

## **Research Article**

# **Legal Issues Supporting Production and Distribution of Biotech Products**

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### **ABSTRACT:**

in article, on basis of works of Russian and foreign academic lawyers, biologists, microbiologists, zoologists, genetics and also representatives of other sciences of natural-science branch, is researched legal relationship on production and distribution of biotechnological products in the Russian Federation, The law provision in considered sphere is highly unified. Peculiarities of legal mode of biotechnological products are not taken into account. Specification and differentiation of legal regulation of relations on production and distribution of biotechnological products is required. Absence of legal definition of "biotechnology" leads to ambiguity of their legal mode and low efficiency of legal regulation. Reasonability of development of separate legal classification by potential hazard of gene-engineering activity for ecological systems is grounded. Necessity of assignment of legal measures directed on development of biotechnologies and active involvement of biotechnological methods into diverse segments of economic and social provision of human is detected. Conclusion is made about the fact that proportion of stimulation and limitation in legal regulation of production and distribution of biotechnological products should be such that maximally complete application of achievements and developments of biotechnology in production with minimal risk of adverse impact on human and natural environment may occur.

**Keywords:** biotechnologies, biotechnological products, gene-engineering activity, ecological risks, ecological safety, legal limitations, legal motivation.

### **1. INTRODUCTION**

At present time biotechnologies, being the brightest example of interaction of cross-disciplinary science and production, determine the innovation renewal of many branches of economic. They can be applied in medicine, industry, agriculture, protection of environment, forestry and forest industry. Global trends in development of biotechnologies cover bio-pharmaceutics, biomedicine (molecular diagnostics, diagnostic means of therapy personalization, cell and tissue engineering for therapeutic purposes, bio-compatible materials etc.), industrial biotechnology (bio-polymers, bio-preparations of industrial intention etc.), bio-energetics, agricultural biotechnology (biotechnologies for waste processing etc.), veterinary biotechnology, food biotechnology, nature protection (ecological) biotechnology, forest biotechnology, sea biotechnology,

biological collections [1]. It turns out that field of production and distribution of biotechnological products covers a substantial segment of social relations that require its legal registration. At this it is important that implementation of biotechnologies should be conducted with taking into account of legislation on ecological safety.

This research was conducted in *order* to detect major factors impacting effectiveness of legal pressure in sphere of creation, use and disposal of biotechnological products in the Russian Federation (hereinafter - RF). At the moment of finishing of study of legal provision of analyzed segment of social relations, legal measures on activation of involving of biotechnological methods both in production processes and in activity of improvement of ecological conditions were left unaccepted.

## 2. MATERIALS AND METHODS

Detection of problems of legal provision of production and distribution of biotechnological products was conducted on basis of analysis of works of foreign (*N. Gunningham, N.S. Sreenivasulu, C.B. Raju* et al.) and Russian (*R.N. Salieva, Z.M. Fatkudinov, A.V. Sheverdin* et al.) legal scholars. Besides, the conducted study was based on works of ecologists, biologists, microbiologists, zoologists, genetics and also representatives of other natural-science branch (*S.A. Benner, M.F. Cantley, A.M. Sismour, B.C. Ksenofontov, O.G. Nikitina, N.V. Tsybalenko* et al.) Methodological basis for study was composed by dialectical method, that allowed to learn in continuous unity and general coherence the essence of legal provision of production and distribution of biotechnological products. Study of problems set up in introduction was also promoted by logical technique in form of analysis and synthesis, induction and deduction, comparison and generalization, analogy and typology. Formal-juridical technique allowed to understand essence and significance of legal standards directed at support of safety of citizens and natural environment in process of conduction of gene-engineering activity and use of its results. Comparative-legal method in limits of intrastate legislation was used for detection of optimal proportion of legal motivations and limitations in mechanism of legal pressure on considered social relations.

## 3. RESULTS

In Decree of Government of RF of January 6, 2015 No. 7-h "List of specialties and directions of preparative higher education corresponding to priority directions of modernization and technological development of Russian economic" biotechnologies are listed as priority directions of modernization and technological development of economic. Stated circumstance indicates the understanding of necessity of transition to biotechnological methods and products, capable to create innovative economic, on state level. In Russian legislation the determination of "biotechnology" is not assigned. Science does not have a unified understanding of named category. One group of

scientists understands biological technologies as application of biological organisms, their parts, systems and processes for extension of production and provision of services [2, 3, 4]. Others are narrowing biotechnologies to technologies that are directed on application of biological systems for copying and manufacturing of diverse types of useful things [5]. Absence of legal concept of "biotechnology" does not allow to unambiguously determine those methods and phenomena that would fall under special legal regime of these objects. Due to this occurs ambiguous or wrong interpretation of standards, adversely impacting on quality of legal regulation in considered sphere [6]. Complex program of development of biotechnologies in RF for period till 2020, app. by Government of RF on April 24, 2012 No. 1853П-П8 (hereinafter - Program of development of biotechnologies) [1], had qualified improvement of legal basis of development of biotechnology as one of its major tasks. We assume that modernization of statutory and regulatory provision of production and distribution of biotechnological products should move in two major directions. First of all is required effective legal provision of ecological safety of all life-cycle from production to disposal of biotechnological products. Second, it is reasonable to develop system of legal motivations promoting activation of involvement of biotechnological methods in different spheres not only of economic but human social provision too. Legal aspects of ecological safety of biotechnology are developed to greater extent relation to sphere of gene engineering. In Federal law of July 05, 1996, No. 86-ФЗ (rev. July 19, 2011) "On state regulation in field of gene-engineering activity" (hereinafter - FL "On gene-engineering activity") is determined the mechanism providing safety of citizens and environment in course of conducting of gene-engineering activity and using of its results. For stated purposes ch. 5 of FL "On gene-engineer activity" assigns requirement about mandatory confirmation of correspondence of production comprising results of gene-engineer activity, with statement of complete information of

method of receiving and properties of a new products. Production received with application of gene-engineering activity products have to meet mandatory requirements in field of environment protection, pharmacopoeial items, sanitary and epidemic requirements, other mandatory requirements of RF legislation. In relation to production created with use of gene-engineer-modified organisms and subject to mandatory certification or declaring of accordance, is issued certificate of compliance or accepted a declaration on compliance.

In ch. 5 of FL "On gene-engineering activity" is spelled out the rule on state registration of gene-engineering-modified organisms intended to release in environment and production received with use of such organisms or their constituent. Procedure of state registration is set by RF Government Decree of September 23, 2013 N. 839 (rev. on June 16, 2014) "On state registration of gene-engineering-modified organisms intended for release into environment and also production received with use of such organisms or containing such organisms", RF Government Decree of January 18, 2002 No. 26 (rev. of July 14, 2006), "On state registration of food stuff received from gene-engineering-modified organisms", RF Government Decree of February 16, 2001, No. 120 "On state registration of gene-engineering-modified organisms". On basis of stated statutory and regulatory acts are kept correspondent State Consolidated Registers and issued certificates of state registration. Dependently on degree of potential hazard occurring at conduction of gene-engineering activity, ch. 7 of FL "On gene-engineering activity" for closed circuit systems anticipates four levels of risk of potential hazardous impact of gene-engineering activity on human health (I - non-hazardous, II - insubstantially hazardous, III - moderately hazardous, IV - hazardous). Stated legal systematization is a legal mean of protection of human life and health, but not of natural environment. We assume that it is necessary to develop a separate legal classification by potential hazard of gene-engineering activity for ecological systems. In perspective is anticipated stiffening of legal regime of gene-engineering

activity via introduction of additional prohibitions and limitations. So, Project of Federal law No. 714809-6 "On introduction of amendments in separate legislation act of the Russian Federation in part of improvement of state regulation in field of gene-engineering activity" (edition accepted by State Duma of Federal Assembly of the RF in I reading on April 24, 2015) anticipates *prohibition* to use for sowing (planting) of plant seeds received with use of gene engineering methods, including incapable of reproduction or transfer of hereditary gene material, excluding conduction of expertises and scientific-research works. There also said about *prohibition* for growing and breeding of plants and animals whose genetic program is changed by methods of gene engineering, excluding conduction of expertises and scientific-research works. Abroad attention is also paid to necessity of introduction of volunteer temporary prohibition of implementation of biotechnological methods until science will determine all possible risks related to use of biotechnologies [7]. In other branches of biotechnology (besides gene engineering) in relation of provision of ecological safety are applied legal means of Federal law of January 10, 2002, No. 7-Φ3 (rev, on December 29, 2015) "On protection of environment". In other words, here are applied general legal standards on environment protection and rational environmental management. However it is necessary to take into account emerging of new directions of scientific researches in sphere of biotechnology. For example, synthetic biology that conducts development and receiving of artificial biological components and systems [8], requires taking into account characteristic peculiarities in legal regulation of ecological safety, because it has its own ecological risks. Distinctive features in system of safety of use of biotechnological developments were also detected in agriculture [9]. In legal literature attention is justly paid to unpredictability of consequences of creation and use of biotechnological activity results, which require refusal from generalized regulation of social relations connected to biotechnology and biotechnological production [10]. Therefore, for

every branch of biotechnology is required differentiated legal regulation that would take into account specificity of ecological safety provision.

At the same time, besides ecological and genetic risks on biotechnological production use, it is capable to solve a vast number of ecological problems too. Biotechnological processes are used in operation of purification facilities of industrial drains [11], at disposal and processing of waste of animal and poultry breeding [12], in purification of water, soil and air, receiving of electrical energy via anaerobic brew of waste waters sediments [13], via them is conducted bio-degradation of toxic compounds [14], and also many other types of activity that are improving ecological condition.

In Program of development of biotechnologies is said about the necessity of creation of organizational and legal basics for formation of new markets of biotechnological production, first of all in industrial biotechnology and production of bio-fuel [1].

Development of system of measures of statutory and regulatory and technical regulation on separate types of production, that is promoting recycle of its manufacturing waste, is important. To legal motivations in analyzed sphere should be also related the development of biotechnologies on basis of state-, municipal-private partnership.

It is reasonable to create statutory and regulatory conditions for active use of a stated private-public mechanism capable to increase scales of industrial production of biotechnological production significantly. In situation when it is necessary to simultaneously improve both legal provision of ecological safety of biotechnological products and legal motivation of use of modern biotechnologies in order to lower a level of environment contamination, arise the issue of proportion of two stated directions. The point is that the maintenance of balance between conduction of state and social control of activity in field of biotechnology, on one side, and ability of development of biotechnology and application of its useful properties, on other side [15]. Exemplary in this case is experience of Australia, where in order to

provide the ability of use of biotechnologies in agricultural industry were introduced more flexible requirements to limitations of negative impact on environment, which allowed to implement biotechnological developments in agriculture [16].

It is important to set such amount of legal limitations for provision of ecological safety of creation, use and disposal of biotechnological production, so they will not become a deterrent in development of biotechnology in general, and at the same time the analyzed activity would not present a hazard for human and ecological systems.

#### **4. RESUME**

Analysis of current statutory and regulatory acts that are regulating relation on production and distribution of biotechnological products in RF allowed to detect problems of legal provision in researched sphere. First of all, it's too unified. There is a need of substantial detalization and differentiation of legal pressure on social relation on production and distribution of biotechnological products, especially in part of their ecological safety. Second, absence of legal definition of "biotechnologies" leads to ambiguity of their legal mode and low efficiency of legal regulation. Third, necessity of assignment of legal measures directed on development of biotechnologies and active involvement of biotechnological methods into diverse segments of economic is detected.

#### **5. CONCLUSION**

Therefore, liquidation of problems of legal provision of production and distribution of biotechnological products in RF will promote increase of effectiveness of regulation of respective social relations. Only just balance of legal motivations and limitations would allow to maximally use achievements and developments of biotechnologies with minimum risk of negative impact on human and natural environment.

#### **CONFLICT OF INTERESTS**

Authors confirm that above provided data do not contain conflict of interests.

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