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THE UTİLİZATİON OF THE GENETİC ENGİNEERİNG AND LEGAL REGULATİON OF BİOSAFETY

Abstract. The societal development promotes the developments of biotechnology. İnnovations in the field of genetic engineering also necesiate the formation of legal regulation. The entry of our State into the economic and tecnological space stipulates legal positivation of biotecnological and biomedical activity at the universal and local levels as well. The researches in the concerned area directly linked with the innovations applied in both the diagnosis and treatment of deterministic genetic diseases and molecular biology. Currently the relevant researches achieved the era where practical hallmarks such as genetic testing, gene therapy, genomic dactyloscopy, various population screening programmes, collecting and maintaining the individual and population genetic data have become a reality. New legislative norms must consider the national security from one hand, and the development of biotecnology from another.

Keywords: biomedicine; international law; bioethics; biotechnology; law.

The vast majority of efforts made in genetic engineering are related to agriculture and food security. The researches in transfer of genetic traits from one species to another in order to improve nutritional values and quality of plants in agriculture has been observed since the 60s of the XX century. The first nutritional crop, genetically improved for trading purposes has been grown in 1966. The US farmers have planted 8 million of genetically modificated soybean and 3.5 million of corns in 1977. Currently, the genetically modified plants in 28 countries and the USA, Brazil, Argentine, Canada, India are especially different among these countries. Globally, 68 percent of genetically modified organisms (GMO) falls to the US, 11.8 percent to Argentine, 6 percent to Canada, and 3 percent to China. The activity aimed at improving the nutritional value of plants in agriculture also focused on livestock and genetic operations have resulted in creation of *"super animals"*. Agricultural Research Center, located in MD, USA tempted to get a large number of pigs

named *Gal Safe* by placing the improved human hormone in an embryonic pig named Pig6707 and consequently achieved this. During the studies, it was found that a pig's secretary glands secrete human growth hormone when it is born. The pig not only did grow too large for its intended purpose, but the human genetic material also caused its digestive system to change unexpectedly and in a bad way[1]. The Food and Drug Administration (FDA) – the american sanitary control organization responsible for the quality of food products and medical supplies had even certified this food product – *Gal Safe* since 2015 as an usable after the GM salmon. Although the experts of the United Therapeutics Corporation repeatedly stated that the main purpose of this project is not to sell pork, but to use for the transplantation in humans.GM pigs were bred to eliminate the sugar molecule *alpha-gal* as the latter was one of the substantial problems during the xenotransplantation. However, the FDA approved the GM pig as suitable for both medical or human consumption. The revision of existing genes in pigs was only one of eleven changes that geneticists planned to implement in a xenotransplantation program (transplantation of organs from animals to humans) aimed at overcoming the acute shortage of transplanted organs in humans[2]. As seen from all noted above GMO unites three group organisms in itself: Genetically modified microorganisms (GMM), genetically modified animals (GMA) and genetically modified plants (GMP). Considering the security and sometimes the criminogenic aspects of this issue, States try to form legal framework for both internationally cooperation and unilaterism. In this regard, from the international perspective, the UN Earth Summit in Rio-de-Janeyro on Biological Diversity plays an important role. The multilateral 1993 Convention on Biological Diversity (CBD)[3], to which about 200 States are party, and the Protocols, thereto, 2011 Bali International Treaty on Plant Genetic Resources for Food and Agriculture, and other norms determine the legal regulation of directions of international cooperation.

In 2011, the Bali International Treaty, the parties have agreed upon that plant genetic resources are essential as a raw material for crop genetic improvement (whether by means of farmer selection, classical plant breeding or modern biotechnologies), and in adapting to unpredictable environmental changes and future human needs[4]. The provisions of the Convention on Biological Diversity shall be taken into account in order to achieve the objectives set forth in the Agreement (m. 1.2) and also, the governing body of the treaty cooperates with the UN Conference on Biodiversity in

[1] 'Генно-модифицированные свиньи – вдвое больше мяса' (30.06.2015) <https://zoom.cnews.ru/rnd/article/item/gennomodifitsirovannye_svini_> (дата звернення: 10.10.2021).

[2] 'Власти США разрешили есть генетически модифицированную свинину' (17.12.2020) <https://naukatv.ru/news/fda_ssha_zayavilo_chto_geneticheski_modifitsirovannaya_svinina_bezopasna_dlya_upotrebleniya_v_pischu> (дата звернення: 10.10.2021).

[3] Конвенция о биологическом разнообразии (ст. 5), 29 декабря 1993 г., 1760 СМД ООН 79 <https://www.cbd.int/doc/legal/cbd-ru.pdf> (дата звернення: 10.10.2021).

[4] V Mammadov, A Mystafayeva, *Bioethics, Law and Human rights* (Baku 2013) 179.

Rio de Janeiro and other relevant international organizations (m.19.3(g)). The Conference on Biodiversity in 2010, in its 10th session held in Nagoya, Japan adopted an international agreements on plant genetic resources to manage food production and agriculture (in accordance with a new protocol and strategic planning for 2011–2020 years)[5]. the most substantial outcome of this session in respect to the Convention is an adoption of Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits, which entered into force in 2014[6]. The Protocol, to which Azerbaijan is not a party, was joined by 130 States[7]. The Nagoya Protocol accepts the International Treaty on Plant Genetic Resources to Manage Food Production and Agriculture in the relevant field as an appendix to the international regime for the sustainable use of plant genetic resources for food production[8] and is not applied to genetic resources, regulating other specific agreements. The Protocol is implemented mutually with other international instruments relevant to this Protocol (Art. 4.3). The Nagoya Protocol promotes financing the tecnology for utilization of gene resources of plants, the exchange and equal access to these technologies, subject to copyright, food security, poverty eradication[9]. The Protocol also envisages development of international cooperation in case of emergency threat to public health, influenza pandemic[10]. Under the Protocol, it is promoted the World Health Organization General Control Laboratory Mechanism, Global Polio Eradication Initiative (GPEI), Global Polymelitis Diagnostics Laboratory Network, Global Influenza Epidemiological Surveillance and Response System, etc.

In case of public emergencies and influenza pandemic, the Parties shall pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health and take necessary legislative measures considering the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources (m. 8(b)). However, the legal bases of scientific researches remain uncertain in sharing of resources while fighting against the influenza viruses. Therefore, during the seasonal and influenza pandemic, the implementation of

[5] Strategic plan for the Cartagena Protocol on Biosafety for the period 2011–2020 <https://bch.cbd.int/protocol/issues/cpb_stplan.shtml> (accessed: 10.10.2021).

[6] Нагойский протокол регулирования доступа к генетическим ресурсам и совместного использования на справедливой и равной основе выгод от их применения к Конвенции о биологическом разнообразии. 12 октября 2014 г. <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-ru.pdf> (дата звернення: 10.10.2021).

[7] Parties to the Nagoya Protocol <https://www.cbd.int/abs/nagoya-protocol/signatories> (accessed: 10.10.2021).

[8] Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications. WHO Study (1 February 2017) <https://www.who.int/influenza/Nagoya_Full_Study_English.pdf> (accessed: 10.10.2021).

[9] International Treaty on Plant Genetic Resources for Food and Agriculture <https://www.fao.org/plant-treaty/en> (accessed: 10.10.2021).

[10] Implementation of the International Health Regulations (2005) Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response <https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf> (accessed: 10.10.2021).

the Protocol was initially ineffective. Hence, the main focus is made to domestic legislation. Due to the weak regulation mechanism of the Protocol, unfair sharing of vaccines in response to the Covid-19 pandemic is still continued. The sharing is implemented mainly on voluntary basis. However, Article 20.1 of the Protocol promotes that each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing. Despite the fact that the implementation of the Nagoya Protocol was ineffective in the beginning, it would be useful for Azerbaijan to accede to the Protocol to benefit from its promotional mechanisms, also considering that many EU countries have joined to the Protocol. The international trade in living modified organisms (LMOs) created using modern biotechnological means and genetic engineering is growing from day to day. So, for establishing relevant international standards, the Cartagena Protocol on Biosafety of the Convention on Biological Diversity was adopted in 2000 (but entered into force in 2003)[11]. The Protocol, which have been acceded by about 170 Member States, was not ratified by Azerbaijan. Pursuant to 2.2 of the Protocol, the Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. The Cartagena Protocol on Biosafety determined international commercial terms for modern biotechnology products and genetically modified organisms and the rules on their preparation[12]. The Protocol on Biosafety established the definitions of modern biotecnology regulating the trade of LMOs. The Cartagena Protocol provides also the agreed import and export mechanism for GMOs (or LMOs due to unwilling of GMOs by the US delegation). The disagreement of opinions proved serious challenges during preparation of the Protocol. The proponents of trade in CDOs (USA, Argentina, Australia, etc.) and others argued that trade in these products should be more strictly regulated[13]. The main purpose of the Protocol is to insure developing countries against the negative consequences of free trade with CDOs. This is because the lack of the necessary internal regulatory tools in these countries could jeopardize the biosafety that could result from trade with CDOs. Therefore, in preparation, many countries have proposed the creation of protectionist customs barriers to international trade with CDOs to protect domestic biodiversity. The EU proposes a stricter application of the "prudence" principle as a compromise option, and this principle applies. As a result, the United States objected and

[11] Cartagena Protocol on Biosafety to the Convention on Biological Diversity. 29 January 2000 <https://bch.cbd.int/protocol/text/> (accessed: 10.10.2021).
[12] Marie-Claire Cordonier Segger, Frederic Perron-Welch, Christine Frison (ed), *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (Cambridge University Press 2013).
[13] The Cartagena Protocol Biosafety: a Record of the Negotiations. Secretariat of the Convention on Biological Diversity, 2003 <http://www.cbd.int/doc/publications/bsbrochure-03-en.pdf> (accessed: 10.10.2021).

did not accept the Protocol[14]. The USA believed that biotechnological products were no different from natural selection organisms. Therefore, it was argued that there was no need for special procedures to preserve biodiversity. The Cartagena Protocol, together with the Convention on Biological Diversity, aims to ensure a compromise on the protection of the environment and human health with economic benefits in regulating the transboundary movement and use of CDOs. Although genetic engineering in modern times promotes the improvement of human living standards, there are also risks of creating negative consequences by introducing new GMOs[15]. Taking into account of new ecological hazards, the State Parties to Cartagena Protocol on Biosafety shall more strictly fulfill the international document, whereas non-state parties can maintain biological safety by joining the implementation mechanism. The Convention on Biological Diversity considered establishment of a special procedure for the regulation of activity and preventing adverse effects of LMOs on the environment. The State Parties have established national control bodies to survelance the cross-border movement of these products. For example, the competent authorities in this field in UK is the Health and Safety Executive (HSE), Ministry of Consumer and Corparate Affairs in Canada, Gene Engineering Commission – *La Commission de Genie Genetique* (CGG) in France and etc. Azerbaijan has also enacted legal acts, regulating the biotechnology activity inasmuch as the importance of the problem. Those are for instance, the Seed Act of 1997 (plant products utilized in seeding, their hybrids, population, clons and lines are seed objects – Article 4), Law on Selection Achievements of 1996 ("Selection achievement" means created as a result of a selection work and useful for the society varieties of plants, animal breed, their hybrids, genotypes, crossings and clones – Article 1); the Law about Protection and Rational Use of Genetic Inventories of Cultural Plants of 2011 (treatment of genetically modified plants – Article 21) and 2006 Law of the Republic of Azerbaijan on Phytosanitary Control[16] and other legal norms. Article 26 of the Seed Act (1997) states that the use of genetically modified plants or agricultural plant materials resulting from modern biotechnological and genetic engineering methods in the production and circulation of seeds is prohibited[17]. As can be seen, although the use of genetically modified or biotechnological products is prohibited, the utilization of biotechnological means is accepted. In Azerbaijan, security management in this area is mainly carried out by the central exetive authorities and their subordinate bodies. As noted, for objective reasons, bioethical norms prevail over legal regulation

[14] The Cartagena Protocol Biosafety: a Record of the Negotiations (n 13).
[15] М Копылов, А Солнцев, 'Международное экологическое право перед вызовами современности (Международная экологическая организация)' (2013) 1 Евразийский юридический журнал 56–8.
[16] Hüquqi aktların vahid elektron bazası <http://www.e-qanun.az> (accessed: 10.10.2021).
[17] Gen mühəndisliyi fəaliyyəti zamanı təhlükəsizlik haqqında Azərbaycan Respublikası Qanunu <https://azkurs.org/gen-muhendisliyi-fealiyyeti-zaman-tehlukesizlik-haqqnda-azerba.html> (accessed: 10.10.2021).

in the field of biomedical technologies. However, I think that all biomedical examinations with human participation should be subject to legal expertise as much as possible. The legislation should prohibit all technology processes, the results of which are likely to harm human health. Due to the lack of an independent legislative act of the Republic of Azerbaijan on security during genetic engineering activity, the solution of the number of issues, including ensuring security, as well as main directions and principles of the state policy remains undetermined. The development of society promotes the achievements of biotechnology. Innovations in the field of genetic engineering requires the legal regulation. With the entry of our State into the single world economic-technological space, biotechnological-biomedical activity also requires legal positivization at the universal and local levels.

Research in this area is directly related to innovations in the field of molecular biological technologies used in the detection and treatment of genetic deterministic diseases, as well as in industrial biotechnology. Relevant research has now reached the stage where practical features such as genetic diagnostics, gene therapy, genomic dactyloscopy, various population screening programs, collection and storage of individual and population genetic information have become a reality. Many private firms, invested significant resources in the development of genome research and generate large profits have been established[18]. All this should be ensured by improving the legislation on biotechnology safety based on the assessment of risks prepared by scientists in the emergence of more modern biotechnology, with special emphasis on continuous monitoring of data for advances in biotechnology with the establishment of an adequate regulatory system[19].

The new legislation should include national security on the one hand, and biotechnological development on the other.

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Хікмет Меджнун Бабаєв

ВИКОРИСТАННЯ ГЕНЕТИЧНОЇ ІНЖЕНЕРІЇ ТА ПРАВОВЕ РЕГУЛЮВАННЯ БІОБЕЗПЕКИ

Анотація. Розвиток суспільства сприяє розвитку біотехнології. Інновації в галузі генної інженерії також зумовлюють необхідність формування правового регулювання. Входження нашої держави в економічний і технологічний простір передбачає правове позитивне забезпечення біотехнологічної та біомедичної діяльності як на загальному, так і на локальному рівнях. Дослідження у відповідній галузі безпосередньо пов'язані з інноваціями, що застосовуються як у діагностиці, так і в лікуванні детермінованих генетичних захворювань і молекулярної біології. Нині відповідні дослідження досягли епохи, коли практичні ознаки, такі як генетичне тестування, генна терапія, геномна дактилоскопія, різноманітні програми популяційного скринінгу, збирання та збереження генетичних даних особи та популяції, стали реальністю. Нові законодавчі норми мають розглядати, з одного боку, національну безпеку, а з другого – розвиток біотехнологій.

Ключові слова: біомедицина; міжнародне право; біоетика; біотехнологія; право.