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Reproductive and Therapeutic Editing of Human Genes and Gene Modification of Plants and Animals in Terms of Legislation and Research Activity Restrictions in Brazil

Ksenia Michailovna Belikova
Doctor of Law, Professor of the Department of Civil Law and Procedure and International Private Law, Law Institute, Peoples' Friendship University of Russia (RUDN University), 6 Miklukho-Maklaya Street, Moscow, 117198, Russian Federation, E-mail: ksenia.belikova@yahoo.com

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ABSTRACT
The article is based on the materials of a number of normative acts and documents. Some aspects are introduced for the current state of legal regulation and ethical problems regarding reproductive and therapeutic editing of human genes and gene modification of plants and animals in terms of legal framework of research activity and its limitations and provisions on biosafety in Brazil.
Keywords: science**,** scientific information, Brazil, BRICS, assisted reproductive technology, in vitro fertilization (IVF), reproductive and therapeutic editing of human genes, humans, animals and plants, discoveries, inventions, ethics, medicine, biosafety, Brazilian Federal Council of Medicine
Correspondence:
Ksenia Michailovna Belikova
Doctor of Law, Professor of the Department of Civil Law and Procedure and International Private Law, Law Institute, Russian Federation
E-mail: ksenia.belikova@yahoo.com
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INTRODUCTION

Nature and scope of the problem

Biotechnology involves processes, mechanisms, and methods to manipulate the living cells of plants, animals, and humans to create various substances or technologies. The aim of this science was to expand knowledge in the fields of biology, medicine, engineering, etc.; human reproduction, the creation of new species of plants and/or animals, to diagnose human pathological conditions and to find a way to correct them. In this respect, Brazil, being one of the BRICS countries was not lagging behind. Legislators, therefore, needed to focus on legally supporting activities related to scientific research and the legal protection of the results of such activities. In our earlier studies, we investigated the organizational and legal development of biotechnology in Brazil on the basis of accumulated scientific information. We have been dealing with another aspect of the development of biotechnology and legislation in the current work.

The subject of the study was the analysis of the Brazilian approaches to gene modification in the context of the implementation and application of assisted and other human reproductive technologies since all the aspects of this issue needed to be identified from different perspectives (law, ethics, psychology, etc.).

The methodology was based on the Dialectical Materialism Philosophy. It presumes the collection of data by means of an analysis of the legal acts and documents and a descriptive approach to the legal regulations in the field under study. The author draws on the dual character of any phenomena and processes of the external world. The following general scientific and special research methods have been applied: formal and dialectical logic combined with induction and deduction, hypothesis and analogy, analysis and synthesis, and systemic analysis. Thus, in addition to induction and deduction, the method of systematic analysis was used for the analysis of the Brazilian legislation to clarify its key provisions and the correlation with other regulations. Formal and dialectical logic methods have helped to understand the correlation between science, technology, and innovation. The materialistic view of the processes and phenomena of the external world enabled us to acknowledge that, under modern conditions, genetic engineering, editing of human genes and embryos, would change people's awareness of the admissibility of such interventions under state control.

The Results of the study and the analysis undertaken have revealed that a thorough approach to the development of regulatory requirements for the implementation of both research and practical activities in the field of gene modification has been implemented in Brazil. Special terms were clearly defined in the current legislation, which almost completely negated the possibility of multiple interpretations of its provisions. In addition to the responsibility for violation of the latter, it also laid down the legal conditions for obtaining and applying biomaterials for practical (therapeutic, commercial, etc.) and scientific purposes.

However, Brazilian legal acts (Law, Decree, Constitution), as well as normative acts and documents of other countries (e.g., the PRC, etc.) in the sphere of gene modification, declare the necessity to meet public interests, as well as ethical and moral norms. This is the weak point in the legislation, since such concepts have a wide but vague meaning, which can lead to negative consequences due to the tendency for originality and competitiveness in this area.

At the same time, it is only the law but not special (medical) acts, reflecting specialized ethics, which become the point for discussion in society. Apparently, those who do not have reproductive problems do not know or are not interested in the issue of the legal status of embryos, the possibilities for their gene modification, etc. Patients with such problems consider Assisted Reproductive Technology (ART) as their only opportunity to become parents and do not want to lose it as a result of discussions and therefore avoid them. We regard this problem as rather a sociopsychological one.

LITERATURE REVIEW

Both domestic and foreign scientists are interested in the issue of reproductive and therapeutic editing of human genes and gene modification of plants and animals. It is worth highlighting the following researchers and their works: Eduardo Soares (Restrictions on Genetically Modified Organisms, 2014); Mônica Cibele Amâncio (Marco Legal Brasileiro sobre Organismos Geneticamente Modificados, 2020); Olivia M.N. Arantes, José M.F J. da Silveira, Izaias de C. Borges, Deise M.F. Capalbo, Dilaine R. S. Schneider, Nilce C. Gattaz, Eliana de S. Lima. (Desenvolvimento de comunicação estratégica sobre biossegurança de plantas geneticamente modificadas – o caso do projeto LAC - Biosafety no Brasil. 2011); Kalline Eler (The Ethical-normative Gap in the Brazilian Regulation of Assisted Reproductive Techniques: The Instrumentalization of Human Embryos for Medical-Scientistic Knowledge through Pre-Implantation Genetic Diagnosis, 2018); Chao, E. (Problemas éticos em la selección de embiones com finalidade terapêutica, 2010); Diniz, D. (Tecnologias reprodutivas, ética e gênero: o debate legislativo brasileiro, 2000); Ponkin, I.V., Ponkina, A.A. (Production of "designer" embryos: legal and bioethical aspects, 2017); Karagyaur, M.N., Efimenko, A.Yu., Makarevich, P.I., Vasiluev, P.A., Akopyan, Zh.A., Bryzgalina, E.V., Tkachuk, V.A. (Ethical and Legal Aspects of Using Genome Editing Technologies in Medicine, 2019), etc.

DISCUSSION

In Brazil, the issue of genetically modified organisms (hereinafter, GMOs) is regulated with Law No. 11.105 of March 24, 2005, which regulates clauses 2, 4 and 5 of §1 of Article 225 of the Constitution (hereinafter, the Law of 2005), and Decree No. 5.591 of November 22, 2005 (hereinafter, the Decree of 2005). These documents are devoted to the principles established by the Constitution of 1988 on the preservation of the country's environment, genetic heritage and the supervision of the activities of the institutions involved in research and manipulation of genetic material.

The Law of 2005 is focused on the implementation of scientific achievements in the sphere of biosafety and technology, the precautionary principle for protection of the environment as well as the protection of the health of plants, animals and human beings.

This Law provided the development of general rules for conducting research in the field of biotechnology, reorganization of the biotechnological sector, and the creation of a National Biosafety Council (Conselho Nacional de Biossegurança, CNBS - *portug.*) (Articles 8 and 9 of the Law of 2005; articles 48-52 of the Decree of 2005), reorganization of the National Biosecurity Technical Commission (Comissão Técnica Nacional de Biossegurança, CTNBio, *portug.*) Articles 10- 15 of the Law of 2005; Articles 4-47 of the Decree of 2005). In addition, National Biosafety Policy was developed.

The functions of the CNBS, CTNBio and CIBio (Internal Biosecurity Commission, Comissão interna de biossegurança, CIBio – *portug.*) are enshrined in the Law of 2005. According to the Brazilian system of Institutional Biosafety:

- CNBS is the highest advisory body responsible for the development and implementation of the "National Biosafety Policy", subordinate to the President of the country. Its main functions are the following:

a) development of biosafety guidelines for federal agencies and institutions;

b) analysis of CTNBio applications regarding the introduction of GMOs and their derivatives into the trade in terms of national interests and socio-economic opportunities

c) the final decision-making on administrative cases as to the commercial use of GMOs and their derivatives;

- CTNBio is a multi-faceted advisory collegial body of the Ministry of Science and Technology. It consists of the main members and deputies appointed by the Minister of Science and Technology. Among them, 27 people must be Brazilian citizens who are recognized experts in science and technology, including the applied aspect of biosafety, biotechnology, biology, human and animal health or the environment and have a PhD degree. The goal of the Commission is the following:

a) to provide the Federal Government with technical and advisory support in creation, implementation and improvement of the "National Biosafety Policy" with respect to GMOs and their derivatives;

b) to develop technical safety standards that exclude risks for human health and the environment when issuing permits for research and commercial activities with GMOs and their derivatives;

b) monitoring the scientific and technological progress in biology (safety, technology, ethics) and related fields for the timely expansion of ways to protect the environment, including the health of its inhabitants (human beings, animals, plants, etc.);

- CIBio (Internal Biosecurity Commission, Comissão interna de biossegurança, CIBio – *portug.*) (Articles 17, 18 of the Law of 2005; Articles 61, 62 of the Decree of 2005) is the Internal Biosafety Commission, which should be created in the framework of any organization that applies (work with) genetic engineering techniques or methods or conducts research using GMOs and their derivatives. In addition, a senior professional technician must be appointed, who will be responsible for each project. In our opinion, it corresponds to Ethics Committees in China.

Thus, in Brazil, any genetically modified product goes through the several stages before the application (for more details, see paragraph 2 of Article 3 of the Decree of 2005). The company that developed the product must be examined at the CIBio level. After that it can introduce the project to CTNBio for approval. CTNBio reviews the project and goes to the place of further manufacture (production) of the GMO and its derivatives to determine if there are conditions for safe implementation of the project. After the approval by CTNBio, the company can set up the development and test of a product containing GMOs. The process must be carried out in a limited and controlled space (laboratories, etc.). If it is a factory, the experiment is controlled by the Ministry of Agriculture. In the next stage, CTNBio evaluates whether the data of the test results meet the biosafety criteria that the Commission adheres to. After that, the product undergoes CNBS's political considerations by a council of eleven ministers who decide whether the release of such a new product

containing GMOs will improve Brazil's competitiveness. Local control (in organizations) is performed by CIBio.

The Law of 2005 defines GMOs as an organism whose genetic material (DNA / RNA) was modified with any method of genetic engineering (Clause 5, Article 3 of the Law of 2005). The GMOs derivatives are defined as products derived from GMOs and do not have autonomous replication capabilities or do not contain a viable form of GMOs (Clause 4, Article 3 of the Law of 2005). Moreover, according to §1 of Article 3 of the Law of 2005, we cannot regard as GMOs the results of the application of assisted methods and technologies used for direct introduction of hereditary material into the body, as long as they are not associated with the use of recombinant DNA / RNA or GMO molecules. Thus, in vitro fertilization, combination, transduction, transformation, polyploid induction and any other natural processes cannot be considered as GMO. Besides, chemically determined pure substances obtained by means of biological processes and that do not contain GMO, a heterologous protein or recombinant DNA are not defined as GMOs derivatives (§2 of the Article 3 of the Law of 2005).

These definitions are also revealed in the Clauses 7 and 8 of the Article 3 of the Decree of 2005.

Other definitions that are useful for understanding the issue under consideration are revealed in Article 3 of the Law of 2005:

- Organism is a biological entity capable of reproducing or transmitting genetic material, including viruses and other classes that are not yet known;
- Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) are genetic materials containing information that determines hereditary characteristics transmitted to descendants;
- Recombinant DNA / RNA molecule are molecules processed outside of living cells with modifying segments of natural or synthetic DNA / RNA and capable of multiplying in a living cell, or even DNA / RNA molecules resulting from this multiplication; synthetic DNA / RNA segments are also considered equivalent to natural DNA / RNA segments;
- Genetic engineering is the production and processing of a recombinant DNA / RNA molecule;
- Human germ cell is the maternal cell responsible for the formation of gametes present in the male and female germ glands and their direct descendants at any level of ploidy;
- Cloning is asexual reproduction process, artificially produced, based on a single genetic heritage, with or without genetic engineering methods;
- Reproductive cloning is the cloning with the intention to produce a human being;
- Therapeutic cloning is the cloning for the production of embryonic stem cells for therapeutic use;
- Embryonic stem cells can become cells of any tissue of the body.

These definitions are also revealed in Article 3 of the Decree of 2005.

The Law of 2005 cannot be applied if the genetic modification was obtained through the methods that are not related to the use of GMOs as a recipient or donor of such modification, namely:

- mutagenesis;
- the formation and use of animal somatic hybridoma cells;
- cell synthesis of plant cells, including protoplasm, that can be produced by means of traditional methods;
- autocloning of non-pathogenic organisms naturally processed (Article 4 of the Law).

For the scientific and therapeutic purposes, the use of embryonic stem cells derived from human embryos created during the in vitro fertilization procedure (hereinafter referred to as IVF) and not used in it are allowed under the conditions introduced in Article 5 of the Law of 2005, paragraphs 13 and 14 of the Article 3 and Article 63 of the Decree of 2005:

I - embryos are not viable, or

II – were cryopreserved three or more years ago, counted from the date of publication of the Law of 2005; or embryos were frozen at the time of publication of the Law of 2005 and were at the end of the third year, counted from the date of cryopreservation.

In this regard, it should be noted that the 3-year period is rather short. In our opinion, in connection with the provision on non-viable embryos, it creates a restriction to scientific research and appropriate therapy. On the other hand, women systematically appeal to various medical centers, intending to get pregnant by means of IVF. Therefore, the indicated restriction can be overcome to some extent.

In any of these cases, it is necessary to point out the necessity:

- to have agreement of parents (§1 of Article 5 of the Law of 2005);
- research institutions and health services that conduct research or therapy with human embryonic stem cells, must have their projects approved by the relevant Internal Biosafety Commission (§ 2, Article 5 of the Law of 2005);
- commercial use of biological material referred to in Article 5 of the Law of 2005 is prohibited, and constitutes a crime in accordance with Article 15 of the Law No. 9.434 of February 4 1997 on the removal of organs, tissues and parts of the human body for transplantation and treatment. According to the Law, selling and purchase of organs, tissues and parts of the human body entail imprisonment for a term of 3 to 5 years and a fine of 200 to 3,560 labor days. Persons participating in such an activity that promote, act as intermediaries or offer any advantages in exchange of such a transaction are also liable (Article 15 of the Law of 1997).

In the context of the IVF procedure study, Brazilian researchers point out that such a treatment is not a priority for the Brazilian Unified Health Service (Sistema Único de Saúde, SUS). However, the Ministry of Health announced in the media in March 2012 that it had established a Technical Committee to discuss this issue. One of the participants of the first meeting of the Committee, who wished to remain anonymous, said that the Committee did not publish reports on the discussion, and that other meetings of the

Committee were not held. Director of the State Center for Human Reproduction at the Regional Hospital of the Administrative Region Asa Sul, Federal District Brasilia (Hospital Regional da Asa Sul, um bairro da região administrativa de Brasília - Distrito Federal) said in an interview that SUS currently offers 31 assisted reproductive technologies, most of which are preliminary tests for more complex treatment, such as IVF. However, by mid-2012, only nine Brazilian government institutions offered IVF: four on a free basis, 5 on a partial payment basis. The number of private clinics offering such services is significant. They must be registered by means of the National Embryo Production System (SisEmbrio) created in 2008 at the National Agency for Sanitary Inspection (Agência Nacional de Vigilância Sanitária, ANVISA). The purpose of SisEmbrio is the following:

a) to register the number of human embryos produced and implanted in the country using the IVF method. Both cryopreserved and research-oriented human embryos;

b) to register the potential number of embryos for research and therapeutic purposes.

Human embryos obtained by means of IVF and those that were not used by patients must be registered in the Ministry of Health (Article 64 of the Decree of 2005). Institutions involved in the cryopreservation and storage of human embryos should inform about the standard they use for verification of the viability of the obtained embryos and cryopreservation of live embryos (§ 1, Article 64 of the Decree of 2005). After 30 days from the date of publication of the Decree of 2005, the institutions referred to in paragraph 1 of Article 64 of this Decree should begin to adhere to the new standard issued by the Ministry of Health (§2 Article 64 of the Decree of 2005).

Approach to IVF, in particular, and ART as a whole are based on the provisions of paragraph 7 of Article 226 (Family Planning) of the Constitution of 1988 and the Law of № 9.263 of 1996. The Constitution provision declares the following: "Basing on the principles of human dignity and responsible parenthood, family planning is the free decision of the spouse, and the state should provide educational and scientific resources to exercise this right, prohibiting any coercive action by public or private institutions". The Law No. 9.263 of 1996 states: "To provide the right to family planning, any citizen will receive all methods and technologies of conception and contraception that are scientifically acceptable and that do not pose a threat to the lives of those involved in this process, guaranteeing freedom of their actions". It also states that "Family planning is the right of all citizens and should be provided at the level of public health to women, men or married couples ... Doctors who conduct surgical sterilization, but do not inform the sanitary authorities about the procedure itself, nor about the conditions under which it was carried out, must be arrested". These procedures highlight the important ethical issue of compulsory spaying of women in the situations when doctors understand the patient's current and potential problems, which can develop if the woman gets pregnant. Therefore, doctors make a decision to eliminate these problems "for the good of the patient" or, perhaps, guided by any other considerations, without informing her about it. We point out that such situations are typical not only for Brazil, but also occur in other countries. They may contradict to the women's will to solve the reproductive problems by means of IVF.

According to Article 6 of the Law of 2005 it is forbidden the following:

I – to implement a project related to GMOs without the registration of its maintenance;

II - *in vitro* genetic engineering on a living organism, natural or recombinant DNA / RNA conducted contrary to the standards set forth in the present law;

III - genetic engineering on human germ cells, human zygotes or human embryos;

IV - human cloning (e.g., by currently practicing somatic cell nuclear transfer- *author's note*);

V –destruction or disposal of GMO and the derivatives in the environment contrary to the standards established by CTNBio, with the norms of the present law and the rules in this field; as well as by bodies and organizations which, in accordance with Article 16 of the Law of 2005 are entrusted to register, inspect and control the implementation of such projects and the activities of relevant organizations;

VI - release of GMOs or their derivatives into the environment in terms of research activities without CTNBio's approval; in the case of commercial release, without CTNBio's positive technical conclusion, or without licensing from the environmental safety authority or organization, etc., if CTNBio considers such activity (i.e., the release of GMOs, etc.) a potential cause of environmental abuses; or without CNBS approval, if the latter was withdrawn by CNBS basing on provisions of this Law or other regulatory requirements.

Considering the provisions of this paragraph, the author introduces the idea that even if the Law of 2005 did not contain the prohibitions set in clauses 2-4 of this article, then "release of GMOs and their derivatives into the environment" in the form of implantation of genetically modified human embryos into women's body during IVF without appropriate permits (approvals) would constitute a violation of this paragraph;

VII – processes that are regarded as the use, commercialization, registration, patenting and licensing of limited-use genetic technologies (tecnologias genéticas de uso restrito) according to Article 6 the Law of 2005, namely:

a) any processes of human intervention (qualquer processo de intervenção humana) for the generation or reproduction of genetically modified *plants* for the reproductive sterile structures;

b) any forms of genetic manipulation, the purpose of which is the activation or deactivation of genes related to the *plants* fertility using external chemical inducers.

In this context, according to Article 18 of the Law No. 9.279 of May 14, 1996 on Industrial Property (as amended by Law No. 10.196 of 2001, hereinafter the Law of 1996), which has been the main patent law in the country since May 15, 1997, the following *objects* are not patentable:

- contrary to morality, good motives (bons costumes - *portug.*) or security, public order or healthcare;
- substances, materials, mixtures, elements or products of any kind, as well as changes in their physicochemical structure and corresponding methods for their

manufacture or changes if they are obtained by means of nuclear transformation;

- living organisms or their parts (o todo ou parte dos seres vivos), except transgenic microorganisms (microorganismos transgênicos), which correspond to three criteria of patentability according to Article 8 of the Law of 1996, i.e., novelty (novidade), inventive activity (atividade inventiva), and industrial applicability (aplicação industrial) and are not ordinary discoveries (mera descoberta).

Firstly, it is worth highlighting that the Law of 2005 analyzes GMO by means of the term "organism". However, there is no contradiction here. Article 18 of the Law of 1996 specifies transgenic microorganisms as organisms, with the exception of the whole plant, animal or a part of them, which, due to direct human intervention in their genetic profile, obtain features that are usually not characteristic for their species in natural conditions. Thus, the last of the three introduced points relates to plants and animals, while the first one (moral, healthcare, etc.), in our opinion, is connected to people (human embryos, cells, etc.).

Secondly, the Law of 1996 does not consider as inventions the following:

I – discoveries, scientific theories and mathematical methods;

II – purely abstract concept;

IV - literary, architectural, artistic or scientific works or any other aesthetic creations;

VI - presentation of information;

VIII – operative and surgical techniques and methods, as well as therapeutic or diagnostic methods which can be applied on the human or animal body;

IX – the whole living creature or biological materials, or part of them, that can be found in nature or even isolated from it, including the genome or germ plasm of any natural living creature and natural biological processes.

This approach is similar to the previously existed in Brazil legislation in the sphere of pharmaceutical products and processes (Article 9 of the Law 5.772 / 71)), which approved the Industrial Property Code of 1971 by prohibiting their patenting. This contributed to the production of domestic generics that were cheaper than foreign drugs and met the needs of the health system. This logic is also presented in judicial decisions made in other legal orders (for example, the decision in the case of the American company *Ass'n for Molecular Pathology v. Myriad* and others).

According to the Law of 2005, the following procedures are mandatory to ensure biosecurity:

I – to identify the causes of the accidents that happened during genetic engineering; to prepare and to send a report to the competent services and authorities within 5 (five) days after the date of the event;

II – to notify the CTNBio, health, agriculture and the environment authorities immediately about the accident that can lead to the spread of GMOs and their derivatives;

III – to provide all the necessary measures to fully inform health, environment and agriculture authorities, communities and other institutions and companies about the risks as well as measures to be taken in case of accidents involving GMOs (Article 7 of the Law of 2005).

The Law of 2005 provides rules for laboratories that work with GMOs; the rules for biotechnological research, including authorization procedures; the rules for the production and marketing of GMOs; restrictions on their release into the environment and reporting requirements on this issue; their cultivation regimes and monitoring of research activities in this sphere; commercial production of GMOs; restrictions on GMO use in food industry; punishment for administrative violations and criminal offenses in this area. In general, the Law elaborates on the provisions of the Constitution regarding safety, inspection and control mechanisms during construction, cultivation, production, manipulation, transportation, transfer, import, export, storage, market entry and commercialization; research, consumption; release into nature and emission of GMO waste products and its derivatives (Article 1 of the Law of 2005, paragraph 1 {research} and paragraph 2 {commercialization of the results} Article 3 of the Decree of 2005). From the moment of its creation until 2012, CTNBio had approved the commercial use of about fifty GMOs, thirty-five of which are plants (beans, cotton, corn and soybeans, etc.). In 2012, for example, Brazil was the second state in the world after the USA, producing GMO crops. It has in disposal 35 million hectares for planting GMOs, while the USA has 69 million hectares.

Only state and private organizations can conduct educational activities and scientific research (§1, Article 2 of the Law of 2005, paragraph 1 of Article 3 of the Decree of 2005), technological developments and industrial production of GMOs, within the framework of the technical or scientific responsibility of such an organization (§1 Article 2) for compliance with the requirements of the Law of 2005 and the Decree of 2005 and for possible consequences of non-compliance. Individuals are prohibited to conduct any activity and projects in the field of GMOs and their derivatives, even if they are employees or are otherwise related to such organizations (§2, Article 2).

In any case, it is necessary to obtain a CTNBio permission to conduct such an activity (§3 Article 2).

In accordance with paragraph 6 of Article 14 of the Law of 2005, CTNbio is responsible for establishing biosafety requirements for issuing permits for the operation of laboratories, institutions or companies engaged in activity related to GMOs and their derivatives.

CTNBio Regulatory Resolution No. 2 of November 27, 2006 contains the classification of GMO risks and biosafety levels that should be applied for safe storage, including the periods of creation, cultivation and production of GMOs; quality control, destruction, etc., as well as permissible limits for research, technological and educational activity with GMOs. It also contains detailed information, on the presentation of the projects start and activity with GMOs, specifications of laboratories and equipment providing safe storage of GMOs and their derivatives, etc.

According to the Law, in order to operate the information received as a result of the activity with GMOs and their derivatives, it was founded the Biosecurity Information System (Sistema de informação de biossegurança, SIB – *portug.* Article 19 of the Law of 2005) on the basis of the Ministry of Science and Technology.

These provisions of the Law of 2005 are related to the fact that the first Law No. 8.974 of January 05, 1995, aimed at regulating various aspects of biosafety connected to the development of GMOs and their derivatives, failed to solve the problems that arose. The difficulties with its use began when CTNBio had adopted the Preliminary Technical Report (Parecer técnico prévio conclusivo), which approved the commercialization of genetically modified soybean that was resistant to glyphosate-based herbicides produced by the company Monsanto do Brazil Ltd. However, the Environmental Assessment Certificate for such a product (Relatório de Impacto Ambiental, RIMA) was not demanded. CTNBio's competence to issue such a conclusion without regard to environmental impact was immediately challenged in court through a public civil lawsuit by the Brazilian Consumer Protection Institute (Instituto Brasileiro de Defesa do Consumidor, IDEC). That was the beginning of a wide discussion in the country on the issue of GMOs with the participation of representatives of all the branches of government and ordinary people. Therefore, the basis for the adoption of contradictory legislation was developed. In 2005, it was replaced by the current Law of 2005.

CTNBio's actions violated several clauses of Article 225 of the Brazilian Constitution of 1988, specifying the general provision of this article (paragraphs 2, 4 and 5) that "Everyone has the right to use balanced ecological environment suitable for general use by the people and necessary for a qualitative lifestyle. The responsibility to protect and preserve this environment for the benefit of living and future generations rests with public authorities and the society." In addition, paragraph 1 was violated, according to which "To ensure the effectiveness of this right, public authorities are competent to the following:"

- "In accordance with the requirements of the Law, any institution whose construction or activity may cause significant damage to the environment, must conduct and publish the preliminary studies regarding the environmental consequences of such an activity" (clause 4, §1 of Article 225);
- "To control the production, sale and use of equipment, technology or materials that constitute a risk to life, a threat to the quality of life and the environment" (clause 5, §1 of Article 225);
- "To preserve the diversity and integrity of genetic heritage of the country and to control the activity of the institutions, which conduct research and practical work with genetic materials" (clause 2, §1 of Article 225). For the development of the last of the aforementioned paragraphs and in accordance with the Convention "On Biological Diversity" of 1992, Law No. 13.123 of May 20, 2015 "On Access to Genetic Heritage ..." was adopted in 2015. According to Article 4 of this Law, it cannot be applied to the human genetic heritage.

Public opinion polls on the issue of GMO trust and assessments of its significance conducted in 2011 showed that people are generally aware of GMOs, but are suspicious of the hidden motives for which the state and private companies protect GMOs, their development and modification. In this context, it is worthy to note the research conducted in 2011 by the Brazilian Agricultural Research Company (Empresa Brasileira de Pesquisa Agropecua, Embrapa), whose goal is to solve the problems of sustainable agricultural development based on scientific research, development and innovation in the interests of Brazilian society.

For the present research, the provisions for embryos are important. The ideas introduced in the Law of 2005 are developed in acts of the Federal Medical Council (Conselho Federal de Medicina, CFM) of Brazil, and in particular, in its Resolutions (Resoluções), i.e., regulatory acts adopted by general meetings (plenums) of CFM and regional medical Councils (Conselhos Regionais de Medicina). The conclusions of these bodies shall be binding in its entirety and directly applicable.

The attempts have been made to adopt a law on the regulation of assisted reproductive technologies in humans. Thus, for example, Bill 3638 (Brazil, 1993) is the oldest, archived in 2002. Bill 2855 (Brazil, 1997) was merged with Bill 4665 (Brazil, 2001) in 2001 and, since April 2003, has been considering by the Constitution, Justice and Editing Committee of the House of Representatives. It was attached to Bill 1184 (Brazil, 2003) in 2003. At the same time Senate Bill 90/99 (Brazil, 1999) was drafted and archived in 2007, but it was not adopted.

This fact was emphasized in the Explanatory Memorandum to the Resolution of Federal Council of Medicine No. 2.168 on "Ethical standards for the use of assisted reproduction techniques" of 2017, alongside with the importance of the adopted Resolution and the social and ontological role of assisted reproductive technologies for the reproduction of the population, including the possibility of gametes cryopreservation, etc. In addition, it was highlighted that the provisions of the Resolution of 2017 were approved by the representatives of the Brazilian Society of Assisted Reproduction (Sociedade Brasileira de Reprodução Assistida), the Brazilian Federation of Obstetrics and Gynecology Societies (Federação Brasileira das Sociedades de Ginecologia e Obstetríied), the Brazilian Society of Human Reproduction (Sociedade Brasileira Reprodução Humana), Brazilian Society of Medical Genetics (Sociedade Brasileira de Genética Médica) and with federal adviser (conselheiro federal) José Hiran da Silva Gallo. Besides, Article 67 of the Decree of 2005 states that the therapeutic use of stem embryonic cells within the provisions of Article 63 of the Decree of 2005 will be implemented in accordance with the recommendations of the Ministry of Health for the evaluation of new technologies.

In this regard, Brazilian researchers note the duality of CFM acts, which in fact, serve as the basis of the ethical approach that practitioners, doctors and the like should reflect in their work, including in conflict situations and in their assessments.

On the one hand, there is no integrity in society regarding the particular provisions of the CFM ethics, because they were not discussed widely, and CFM acts are not legal for the Brazilian society. On the other hand, the majority of the society was not interested in the question because of a conviction that the issue of establishing common ideas in the field of medical ethics and mediation in ethical conflicts in medicine concerns CFM exclusively, and this has never been called in question.

In the framework of the present study the authors analyzed this CFM Resolution No. 2.168 / 2017 which adopts the

ethical standards for the use of assisted human reproduction methods for the improvement of this activity, adhering to the principles of ethics and bioethics, which contribute to the efficiency and safety of treatment and medical procedures; and medical deontology, which should be followed by Brazilian doctors. This Resolution (briefly "On Ethical Standards in the Field of ART"), which repealed the previous CFM Resolution of 2015 No. 2.121 on this issue, contains some provisions that we concern.

Human assisted reproduction technologies cannot be applied to select gender (presence or absence of the Y chromosome) or any other biological characteristics of the unborn child, unless it is necessary to prevent descendants' diseases (clause 5 of Section I "General Provisions"). Therefore, negative eugenics is allowed, which helps people to get rid of diseases; and positive eugenics, which makes possible to choose certain human qualities, is forbidden etc.

Human oocyte fertilization for any other purpose than the procreation is prohibited (Article 6 of Section I "General Provisions").

The donation of gametes and embryos cannot be carried out for commercial purposes (paragraph 1 of Section IV "Donation of gametes and embryos").

Clinics, centers or services may cryopreserve spermatoids, oocyte, embryos and reproductive tissues (Section 2, Section 5, "Cryopreservation of Hamet or Embryos").

The total number of embryos received in the laboratory by means of ART should be reported to patients who decide how many embryos will be transferred "fresh" (a fresco). According to the provisions of this resolution, transfer is carried out depending on age:

a) women under 35 years old can be transferred up to 2 embryos;

b) women aged 36-39 years old can be transferred up to 3 embryos;

c) women aged 40 years and over can be transferred up to 4 embryos;

d) in cases of donation of oocyte and embryo, the age of the donor at the time of collection of oocyte is taken into account.

Thus, the number of embryos to be transferred cannot exceed four (clause 7, Section 1). If ART contributed to multiple pregnancy, embryo reduction would be prohibited (clause 8, Section 8). Possible surpluses should be cryopreserved (clause 2, Section 5).

At the time of cryopreservation, patients must express their will in writing regarding the cryopreserved embryos in case of divorce or breakdown of a stable union, serious illness or death of one of the married persons (union), or their will to donate (clause 3, sections 5).

Cryopreserved embryos stored for 3 (three) or more years can be eliminated at the patients' request (clause 4, Section 5). Cryopreserved embryos left by patients (embriões criopreservados e abandonados) for a period of 3 years or more can also be eliminated (clause 5, Section 5). Embryos are considered to be abandoned if the responsible persons (patients, doctors – *author's note*) did not conclude a preimplantation agreement and were absent in the clinic (Embrião ... que os responsáveis descumpriram o contrato pré-estabelecido e não foram localizados pela clínica - Section 5).

As far as the attitude of society towards the indicated approaches is concerned, it is mostly expressed with the scientists' opinions (lawyers, physicians, etc.). In this connection, it is noted that laws on ART are focused on the promotion and protection of the interests of specialists who make profit from such procedures (clinics, pharmaceutical laboratories). For example, IVF procedure requires preliminary and ongoing hormonal therapy, etc. ART is involved in the logical chain of biotechnological consumption and commercial production of "life". Taking into account their concentration in the sphere of the private medicine, the child (embryo) is equated with things, luxury goods that are objects (for example, in the norms of the Brazilian Civil Code of 2002, Articles 79-103 et al.). Constitution of 1988 protects human dignity in all its derivatives. Article 1, in particular, states that "The Federative Republic of Brazil, which is an indissoluble union of states, municipalities and the Federal District, forms a democratic state of law and proclaims human dignity as its foundation", etc.). Human embryo is not recognized as a subject, although, an embryo created by in vitro fertilization carries all the meaning and attributes of the concept of "human being", all the necessary characteristics for the development of a born person. It transforms constantly until the day of death, due to the multiplication and mutation of his or her cells. Therefore, there is no reason to exclude him from the category of person, i.e., subject.

CONCLUSIONS

The authors came to the conclusion, that the convergence of capital, science and technology subordinates the sphere of social life to the market laws. In this context, ART services follow the consumption strategy supported in Western society, where family is regarded as business. However, scientific and technological progress should not be condemned as vicious. It carries a positive energy and is focused on providing a better quality of life due to its achievements and innovations. Within the framework of ART it means that scientific and technological progress is focused on safe and reasonable enforcement of parental reproductive rights. We admit that the development of information technologies, their convenience and other advantages will not allow (if there are no global cataclysms) to return to the traditional economy. If there is an adequate legislation, such technologies will only develop. Modern medical technologies which not only allow editing genes for therapeutic purposes, but also producing therapeutic cloning of organs, their 3D printing, etc., will develop in the direction of human reproduction. Of course, there can be some difficulties, but the new always has to struggle its way through. In this context, it is important to provide state control over the process.

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