

# RUSIA

## FEDERAL LAW ON STATE REGULATION IN THE FIELD OF GENETIC ENGINEERING ACTIVITIES OF JUNE 5th, 1996

The principal provisions of this Federal Law read as follows:

### *Scope of this Federal Law*

*Article 1.* This Federal Law governs, in the fields of the utilization of natural resources, the protection of the environment, and the assurance of ecological security, the aspects associated with the carrying out of genetic engineering activities. The way that genetic engineering activities are carried out and the application of genetic engineering methods to human beings and to the constituent tissues and cell of the human body are not governed by this Federal Law.

### *Definitions*

*Article 2.* For the purpose of this Federal Law, the following terms are defined: *Genetic engineering*: all procedures, methods, and technologies, including the techniques for obtaining recombinant ribonucleic acid (RNA) and deoxyribonucleic acid (DNA), used in the identification of the genes of an organism, the carrying out of genetic manipulations, and the introduction of genes into other organisms.

*Genetic engineering activities*: activities carried out by means of genetic

engineering methods and genetically modified organisms.

*Genetically modified organism* [hereinafter GMO]: (acellular, unicellular, or pluricellular organism(s) capable of reproducing or transferring genetic material, other than natural organism, obtained by genetic engineering methods and containing genetic material, such as genes or fragments or combinations of genes.

*Release of GMOs into the environment*: action or lack of action entailing the introduction of GMOs into the environment.

*Biological protection*: creation and utilization in genetic engineering of a combination of biological material, without danger to man and the environment, whose properties exclude the undesirable survival of GMOs in the environment and/or the transfer of genetic data by such material.

*Physical protection*: creation and utilization of special technical means and procedures to prevent the release of GMOs into the environment and/or the transfer of genetic data by such organisms.

*Contained environment*: framework of genetic engineering activities in which organisms are genetically modified or GMOs are developed, cultured,

stored, used, transported, destroyed, or disposed of under conditions in which physical, chemical, or biological barriers or a combination of such barriers are used in order to prevent the contact of GMOs with the population and the environment.

*'Open environment'*: framework of genetic engineering activities presupposing contact between GMOs and the population and environment during their deliberate release into the environment, their use for medical or food purposes, their export or import, or during the transfer of technologies.

*Transgenic organism*: animals, plants, microorganisms or viruses whose genetic programme has been modified by genetic engineering methods.

#### *Legislation of the Russian Federation on Genetic Engineering Activities*

*Article 3.* The legislation of the Russian Federation on genetic engineering activities shall consist of this Federal Law, other Federal Laws and regulatory texts of the Russian Federation, and the laws and regulatory texts of the administrative divisions of the Russian Federation.

#### *Objectives of State regulation with Regard to Genetic Engineering Activities*

*Article 4.* The objectives of State regulation shall be the following:

— The determination of the basic orientations of the Federal bodies of State administration, the State administration bodies of the administrative divisions of the Russian Federation, the local administration bodies, legal persons, and citizens (natural persons) in the field of genetic engineering.

— The formulation of the basic provisions of the legal regulation of aspects associated with genetic engineering.

— The determination of a mechanism assuring the safety of citizens and the environment during the carrying out of genetic engineering activities and the utilization of the results thereof.

— The establishment of the legal bases of the international cooperation of the Russian Federation in genetic engineering.

— The creation of conditions enabling the formulation of priorities in genetic engineering.

In order to attain the above-mentioned objectives, Federal and regional programmes shall be adopted in the field of genetic engineering.

#### *Basic Orientations of State regulation with Regard To Genetic Engineering*

*Article 5.* The basic orientations of State regulation with regard to, genetic engineering shall be the following:

— The improvement of the living conditions of human beings and the protection of their health.

— The protection and restoration of the environment and the preservation of biodiversity.

— Enhanced agricultural efficiency;

— Enhanced efficiency of the extractive industry and the processing industry.

— The retention and further training of staff, and also the professional training of specialists in genetic engineering.

*Genetic engineering shall be based on the following principles:*

— The safety of citizens (natural persons) and the environment.

— The accessibility of data concerning the safety of genetic engineering.

— The certification of products, including the results of genetic engineering activities, and full information on the methods used in obtaining, and the characteristics of, the product concerned.

#### *Types of Genetic Engineering Activities Subject to Authorization*

*Article 6.* Genetic engineering activities corresponding to risk Class III or IV shall be subject to an authorization issued in accordance with the modalities laid down by the Law. The following types of genetic engineering activities shall be subject to an authorization:

— Genetic manipulations at the molecular or cellular level with recombinant RNA or DNA in order to create GMOs (viruses, microorganisms, plants, or transgenic animals, and also their cells).

— All types of GMO trials, including laboratory trials, clinical trials, field trials, or trials for experimental industries.

— The release of GMOs into the environment.

— The manufacture of preparations obtained by means of GMOs.

— The storage, disposal, and destruction of GMOs and/or products derived therefrom and the use of GMO wastes.

—The purchase, sale, exchange, and other operations and activities associated with genetic engineering, GMOs and/or their products, in the absence of a certificate of quality or a label of conformity issued or recognized by the authorized administrative body, including within the framework of international activities.

#### *Safety System in the Field of Genetic Engineering*

*Article 7.* The overall coordination and development of a safety system in the field of genetic engineering shall be carried out in accordance with the modalities determined by the Government of the Russian Federation.

Legal persons and citizens (natural persons) carrying out genetic engineering activities shall be required to assure the biological and physical protection of the personnel of genetic engineering establishments, the population, and the environment according to the class of risk of the potentially detrimental nature of genetic engineering activities for human beings and the environment.

In keeping with the level of the potential dangers involved, genetic engineering activities carried out in a contained environment shall be divided into four classes of risk potentially detrimental to the health of human beings:

— Class I risk corresponds to activities that do not endanger the health of human beings and is comparable to the risk associated with work involving the use of non-pathogenic micro-organisms.

— Class II risk corresponds to activities presenting a negligible danger for the health of human beings and is comparable to the level of danger associated with work involving the use of micro-organisms that might be pathogenic.

— Class III risk corresponds to activities presenting a moderate danger for the health of human beings and is comparable to the level of danger associated with work involving the use of micro-organisms that are potentially capable of transmitting infection.

— Class IV risk corresponds to activities presenting a danger for the health of human beings and is comparable to the level of danger associated with work involving the use of particularly dangerous infectious agents.

Activities carried out with micro-organisms in a contained environment on a scale that goes beyond the framework of laboratory research shall be classified in risk Class III or IV.

Genetic engineering activities carried out in an open environment shall be deemed to belong to risk Class III or IV.

Legal persons and citizens (natural persons) working in the field of genetic engineering shall evaluate the risk during the planning, preparation, and carrying out of genetic engineering activities.

Genetic engineering activities corresponding to risk Classes I and II shall be registered within the context of the establishment concerned.

Authorizations to carry out activities corresponding to risk Classes III and IV shall be issued in accordance with the modalities determined by the Government of the Russian Federation.

### *Conditions Applicable to Persons Carrying out Genetic Engineering Activities*

*Article 8.* The following may carry out genetic engineering activities:

— Citizens (natural persons) whose professional training and state of health satisfy the requirements of the safety rules of genetic engineering.

— Legal persons who have the appropriate premises, equipment, and personnel and who satisfy the requirements laid down in the second paragraph of this Section.

The carrying out of genetic engineering activities corresponding to risk Classes III or IV shall be subject to an authorization issued according to the modalities determined.

[Financing of genetic engineering activities and safety measures governing the conduct thereof (Section 9)].

### *Assurance of the Accessibility of Data Relating to the Safety of Genetic Engineering Activities*

*Article 10.* Data relating to the safety of genetic engineering activities shall be accessible.

Legal persons and citizens (natural persons) carrying out genetic engineering activities shall be required to provide, at the request of the persons concerned, information on the level of risk and the measures taken in order to, ensure that genetic engineering activities are safe. In addition, information relating to genetic engineering activities that constitute a State or service secret or a trade secret shall be communicated in accordance with the modalities determined.

*Standardization and Certification of Products and Services in the Field of Genetic Engineering*

*Article 11.* Products obtained and services offered as the result of genetic engineering methods shall satisfy the requirements of ecological safety, health standards, and the pharmacopoeia, and also the obligations deriving from State standards of the Russian Federation.

Products obtained and services offered as the result of the use of GMOs and which are subject, in accordance with the Federal legislation, to compulsory certification shall be accompanied by a certificate of quality and a label of conformity issued or recognized by the administrative body authorized for that purpose.

*Liability in the Field of Genetic Engineering*

*Article 12.* Legal persons and citizens (natural persons) who carry out genetic engineering activities and whose action or lack of action has been detrimental to the personnel of a body working in genetic engineering, the population, or the environment shall be liable in accordance with the legislation of the Russian Federation.

*International Cooperation of the Russian Federation in the Field of Genetic Engineering*

*Article 13.* The Russian Federation shall conclude international agreements with a view to continuing the development and strengthening of international cooperation in the field of genetic engineering.