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COMPONENTS OF THE MECHANISM OF THE LEGAL RELATIONS REALIZATION IN BIOTECHNOLOGY SPHERE

O.Yu. PIDDUBNYY, ***PhD (Law), associate professor, National University of Life and Environmental Sciences of Ukraine***

The article contains an analysis of the components of the mechanism of relations in the field of biotechnology, broadly outlines the features of each element, such as the transfer of biotechnology, innovation, risk assessment, ensuring biosafety.

Biological technology, biotechnology, biotechnology transfer, assessment of risk.

In this study, we would like to draw attention to the general problem of the mechanism of relationships, especially for its vision in the context of environmental law, and even more narrowly – the scope of legal regulation of biological technology, to identify elements of the mechanism of how security relationship, attention is paid to what some researchers as and stimulating, as it is much less, and yet, determining the mechanism of law, in our opinion, is the most recent. Background information of public relations in the field of biotechnology from the standpoint of law are in the works of famous scientists in the field of environmental, natural resource, agricultural law. In particular, the study of such scientists like V.I. Andreytsev, G.I. Baliuk, S.B. Gavrish, V.M. Yermolenko, A.P. Hetman I.I. Karakash, O.S. Kolbasov, V.V. Kostytsky, M. V. Krasnova, A.I. Krassova, N.R. Malysheva, M.I. Malishko, V.L. Muntean, V. I. Semchyk, Y.S. Shemshuchenko, M.V. Shulga give us an idea about the general legal principles of environmental management, natural resource management, conservation and recreation, the application of technological innovation in agriculture field. Various aspects of biotechnology, biotech activity, biosafety, bioethics, genetic engineering, cloning explored in his writings experts in law, management theory: N.Bilan, D. Bystrov, O.Hrybko, V.Zavhorodnya, A.Yoyrysh, O.Krasovskyy, T. Korotka, B. Kurzova, M. Medvedeva, N. Melnychuk, J. Razmyetayeva, R. Stefanchuk, B . Tretyakov, Y. Hramova, H.Chebotarova, K.Shahbazyan and others.

Scope of this research, like others similar, is that along with all commonly used and understood the concept of law as a set of mandatory standards established or authorized by the State regarding the mechanism to bring these provisions into force no such certainty. There is a prevailing belief that the basis of the implementation of law is state coercion does not explain the mechanism of such coercion, as coercion is not applicable to every case of law, if every act of enforcement, as millions of them in everyday life, accompanied by coercion, it would be simply absurd situation. So coercion is used only in rare cases, what then is the guarantee of law enforcement in most of the facts, together with the said duress as a whole constitute a mechanism of law? This specific set of rules, certain conditions described in the law, a framework that guide the movement of the actual relations in a given direction, and the study of the application to the field of biotechnology have problems of this paper.

The purpose of this paper is to determine what the author meant by the mechanism of legal, theoretical concepts which formed in the general theory of law in its application to the implementation of relations in the field of biotechnology. Identification and description of the features of these structural components in their entirety using the method of synthesis will in subsequent studies using the method of analysis to consider in more detail each component of and identify areas of application of these theoretical elements in the existing legislation.

In connection with the concept of the mechanism used and the concept of legal forms, in the form of institutions, legal regimes or systems related legal entities and regimes that are legally actionable form solution of vital problems. The notion of forms and associated issues of determining origin of natural resources, methods of use, reproduce, environmental carried out based on specific relationships. As an example of new forms and procedures for their application in the field of ecology provides environmental audits, environmental control, environmental impact assessment, environmental insurance, environmental licensing, however, observed that there was investigated environmental and legal mechanism of these forms or carried out their scientific classification [9, p. 75].

In relation to living organisms registration is required at the first release into the environment, in the absence of introduction into the environment, but the intended industrial use, the import of genetically modified organism no further contact with the environment [13, p. 69].

Legal safeguards consumers is food labeling and other products made from genetically modified raw materials, which in itself is only a

means to inform his family legal fact in information ecological relationships than actual guarantee, security product. It is also observed in the Russian legal doctrine as having a fully informed choice [13, p. 72].

The next element can be regarded as a presumption of guilt manufacturer, even if it is impossible to predict negative consequences if the current level of science and technology [13, p. 72].

A separate legal remedy should be considered no limitation on the requirement for harm caused by the use of GM foods, so there is a theoretical possibility of litigation and in 50–100 years [13, p. 72], which however seems rather hypothetical, although potential damage in subsequent generations has certain precedents, such as the use of thalidomide.

Much more effective given the introduction of environmental insurance activities in the field of biotechnology in the amount of 13 per cent of the profits derived from the products of biotechnology. In literature there are similar proposals concerning, for example, an insurance company in liquidation payment to cover the corresponding flow in identifying future victims [13, p. 72], but as often happens liquidation, to put it mildly, not at the peak of the company, the receipt of certain payments that time seems almost real. However, the principle of environmental insurance offered should be subsidiarity insurance claim, and in any case not release the operator of biotechnology from liability for damage caused.

A major problem, typical in general for environmental responsibility is a modern structure of the world in which multinational corporations owning at least, and often much more resources than governments, characterized in that the light appeared about the excess funds in the accounts of Apple on funds held on budgetary accounts at the end of the U.S. in July 2011, which was discussed in connection with possible U.S. default. This once again shows the possibilities of multinational companies, and if the developed countries, they may adhere to environmental standards and requirements, in the third world can turn a blind eye to them, with the tacit approval of weak and corrupt governments. The basic international document, which should be targeted in the model responsibilities of transnational corporations are the norm concerning the obligations of TNCs and other business enterprises with regard to human rights, adopted by the Commission of the UN Human Rights Council August 26, 2003 According to this document, TNCs and other business enterprises are responsible for the impact of all of its activities on the environment and are required annually to assess the impact of its activities on the environment and

human health, based on the precautionary principle and the precautionary principle, and should not use the lack of completely reliable scientific information as an excuse to delay implementation means to end the negative impact [2, p. 18].

Another important element in the mechanism of legal regulation in the field of biotechnology is civil, administrative and criminal liability for improper handling of food biotechnology. The most radical kind of responsibility are responsible for massive environmental crimes that infringe on human and environmental safety cause serious, long-term and extensive environmental damage, such as flora and fauna, especially, and additionally as a consequence – the health and lives of people [6, p. 8] There is an understanding of the responsibility by the use of biotechnology as an absolute liability for activity that causes harm to the environment or human [7, p. 29].

The objects of attack in this case should be sanitary and epidemiological welfare of the population, causing damage to the environment. As the list of required actions A. Grybko proposed list, which includes a network of specialized laboratories for biological control of Sales GMOs, harmonization of technical equipment such laboratories, the creation of biological, genetic and environmental control and monitoring, independent of the manufacturer at all stages of production and sale of food and feed containing GMOs and a number of other measures [1, p. 275].

An important element of the mechanism is the duty of nature to prove the legality of their environmental business. For example, the right to produce food products of biotechnology should be due to an associated license that is issued in the presence of environmental certificate for this technology, confirming that this technology given environmental requirements [3, p. 158].

The principal also to implement relationships in biotechnology regulation is transfer of existing biological technology and innovation, because without it, very protective «security» of regulation, as we have repeatedly pointed out, limping on one leg.

It seems that the relationship, which consist on research and innovation in biotechnology have certain characteristics that distinguish them from most scientific and innovation. This assertion is based on the potential danger of such research, which leads to their special legal regime. Home and preparation conditions such relationship is with the 80s of last century, and was not visible through the euphoria caused by the

development of information technology, the potential for explosive growth which is now depleted, making their own assumptions dialectically reborn into kinetic energy of the new phase of technological development, which item is a biological engineering, biological products, biological science, and even electronic.

Over the past decade, many developing countries have realized that technology transfer from other countries is practically no effect on the establishment in which the foundations of the so-called high-tech industries, where such transfer is not accompanied by the formation of a mechanism that would give an opportunity to local researchers, engineers, entrepreneurs and other technology innovators use these as a springboard to create new knowledge. It was found that for developing countries is far enough to invite foreign high-tech business, so he made an investment and started production. The effect solely on technology transfer is usually small. Benefit from the transfer of biotechnology does not come automatically, but appears only when this process is continuous and it involved local industry.

The solution according to the researchers clearly the technology transfer from private universities and public research institutions and the private sector in the form of intellectual property. In many countries, it is in the public sector research institutions and academies established primary source of knowledge [11, p. 368].

Consequently, when implementing legal regulation of biotechnology transfer as part of the mechanism of relations in the field of biotechnology in Ukraine should be understood that currently exists a significant gap Ukraine from world leaders in the field of biotechnology, which is independent efforts to overcome the impossible, but an extensive network of research scientific and industrial establishments, together with the intellectual potential may contribute to various projects of joint activities in the field of biotechnology, which begins with the transfer of biotechnology and logically continues the development of such technologies is the national development, by analogy with nuclear, missile and space technology borrowed Third countries in the developed countries and successfully extended to their own territory.

Innovation is an important part of the life cycle of any scientific development, as well as what is considered «basic science» through a sometimes very short time finds its first introduction in advanced industries such as space-rocket complex, and subsequently in production of consumer goods.

Legislative regulation of innovation activities in the field of biotechnology, we believe that this is part of the mechanism of relations in the field of biotechnology, without which one can not speak of a complete mechanism, but only a series of restrictive measures advocated apologists of only biosafety regulation, and which in all due respect, clearly can not agree.

Importance of innovations according to prof. V.I. Semchyk, is the subject of innovation is much wider than the objects of scientific and technological activities as objects first have ideas, new knowledge, technological developments and achievements, their practical implementation and use competitive and commercial basis, and scientific and technological activities - a creative intellectual activity aimed at the production and use of new knowledge in all areas of engineering and technology at the stage of research and refinement of scientific and technical knowledge to the stage of practical use [11 , p. 14].

This should be the only reasonable, predictable and balanced state program on bioenergy, agriculture and food in the long term [11, p. 32].

When it comes to innovations in biotechnology should be understood that in order to implement these developments is the increasing needs of the individual and society, very different – and on improving the quality of life, efficiency solve the food problem, the implementation of comprehensive spa and health effects on the environment.

By itself, the activities in the field of biotechnology is currently the innovation, so everything about innovation control activities in the field of biotechnology, to some extent concerning biotechnology in general. Proof of this is a breeding ground that at the end of the 80s of last century, was established in the U.S., where biotech industry developed at about the same "garage" schemes, commonly known as the history of computer technology, the founders of the largest companies which started with small workshop. Legislation in the field of biotechnology was oriented so that the financial assistance carried out by so-called «start-ups» – a small creative teams are usually organized around a talented scientist whose purpose was to develop suitable to commercialize a product or method. What does not always treated task of developing specific varieties of genetically modified products, such as for a startup was a separate method or acceptance of transfer of genetic information, extracting the desired genes with chains of nucleic acids. By itself, the problem is not solved globally, but this method, after testing and proof of efficacy, once has been patented and implemented large agricultural, chemical, pharmaceutical concerns,

which together with many other techniques developed in a «mosaic» of innovation, which began work on a biotechnological product.

It is obvious that this experience, its legal framework should be carefully examined in the search for the optimal innovation model for Ukraine. From this point of view is reasonable to link the modern Ukrainian researchers D.Kerymov opinion regarding two fundamental problems of law – the right research methodology and collaboration with other technical, natural and social sciences [11, p. 115].

To stimulate the development of innovative biotechnology offer a special investment fund with strict control of the use of funds, as well as increasing the share of biotech products in public procurement in agriculture, medicine and areas such as energy, information, information and communication technologies [4, p. 164].

One variation of this incentive can be considered the law on public-private partnership that must evolve and became more concrete on Pine adopted in Ukraine eponymous law. On this issue active legal scholars NUBiP Ukraine, in particular during 2012 there were several meetings and roundtables, including two held in conjunction with the Institute of Legislation of the Verkhovna Rada of Ukraine, with Ukraine NUBiP Rector and Director of the Institute of Legislation Parliament, which actively discussed question goals, objectives and directions of public-private partnerships.

The first observation analysis in the field of public-private partnership is reset according to the apparent discrepancy between the goals and objectives of the partners that they should unite. On the one hand – a private equity wants to make profits, and even better, as we know from classical political economy - profits.

On the other hand the function of the state, and from liberal and from socialist position is to ensure the needs of citizens, these two concepts differ only as to how much and how needs should be provided. Occupation business - it does not state the problem, the state as owner of the company all the profits from their activities should be counted in the state budget and spend budgeted needs. The very same logic in business is the desire of certain private entities to improve your material wealth, which is useful incentive in life for everyone.

Moreover, the current understanding of the role and tasks of the state government is to provide a given level of social standards, which require the government to different social groups, and overlooked is that the state should not focus only on the constant removal of social tensions, meeting

current public interests the state should ensure sustainable development of society and the preservation of its institutions, including the state itself, in other words all means to ensure public safety perspective, combining it with the above social function.

So any projects handled by the state, relatively speaking, should be worth getting them engaged state, Otherwise, point to help separate business entities benefit from entering the partnership with the government there, and moreover, it will provide a non-based benefits to citizens or foreigners-business owners to all other citizens, because of all the state has to take care to the same extent, I think everyone present would agree with that.

Therefore, the purpose of the state is a social activity, such as ensuring job creation and national security, so access to the regional and world leaders in certain parameters, the so-called growth points. And if such a project is, who would partner was his initiative, the state should examine a startup, and outline prospects for 5-15 years, after which the expected breakthrough design of the trailer into a locomotive, then it is possible and give the investor provided that he invested the money contributed to the implementation and waiting for the result of longer or faced higher risks than his colleagues who have implemented their own projects, designed for a quick profit.

So the criteria necessary for the state participation in public-private partnerships, particularly in the field of biotechnology should be taken together

a) Implementation of social features – creating jobs or other social effects;

b) Providing leadership of the state in certain areas of regional or global scale in the case of a successful project

c) The need to raise funds in excess of 3 % of the state budget for the year in which the decision on public-private partnership

d) Economic indicators planned payback in future 5 years is negative or less than 50 % of the average return for the sector.

e) Risks to project higher than those for the economy as a whole

On the other hand, the criteria for participation in the partnership for the private partner is the opportunity then receive significant competitive advantage in the success of the project, including the results of the project to private ownership, as in the case of project success is not in any way reduce its social benefits and the same time, will relieve the state to participate in the new at the time of promising projects.

One of the problems encountered in the implementation of legal relations in the field of biotechnology at the stage of deciding on making genetically modified organisms in an open system is the question of who is authorized to assess the possible consequences of such a move and what criteria it should be guided. This issue can be attributed to the methodology of risk assessment. The search for absolute truth in any matter is futile because any administrative decision of security, including environmental security in agriculture in the area of safety and quality of food should be taken under the influence of certain facts, they set a fixed time and logical conclusions and predictions made on the basis of this information.

The Doctrine of the European Community more sensitive to public discourse in this area, including that scientific risk assessment alone, in some cases, can not provide all the information necessary for making decisions on risk management, and other factors relating to matters consideration should be to the same extent taken into account including societal, economic, traditional, ethical factors and environmental factors, and the ability to control [10, p. 131].

As noted in the scientific literature, due to the extremely rapid progress of genetic engineering, resulting in a relatively short time intervals to a completely new level of knowledge, qualitative and quantitative changes, public policy should focus on continuous improvement of legislation on the safety of genetic engineering to based scientists developed new risk assessments, as well as to a permanent promotion of knowledge in this area to reduce unfounded fears of the population [5, p. 7].

Of course, a very important area of legal relations in the field of biotechnology is to ensure biosafety, regardless of the industry in which you make the results of research or applied biotechnology.

N. Medvedeva said that most foreign researchers linked the issue of legal regulation of biotechnology concept biosecurity, which refers to efforts aimed at reducing and eliminating potential risks arising from the use of biotechnologies and their products for humans and the environment [7, p. 34].

Model law on security activities related to genetically modified organisms, adopted at the twenty-seventh plenary session of the Interparliamentary Assembly of the CIS [8]. In particular, the law states that the human body can not be the subject of genetic modification. An interesting concept of genetically modified organism – any organism except

human, whose genetic material has been altered other than mating and / or natural recombination path.

Biochemical, biotechnical and pharmaceutical production included on the list of kinds of activities that constitute an increased risk of ecological approved by the Cabinet of Ministers of Ukraine dated July 27, 1995 № 554 [12].

Thus, biological safety, in our view, this should be a condition which ensures that no threats to all biological objects, which in turn are part of the environment, from the harmful effects of biological factors, which may come from various natural or artificial living organisms and structures.

This list should provide proper safety biotechnology because biological security is broader as bio-hazardous effect is not always associated with food biotechnology. In turn biotechnologically-hazards should be divided into direct – that is, those that were created deliberately, but have proven or suspected hazardous properties under certain conditions, and those arising as a by-product, such as microorganisms that have become resistant to antibiotics and biotechnology are present increased risk. It is also a product of biotechnology.

Thus, safety of biotechnology is a state control over the use of biological technology in which guaranteed the absence of threats to life and health of citizens and excluded any negative effects on the environment of artificial biological agents and factors produced by such technologies.

Security is actually biotechnology activities and social value, over which consist of legal security in the field of biotechnology. It represents a level of analysis, monitoring, control, law enforcement, which is guaranteed safe for humans and the environment of any research project, experiment, development or finished product associated with biotech activity as well as the objectives and results of these phenomena morals of society and the strict observance of human rights.

Summing up the above, it should be noted that the mechanism of relations in the field of biotechnology is not limited only to the use of state coercion in matters of biosafety regulation, but instead is a system of components, which includes the regulation of biotechnology transfer, innovation, risk assessment and as a result - optimal balance of scientific and technological progress in the area described and appropriate level of protection of human life and health products using biotechnology.

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