the environment;
- The universal accessibility of information on the safety of genetic engineering activity;
- Certification of products containing the results of genetic engineering activity, with the requirement that certificates provide full details regarding the methods of obtaining the product in question and regarding its properties.

Article 6. Types of genetic engineering activity subject to licensing

Operations in the field of genetic engineering classified as having risk level III or IV shall be undertaken on the basis of authorizations (licences) issued in conformity with the procedures established by law. The following types of genetic engineering activity shall be subject to licensing:

- Genetic manipulations at the molecular and cellular levels involving the use of recombinant ribonucleic and deoxyribonucleic acids for the purpose of creating

genetically modified organisms (viruses, micro-organisms, transgenic plants and transgenic animals, and also their cells);

- All types of experiment performed on genetically modified organisms, including laboratory experiments, clinical and field trials, and industrial pilot tests;
- The release of genetically modified organisms into the environment;
- The manufacture of preparations involving the use of genetically modified organisms;
- The storage, disposal and destruction of genetically modified organisms and (or) their products; and the utilization of by-products of genetic engineering activity;
- The purchase, sale or exchange of, or other transactions or activities relating to, genetic engineering technologies or genetically modified organisms and (or) their products for which no certificate of quality or mark of conformity has been issued by a competent authority, whether in the field of national or international activity.

Article 7. Safety regime applicable to genetic engineering activity

The overall coordination and development of the safety regime applicable to genetic engineering activity shall conform to the procedures established by the Government of the Russian Federation.

Corporations and citizens (individuals) engaging in genetic engineering activity shall be required to ensure the biological and physical protection of the personnel of organizations undertaking genetic engineering activity and of the public and the environment, in accordance with the levels of risk associated with the potentially harmful effects of genetic engineering activity on human beings and the environment.

Depending on the degree of the potential danger presented by genetic engineering activity, four levels of risk associated with the potentially harmful effects of genetic engineering activity for human health shall be established for closed systems:

- Risk level I corresponds to activities presenting no danger to human health and is comparable to the level of risk associated with working with non-pathogenic micro-organisms;
- Risk level II corresponds to activities presenting an insignificant danger to human health and is comparable to the level of risk associated with activities involving some micro-organisms that are pathogenic under certain conditions;
- Risk level III corresponds to activities presenting a moderate risk to human health and is comparable to the level of risk involved in working with micro-organisms

potentially capable of transmitting infectious disease;

- Risk level IV corresponds to activities presenting a significant risk to human health and is comparable to the level of risk involved in working with pathogens associated with particularly dangerous diseases.

Activities involving micro-organisms in closed systems on a scale reaching beyond the boundaries of laboratory research shall be assigned risk level III or IV.

Genetic engineering activity conducted under the conditions of open systems shall be assigned risk level III or IV.

Corporations and citizens (individuals) engaging in genetic engineering activity shall perform evaluations of the associated risk when planning, preparing or conducting such activity.

Activities assigned risk level I or II shall be registered by the organization engaging in the genetic engineering activity.

Authorizations (licences) for activities assigned risk levels III and IV shall be issued in conformity with procedures established by the Government of the Russian Federation.

Article 8. Requirements imposed on corporations and individuals engaging in genetic engineering activity

The following shall be permitted to engage in genetic engineering activity:

- Citizens (individuals) whose professional background and state of health fulfil the requirements of the safety provisions applicable to genetic engineering activity;
- Corporations having at their disposal premises, equipment and personnel fulfilling the requirements of the preceding subparagraph.

In order to engage in genetic engineering activity assigned risk level III or IV, it shall be necessary to obtain an authorization (licence) in the established manner.

Article 9. Financing of genetic engineering activity and of its safe conduct

Genetic engineering activity and its safe conduct shall be financed in the established manner from the respective budgetary appropriations for such purpose, from the specially designated resources of organizations and funds, and from other sources not prohibited under the legislation of the Russian Federation.

Article 10. Guarantee of the universal accessibility of information on the safety of genetic engineering activity

Information on the safety of genetic engineering activity shall be universally accessible.

Corporations and citizens (individuals) engaging in genetic engineering activity shall be required at the request of interested entities or persons to furnish information on the level of risk of genetic engineering activity and on safety precautions to be taken in its regard. In this connection, information on genetic engineering activity protected by State, official or trade secrecy, shall be furnished in the established manner.

Article 11. Standardization and certification of products (services) in the field of genetic engineering activity

Products (services) developed by means of genetic engineering techniques shall fulfil the requirements of environmental safety, public health, pharmacopoeial provisions and the mandatory provisions of Russian Federation national standards.

A certificate of quality and mark of conformity issued or recognized by a competent authority shall be required in respect of products and services developed and furnished respectively by means of genetically modified organisms and subject to the requirement of certification under federal legislation.

Article 12. Liability in respect of genetic engineering activity

Corporations and citizens (individuals) engaging in genetic engineering activity whose action or inaction causes harm to the personnel of an organization engaged in genetic engineering activity or to the public or the environment shall bear liability for such action or inaction under the laws of the Russian Federation.

Article 13. International cooperation of the Russian Federation in the field of genetic engineering activity

The Russian Federation shall enter into international agreements with a view to the further development and consolidation of international cooperation in the field of genetic engineering activity.

Article 14. Entry into force of this Federal Law

This Federal Law shall enter into force on the day of its official publication.

B. YELTSIN

PRESIDENT OF THE RUSSIAN FEDERATION

Kremlin, Moscow

5 July 1996

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