LEX GENETICA

VOL. 1
NO. 1
2022

TOPICS OF THE ISSUE:

МГЮА

www. lexgenetica.ru

LEX GENETICA

SCIENCE JOURNAL

Volume 1,
No. 1
2022

МГЮА

LEX GENETICA
SCIENCE JOURNAL

Founder -

Published since 2022
Four issues per year

OSGRIN@MSAL.RU
+ 7 (499) 244-88-88 #573 #678
https://lexgen.elpub.ru

Publisher address
Kutafin Moscow State Law University (MSAL)
9 Sadovaya-Kudrinskaya ulitsa,
Moscow 125993, Russia

Editorial Office
https://msal.ru/en/
vsmakarenko@msal.ru + 7 (499) 244-88-88

Original article

https://doi.org/10.17803/lexgen-2022-1-1-4-19

Original article

The Principle of Inviolability of the Human Genome and Information about the Human Genome

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Abstract

The principle of inviolability of the human genome is discussed in the context of biomedicine and related areas. The 'pros' and 'cons' of interference in the human genome are presented in terms of somatic and germ cells, as well as those interventions affecting the human genome at the embryonic stage of development. In connection with the development of synthetic biology, the human genome, as well as its fragments, genes, and genetic information, is increasingly becoming of practical interest for various parties (entities and individuals), and, therefore, need protection, including legal protection. From a systemic approach, the principle of inviolability of the human genome cannot be absolute. The limits of its applicability (force and effect) can be affected by: the degree of development of genetic and information technologies; availability of effective institutions for control over modern technologies; functioning of the mechanisms ensuring biological, information and other types of security; national, cultural, religious peculiarities; established legal and ethical traditions, and practices in a number of sectors and fields of activity (research, medicine, information, etc.).

Keywords: genetic technologies, information technologies, genetic information, human genome, genome editing, somatic research, law

Acknowledgments. This work is supported by the Russian Ministry of Science and Higher Education Topic: Legal Regulation of Accelerated Development of Genetic Technologies: Research and Methodology Framework; (No. 730000Ф.99.1.ББ16АА02001).

To cite this article: Mokhov A.A. (2022). The principle of inviolability of the human genome and information about the human genome. *Lex Genetica*, 2022;1(1):4–19. https://doi.org/10.17803/lexgen-2022-1-1-4-19

Received 15.11.2022
Review completed 16.12.2022
Passed for printing 03.01.2023

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Introduction

The human genome became the subject of research in the second half of the 20th century following revolutionary discoveries in the field of genetics, especially those clarifying the role of deoxyribonucleic acid (DNA) as a carrier of genetic information. At the turn of the century, fundamental work on decoding the human genome was completed; by 2018, a correlation between a number of genes and gene mutations with genetically determined human diseases was identified *(Yavorskiy, 2021)*. Special mention should be made of the wide spread of genome editing technologies in scientific practice, in particular, CRISPR/Cas9 or 'genetic scissors' *(Doudna & Charpentier, 2014)*.

From that moment on, it became possible to talk not only about the research in the field of biology and medicine, but also about attempts to control the human genome and genetic information for resolving medical and other issues. In the field of medicine, problems involved direct human cell genome editing *in vitro* or *in vivo* for disease treatment have begun to be set and accomplished *(Hirakawa, Krishnakumar, Timlin, Carney, & Butler, 2020; Maeder & Gersbach, 2016; Li et al., 2020)*.

The modern genetic technologies and the potential thereof have triggered the scientific discussion regarding the future 'destiny' of the human genome. The present work is dedicated to legal and ethical issues associated with this discussion.

Genetic technologies and human genome editing: background

At the initial stage of the development of genetic technologies, when the human genome is being used or even synthesized based on the available data about it, two unequal groups can be distinguished: 'natural' or 'synthetic' human genome *(Mokhov, 2020)*, whose fragments are used to accomplish medical (diagnostics, prevention, treatment) or non-medical (science and research, education, military affairs, IT, crime, etc.) tasks. In terms of potential regulation, a further distinction should be made between the 'working' human genome (pertaining to public domain material used in science and research, education, etc.), the genome of a group (a lineage [genus], an ethnic group, population living separately in a certain territory), and that of a specific individual (constituting personal benefit, personal data).

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We will limit our discussion in this paper to the genome of a particular individual, as well as, in some instances, examples related to the 'working' genome. These distinctions form the basis for the possible construction of models and the opportunity for resolving issues of legal regulation.

Research on the creation of new biological objects using the genome and (or) available information about the genome of microorganisms or viruses has been conducted since early 21st century. For instance, in 2002, poliovirus had already been synthesized, and in 2005, the possibility of recreating a strain of the influenza virus – namely, the 'Spanish flu (which triggered a pandemic just over a hundred years ago) – was demonstrated. In 2015, an article on the synthesis of CHC014 hybrid virus (similar to SARS-CoV-2 coronavirus) was published, while 2018 saw the synthesis under laboratory conditions of a horsepox virus very similar to the natural smallpox virus, the causative agent of a particularly dangerous human infection.

Advances in synthetic biology prompted a number of scientists to conduct a fairly wide range of experiments with the human genome. Recently, it was reported that a human gene responsible for obesity had been introduced into the ribonucleic acid (RNA) of some plants. The experiment demonstrated that this modification results in larger potato and rice specimens *(Robakidze, 2021)*. Reports were also made concerning the insertion of a human gene into the brain of a monkey *(Regalado, 2019)*. The scientists noted an increase in the number of neurons along with other noticeable, objective changes.

Currently, other work is underway to create chimeras with human genome insertions. There are attempts to create biomodels as close as possible to human beings by introducing certain genes into animal tissues and organs. On the one hand, such biomodels can make a significant contribution into the creation of new pharmaceuticals and products for other medical-purposes, while, on the other hand, they potentially allow the creation of highly specific pathogens that can be used as weapons of mass destruction or by bioterrorists.

In the future, hybridisation involving the emergence of chimeras containing some parts (from cells to tissues and organs) belonging to other species cannot be ruled out. Although experiments to create chimeras have been ongoing for some time, the presence of formidable technical barriers prevented significant practical and (or) scientific results. However, modern technologies open up new possibilities. Researchers are already working on creating human-pig chimeras (for growing organs for specific customers), and human-monkey chimeras (for transplantation, and creation of organisms with predetermined properties in terms of mass, behaviour, etc.) *(Koplin & Wilkinson, 2019; Koplin & Savulescu, 2019)*.

Along with the potential for medicine (increasing the availability of donor organs and tissues while reducing the risk of transplant rejection), emergence of new biological objects or even biological subjects (quasi-subjects) possessing unique, previously unknown properties and abilities becomes possible. Such objects, and – even more so – subjects, can have a significant impact on various groups of social relations, including established traditional, family and other values.

As we can see, the genome, including the human genome and parts thereof, and individual genes, as well as the genetic information about the human genome, can already be used in scientific research and practice to solve various problems that are not directly related to the purpose of the genetic program that was established by evolution for human reproduction.

Therefore, for objective reasons, experiments with the genome and genes are not harmless – neither of a neutral, nor of a unequivocally positive nature – at least in terms of ensuring biological safety and biological diversity *(Baker, 2016; Coller, 2019)*. It is also impossible to disregard the subjective factors – socio-cultural, religious and other attitudes on the part of the population, which, on the whole, is wary of any experiments with living matter. Such technologies definitely have the potential to change ways of meeting people's needs – if not such needs themselves – in a short time. Besides, the very possibility of achieving respect, recognition, and self-realisation in a 'natural' way – through the use of the entire arsenal of natural and acquired properties or qualities (intellectual, will-related, etc.) of a person – is questioned.

Those who have access to new technologies (e.g., through membership of a certain group, or practicing a certain profession, or having sufficient funds, etc.) become tempted to obtain a tangible result, to achieve a certain goal, earlier than others. An illustrative example is high-performance competitive sport, which – despite measures taken by international and national anti-doping, sports, public and other organisations – continues to be shaken by doping scandals.

Debates regarding genetically modified organisms (GMOs) and the permissible limits of their use by human beings as a food source are ongoing *(Walters, 2010)*. However, in the instance under consideration, a rapid artificial erasure of interspecies barriers and boundaries is taking place, which can result in emergence of new biological objects, living objects of nature, with properties that are not characteristic of a particular plant or animal, as well as products obtained therefrom through the use of new technologies. All this is happening against the backdrop of an overall increase in the biomass formed by human beings and a decrease in the 'natural' biomass (i.e., wild animals and plants, the reduction of the populations and species of which is proceeding at an unprecedented rate).

In this connection, recent publications have raised issues of balancing the interests of the key subjects of [stakeholders in] this sphere (scientists, business, citizens, the state), effective control over genetic and other modern technologies, classifying some of them as dual-use technologies *(Mokhov & Yavorskiy, 2019)*, and the need to find a scientifically valid (substantiated) and practically realisable way out of the vicious – pathological – circle of growing environmental and other problems of the current civilisation.

A look at the existing legal and ethics-related documents reveals that most of them are rather out-of-date due to their failure to fully take into account emerging technological challenges and threats. For example, the Convention on Biological Diversity *(Rio de Janeiro, 5 June 1992)*[1] recognises the intrinsic value of biological diversity as well as the genetic values of biological diversity and its components. Genetic resources are classified by the document as biological resources offering actual and potential value. Here, it is assumed that genetic research and experiments should be carried out under state control. Each party to the Convention develops national strategies, plans or programs for the conservation and sustainable use of biological diversity.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted by the Committee of Ministers of the Council of Europe on 19 November 1996)[2] is focused on protecting the dignity and identity of all human beings, guaranteeing respect of their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The Preamble to the document points out that the misuse of biology and medicine may lead to acts endangering human dignity. It also emphasizes that progress in biology and medicine should be used for the benefit of present and future generations. The articles of the Convention are mainly aimed at regulating the relations in the sphere of biomedicine, and certain

[1] Ratified by Federal Law No. 16-FZ of 7 February 1995 '*On Ratification of the Convention on Biological Diversity*'.
[2] The Russian Federation does not participate in this Convention.

medical interventions. Article 13 of the Convention is dedicated to the medical issues related to the interventions seeking to modify the human genome.

According to the Federal Law of the Russian Federation No. 86-FZ dated 5 July 1996 'On State Regulation in the Field of Genetic Engineering Activities'[3], the concept of genetic engineering includes technologies associated with extracting genes from an organism, performing manipulations with genes, as well as involving the introduction of genes into other organisms. The list of the extracted and (or) introduced genes, as well as the organisms, is not defined by the Law. Importantly, it codifies the principle of the safety of citizens (individuals) and the environment in course of genetic engineering. However, the mechanisms for implementing this principle – especially in terms of research and experimenting – are not fully commensurate with the level of the existing risks. Article 7 establishes the levels of the risk associated with the potentially harmful effects of genetic engineering, but only for human health.

Legislators made an attempt to settle the issues of ensuring biological safety, which was reflected in Federal Law No. 492-FZ dated 30 December 2020 'On Biological Safety in the Russian Federation'[4]. This document cites genetic manipulations which may potentially result in the emergence of pathogenic biological agents, strains of microorganisms, or viruses. The concept of a source of biological hazard includes the objects created or emerging as a result of implementation of certain types of activity or uncontrolled use of genetic materials and synthetic biology technologies. Among the measures aimed at protecting the population and the environment from the effects of hazardous biological factors, Article 9 mentions the prevention and preclusion of technological hazards, including the potential uncontrolled use of genetic materials and synthetic biology technologies. However, this measure has not received further development in the Law.

Although it would be also possible to cite a few more regulations governing genetic technologies, we would see that they neither contain any direct restrictions or prohibitions related to the activities with the human genome, nor establish a necessary and sufficient set of mechanisms ensuring proper observance thereof.

Currently, the circulation of genetic information in Russia takes place based according to the existing legislation concerning information, information technologies, and protection of secrets (medical, trade, etc.). The insufficiency of the regulatory framework governing the relations associated with the circulation of genetic information is noted as being due to its peculiar nature (Rassolov et al., 2020).

General aspects associated with the principle of inviolability of the human genome

In connection with the above, the issue of formulating the principle of inviolability or integrity of the human genome, as well as information (data) about the genome of a particular individual, can be brought up for discussion for the sake of both doctrine and legislation. Russian researchers are becoming increasingly aware of the need to formulate the legal principles in connection with the development of genetic and information technologies (Maleina, 2019).

[3] Corpus of Legislation of the Russian Federation (1996). 28, art. 3348.
[4] Corpus of Legislation of the Russian Federation (2021). 1 (I), art. 11.

Along with privacy, the principle of personal integrity is well known to the Russian legal doctrine *(Rudinskiy, 2006)*, the legislation (e.g., Article 10 of the Criminal Procedure Code of the Russian Federation; paragraph 7, Article 3 of Federal Law No. 149-FZ dated 27 July 2006 'On Information, Information Technologies and Information Protection'), and judicial practice (e.g., Resolution of the Constitutional Court of the Russian Federation No. 20-P dated 24 May 2018 'On checking the constitutionality of Article 435 of the Criminal Procedure Code of the Russian Federation in connection with the claims submitted by citizens D. and K.'; Resolution of the Constitutional Court of the Russian Federation No. 8-P dated 28 June 2007 'On checking the constitutionality of Article 14.1 of the Federal Law 'On Burial and Funeral Business' and the Regulation with regard to burial of persons whose death occurred as a result of suppression of a terrorist act committed by them in connection with the claim submitted by citizens K.I. Guziev and E.Kh. Karmovaya'). In recent years, the principle of integrity has been becoming a focus of attention in biomedicine *(Savoshchikova & Voronina, 2019)*, especially in the context of the risks associated with the implementation of genetic, information and other technologies in medicine *(Rassolov & Chubukova, 2019)*, healthcare and related spheres of activity.

The logic behind the relationship 'human genome – person – personal integrity' is as follows. The human genome comprises a biological code (strictly defined, fixed, sustainable, reproducible, and inherited information) imparting a person (a future person as well) with heredity and variability comprising fundamental properties of a living being. The code of a specific genetic subject (individual) is unique. Heredity has a significant impact on the formation of an organism, a person as a whole, especially at the early stages of development. Some parameters or features of an organism (for example, its height) are determined by genes to a large extent, while some others – to a moderate or insignificant extent. The human psyche, character and intelligence depend on many factors (both predetermined and acquired in course of development, upbringing/education, training). Many human diseases and the severity thereof are also determined by various aspects (heredity (primarily for monogenic ones), lifestyle (diet, habits, etc.), environment). Despite the very high similarity between the genomes of human beings and the fact that the planet is already inhabited by several billion people, each individual has characteristics that render him or her individual, unique and inimitable. Due to the large volume of the human genome, the number of individual differences can be quite significant – up to several million out of about six billion symbols of the overall genome *(Wong et al., 2007)*.

Variability is an independent property of a daughter (offspring) organism allowing it to differ from the parental forms and change its properties under the influence of environmental factors. Such changes can be both non-inherited and inherited. Inherited changes may turn out to be useful, in which case their 'owner' or 'carrier' may gain certain advantages. However, 'breakdowns' of varying degrees occur more often (manifesting themselves in changes that are compatible or incompatible with life).

Due to the existing direct and indirect connections, even apparently insignificant interventions into the human genome may affect the ontogenesis of the organism or its personality development, as well as

the emergence and course of various human diseases. It should also be noted that the purpose of many genes (especially of the so-called 'junk' DNA) has yet to be fully clarified. The mechanisms of variability have also been insufficiently studied *(Palazzo & Gregory, 2014; Wells, 2011)*.

Concerning established relationships, the following examples may be cited. Since the beginning of the 21st century, biologists around the world have been increasingly using 'knockout' laboratory animals (Gaidai & Gaidai, 2019). Such animals are obtained through destroying, switching off, 'knocking out' an individual gene, thus obtaining a biological model (including biological models of some diseases) for subsequent studies and experiments.

To date, a large number of monogenic diseases caused by gene mutation and leading to severe diseases (galactosemia, phenylketonuria, leucinosis, porphyria, tyrosinemia, haemolytic anaemia, etc.) have been described. The active search for drugs for treating such diseases, along with multifactorial human diseases, is underway.

The first scientist to openly interfere with the genome of a future human being at an early stage of development and to make an explicit statement about it (in 2018 at an international research platform) was He Jiankui from China. When combined with *in vitro* fertilisation (IVF) procedures, such editing of the human genome at the embryonic stage, effectively cutting out the CCR5 gene with 'genetic scissors', is justified by the discovery that two girls with a mutation in this gene were born with HIV immunity. Although this genetic mutation is known, it rarely occurs in the human population *(Kofiadi, 2008)*.

Based on the presented analysis of specialised publications, as well as relevant legislation and judicial practice, it appears to be possible to present for discussion the following tentative definition of the principle of inviolability of the human genome. The principle of inviolability of the human genome is a legal idea designed to ensure the protection of the interests of a particular individual, as well as other individuals, from any potential interference with or modifications to the human genome. A human being has the right to the inviolability of their genome. This right is an integral element of their right to liberty, since it determines (as we have discussed) their individuality.

The above definition can be fully applied to the information about the genome of a particular person comprising an individual code characterising heredity (potential/inclinations) and variability (within certain limits) of an individual. Thus, it appears to be necessary to introduce a legislative ban on free performance of any actions/manipulations with the human genome, as well as to implement effective mechanisms protecting the rights of an individual in the event if someone, without sufficient legal grounds, attempts to interfere with the human genome.

While the protection of genetic information is a more challenging task, it is resolvable by establishing a legal framework for ensuring inviolability of genetic information about a specific person, the limits of possible interference/intervention, the range of subjects (participants) and the procedures/mechanisms for genetic information protection, as well as the limits of permissible genetic information circulation.

However important for people, medicine, pharmaceutics and healthcare, such an understanding of the principle of inviolability would be an incomplete and excessively narrow understanding of the principle of in-

violability of the human genome. As well as individual genes, we have also discussed the possibility of using the human genome or some fragments thereof to accomplish the tasks completely unrelated to genetic manipulations with a specific person, i.e., by introducing genomes or genes into animals or plants to creating biorobots, 'human-like' artificial intelligence systems, or chimeras.

Since science is making its tentative first steps in this area, the amount of knowledge about the human genome is rather small. Nevertheless, it is growing rapidly. Thus, while the real prospects for 'non-medical' application of technologies based on or using the human genome are not yet clear, the risks are already visible. For example, since prions and prion diseases have not yet been fully studied *(Zuev, 2013)*, people working in research laboratories or medical organisations are running the risk of contracting rare and incurable diseases *(Ena, 2005)*. At the same time, some publications draw attention to the existing links between a certain sequence of genes, RNA, prions and development of certain diseases *(Mustafin & Khusnutdinova, 2018)*. Recognising the dangers of prion diseases, in 1999, the World Health Organization (WHO) issued infection control guidelines for transmissible spongiform encephalopathies with the aim of reducing risks and ensuring control *(WHO, 2000)*.

The existence of barriers between species (e.g., between animals and humans) are also well known, along with various possibilities of overcoming them. Whether conscious or unintentional, the overcoming (crossing) of such barriers as a result of current research, economic or other activities risks the emergence of increasingly numbers of human diseases.

In line with the precautionary principle *(Vasenkin & Vasilyeva, 2020; Kalinina, 2019; Chuyko, 2011)*, the widespread use of the human genome or genes in manipulations with plants, animals, or 'artificial' biological objects should be either completely prohibited or limited to specific kinds of research carried out based on the dedicated temporary regulations (provisions of law) under strict governmental and public control. The procedure for such activities, if they are allowed at all, should be permission-based. For instance, Article 6 of the Guidelines for Ethical Principles in Human Embryonic Stem Cell Research (2003) prohibits the combination of human germ cells with cells of other species of living beings.

Particular risks are posed by biological chimeras – artificial intelligence systems combined or integrated with biological objects. Thus there might be a need for a complete or partial legislative moratorium on the development of certain vectors of manipulation with the human genome involving the admissibility of some kinds of research, work with 'new' objects at certain stages of their lifecycle (as a rule, initial stages) and in closed systems (both natural, and modified, as well as those created based on the publicly available information about the human genome).

Returning to the principle of inviolability of the human genome in its narrow sense, it is necessary to determine the possible boundaries of application of this principle, since it is within the boundaries established by law and ensured by the government that inviolability – as a property – acquires actual sense.

The development of genetic technologies for solving medical problems is currently following two main directions: editing of the natural human genome and chemical synthesis of the human genome.

Chemical synthesis of the human genome consists in the reproduction of DNA or individual nucleotides. In general, it refers to the writing and subsequent reproduction of a genetic program under specially created conditions. This direction is developing within the framework of synthetic biology, which is still making its first steps dealing with such objects as microorganisms and viruses. In this instance, the tasks to be resolved are the same as in the case of the natural genome.

Natural genome editing already allows deleting, moving, inserting or replacing DNA fragments in the human genome. It is possible to distinguish between the following three main forms: *in vitro* somatic cell genome editing, where somatic cells previously extracted from the organism are subsequently returned into the organism; *in vivo* somatic cell genome editing directly inside the organism (in situ); embryo genome editing.

The principle of inviolability of the human genome and somatic cell editing

Somatic cell editing (regardless of the specific technology) is under actively development both globally and in Russia, albeit already involving some potential differences in legal regulation. When it comes to diseases, there are hardly any sufficient arguments against such technologies and the products created through the use thereof. The practice and the legislators steer the healthcare industry and society towards reducing morbidity and mortality, as well as increasing longevity (life expectancy) and quality of life.

Federal Law No. 323-FZ of 21 November 2011 'On the Fundamentals of Public Health Protection in the Russian Federation'[5] codifies the principles of priority of the patient's interests in course of healthcare provision, healthcare accessibility, and inadmissibility of refusal to provide healthcare.

The Decree of the President of the Russian Federation No. 680 of 28 November 2018 'On Genetic Technologies Development in the Russian Federation'[6] encourages the government to accelerate the development of genetic technologies, including technologies for genetic editing, and development of biological medications, diagnostic systems and immunobiological products for healthcare.

The Decree of the President of the Russian Federation No. 474 of 21 July 2020 'On the National Development Goals of the Russian Federation for the Period up to 2030'[7] establishes preservation of the population, public health and well-being of people as national goals.

Among the key 'cons' of the active introduction of genetic technologies into medical practice, the following arguments can be made: high risks for the health and life of patients associated with the new technologies, as well as the lack of sufficient evidence demonstrating the safety thereof; the impossibility to fully control all the occurring processes at the current level of science, research and technology; the possibility of 'non-medical' application of genetic technologies meant for solving clinical problems by healthcare professionals; violations of the rights of citizens due to the gaps in the existing national legislation *(Mokhov, 2021)*.

Most of the above-presented arguments are not new. The development of innovative medical technologies is always highly risk-

[5] Corpus of Legislation of the Russian Federation (2011). 48, art. 6724.
[6] Corpus of Legislation of the Russian Federation (2018). 49 (VI), art. 7586.
[7] Corpus of Legislation of the Russian Federation (2020). 30, art. 4884.

prone: such technologies cannot in principle be fully controlled, especially at the initial stages (phases). Further on, as experience is gained and accumulated, and the technology and the side effects are monitored, a number of parameters and indicators become capable of clarification and more precise specification. This is common practice for pharmaceuticals, and medical products, as well as some other products and technologies. Another issue involves the effective protection of the citizens' rights. Here, a sufficient resource of means and mechanisms, comprising various expert assessments, as well research (in terms of efficiency, safety, ethics, etc.) to support risk insurance and liability insurance, has been accumulated. However, in order to make such development anticipatory of future development, it is necessary to advance the development of the regulatory framework in the field of biomedical and genetic research and experiments. Bioethical norms have an important role to play here due to their high application potential when used correctly. Issues in determining the benefits and risks of technologies, ensuring compliance with the principles of 'do good' and 'do no harm' should be given the utmost attention at the national level, requiring the development of an ethics-related and legal base governing the lifecycle of new technologies at critical stages.

Since transparency is one of the conditions for public discussion and formation of the correct vector of their application in a particular society, a separate issue arises concerning the provision of proper information support for the lifecycle of genome editing technologies.

The issue of non-medical application of human genome editing technologies is really quite urgent. Biohacking is already well-known. It is difficult to overestimate the role of law, along with research and professional ethics, in mitigating the risks of non-medical application of genetic technologies. There are many precedents for the development and adoption of special legislation restricting the circulation and non-medical use of narcotic drugs, comprising psychotropic and intoxicating substances, as well as legislative penalties for violations in this area (up to criminal liability). Suffice it to recall such acts as Federal Law No. 3-FZ of 8 January 1998 'On Narcotic Drugs and Psychotropic Substances'[8] or Federal Law No. 472-FZ of 29 December 2020 'On Restriction of Nitrous Oxide Turnover in the Russian Federation'[9].

Simultaneously with the legal measures and the work of government authorities in this sphere, the science and research professional community should be actively involved in the control over and application of the technologies. This requires further development of self-regulation and self-governance in the sphere of science/research and certain other types of professional activities (biology, medicine, information sector, etc.), as well as institutionalisation of ethics and bioethics.

The World Health Organization (WHO) also demonstrated its awareness of the problems that arise and are discussed in connection with the development of genetic technologies. Human genome editing led to the creation of a dedicated Advisory Committee under the auspices of WHO. In the summer of 2021, its first recommendations were

[8] Corpus of Legislation of the Russian Federation (1998). 2, art. 219.
[9] Corpus of Legislation of the Russian Federation (2021b). 1(I), art. 31.

published *(WHO, 2021)*. The document developed by the experts highlights the need to maximise the potential benefits of and minimise the potential harm from the human genome editing technologies. In other words, in a way different from what is customary for lawyers, it speaks about the need to ensure a certain balance of interests, about a possibility of developing technologies in general subject to mitigation of the risks already known to researchers and practitioners as well as of any potential other risks.

Attention is also paid to the choice of priorities, i.e., the effort application vector, which may differ in different countries (depending on the most significant tasks on their agenda). Reportedly, one of such priorities for some regions and their healthcare systems is sickle cell anaemia.

The absence of serious problems hampering the application of the technology under consideration for medical and healthcare needs is also highlighted by the launch and support of a pilot project dedicated to somatic genome editing research.

At this stage, experts are concerned about the so-called 'ethics dumping' consisting in weak ethical control over such research in some countries which can lead to 'science tourism' (migration of certain types of research and experiments to the countries which do not pay due attention to compliance with ethical standards and procedures).

Russia belongs to the category of countries where ethics reviews (expert assessments), ethical control over science-and-research activities, clinical research, trials, and experiments are still under development. However, a legal framework exists for regulating the activities of ethics committees (councils) in the sphere of clinical trials of pharmaceuticals (drugs), biomedical cell products, and medical devices. Ethical standards in the sphere of research are generally underdeveloped. Thus, Russia needs to urgently build and fine-tune the ethical foundations for modern technologies (primarily, those involved in biological and information spheres).

The principle of inviolability of the human genome and germline editing

Germline genome editing has a lot in common with somatic editing. In essence, it acts as a method or means for preventing hereditary diseases. In this connection, most of the 'pros' and 'cons' will tend to coincide (Baylis, 2017; Mokhov, Levuskhin, & Yavorsky, 2020; Ormond et al., 2017). However, there are also fundamental differences. First, such editing entails or may entail hereditary changes. Second, it gives rise to the problems concerning the parties to (participants of) the arising legal relations, as well as the problems with the corresponding actual and potential legal consequences.

Article 13 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Adopted by the Committee of Ministers of the Council of Europe on 19 November 1996)[10] mentions the admissibility of interventions in the human genome for preventive, diagnostic and therapeutic purposes, but at the same time points out that such interventions should not be aimed at introducing any modifications in the genome of any descendants. The number of countries that have ratified this document to date remains disappointingly low.

[10] The Russian Federation does not currently participate in this Convention.

The discussion about the individual articles thereof, which has continued for the last quarter of a century, hinges on the consideration whether, if a defective gene leads to hereditary disease development, it would not be better to make the necessary modifications or corrections in order to make it normal. The accumulation of defects or breakdowns and increase in the number of 'broken' genes leads to diseases for a particular person, as well as being capable of interrupting the lineage (procreation). Consequently, certain obstacles for the performance of such a person's biological functions arise. While this occurred earlier due to impossibility of correction, when such corrections become possible due to the emerging legal or ethics-related prohibitions, how ethical can it be to prohibit such activities at the legislative level? This remains an extremely difficult point to answer. However, the proposed introduction of a moratorium (temporary ban) is justified by the lack of current knowledge about the human genome, individual genes, and the possible interactions between them, as well as by in terms of the imperfection of technologies and a lack of a proper ethical and legal basis for such manipulations at the level of individual countries, as well as at the supranational level.

There is also another aspect of human genome editing at the early stages of development associated with modifying it in the way which is supposed to create benefits for a human being (individual). Such modifications can be both within the limits of a known norm with its variations, and beyond its limits. How ethical and acceptable are the interventions in the human genome aimed at creating prerequisites for improvement of a human being? Such interventions can be directly beyond the scope of medical (therapeutic) indications/grounds, or only relatively ('at a stretch') fall within such scope. These issues are the subject of active scientific debates of philosophers and bioethicists *(Belyaletdinov, 2018; Popova, 2015; Yudin, 2016)*. Due to the contradiction with the fundamental legal principles (equality, justice, etc.), at the current stage of civilisation development, at the existing level of science/research and technologies, as well as within the existing segregation, lawyers are more likely to give a negative answer, rather than a positive one.

When it comes to somatic editing, the parties to the arising legal relationship are clear: as a rule, they are between a doctor and a patient or the patient's legal representative (for individuals under a certain age or recognised incapacitated). Their respective rights and obligations, as well as the procedures for obtaining voluntary informed consent to intervention, are enshrined in legislation. However, when the genome of an embryo or an individual cell is edited, the parties to legal relationship are not currently defined in the Russian legislation. In some countries, the embryo is recognised as a subject of some rights (or a party to some legal relationship) from a certain period of development. In any case, the following questions to be resolved arise: In whose interests is the customer acting? From whom and how is it possible/necessary to obtain consent for participation in research / in an experiment? How can the interests of the unborn child be protected at this stage? Who and under what acts/regulations exercises control over and assessment of the possible intervention into the embryo's genome? Should the information on the performed intervention be stored and for how long? Who should have access to the information about the performed edit-

ing and on what basis? There are no clear answers to most of these questions yet. A broad discussion involving researchers, policymakers, and legislators is needed in order to get the answers that would satisfy the society.

Although the aforementioned recommendations by WHO experts *(World Health Organization, 2021)* are very cautious about the editing of the human genome that can be inherited, they do not completely rule out the future possibility of related research being carried out subject to ensuring transparency and adequate supervision/control. Therefore, further research in this area is required with wide coverage in research-related and general publications, as well as in mass media.

Conclusion

In connection with development of genetic technologies, and the attempts to widely use the genome, its fragments, or individual human genes, achieving the goals and objectives facing society and the State in terms of safeguarding the population and the population's health, ensuring biological diversity, as well as biological and other kinds of safety, raises the issue of inviolability of the human genome, the determination of the boundaries of this principle, and appropriate mechanisms for ensuring strict observance thereof.

In a narrow sense, it is proposed that the principle of inviolability of the human genome be understood as a legal idea aimed at ensuring the protection of the interests of a particular individual, as well as other individuals, from any potential intrusion into (interference with) the human (individual's) genome, as well as prohibiting certain modifications to it. The same applies to the genetic information about the human (individual's) genome, taking into account the peculiarities of information as an object of rights and legal protection.

In a broad sense, the principle of inviolability of the human genome implies general prohibition on the use of the human genome, as well as its fragments, genes, and genetic information. However, exceptions to this principle are possible and cannot be completely ruled out. Nevertheless, they must be directly established by federal law.

The principle of inviolability of the human genome is relative, rather than absolute. Its boundaries can be flexible and influenced by: tasks solved by the government; the significance of such tasks for the individual, society, or the country; the need for genetic technologies, or for genome manipulation for the sake of citizens, medicine, and society; the level of development of the technologies through which the human genome is used; the degree of accuracy, selectivity, and safety thereof; sociocultural, religious and other peculiarities; established legal and ethical traditions; the development and efficiency of the mechanisms of control over the technologies using the human genome or the information about it.

Technologies for editing the human genome should be paid close attention, requiring ethical and legal support for their life cycle at critical stages (research, experiments, innovations, new technologies application monitoring).

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https://doi.org/10.17803/lexgen-2022-1-1-20-33

Original article

Genetic Knowledge: a Gift or a Curse?

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Abstract

The origins of genetic research in the molecular era are discussed along with the prospects for development of the system of the values underlying their legal regulation. Heredity and variability are included into a historically defined worldview as socially significant values respectively occupying alternate leading positions in archaic and modern societies. The article substantiates a connection between ideas about heredity and variability and the social structure, institutions and social practices of the two main types of the pre-molecular era societies. The article also discusses the significance of pre-scientific ideas concerning blood as a special substance ensuring biological, social and legal inheritance in the system of social action of the archaic society. Analysis is given to the conceptual foundations of the strategy of overcoming the 'right of blood' in modern societies, where the value of heredity is replaced by the value of variability to serve as a value-system basis for development and progress. Examples of coexisting worldviews and values inherent in both archaic and modern forms that still interact in present-day societies are presented and generalized. The example of the parascientific blood-type theory prevalent in today's Japan is used to illustrate the ability of collective consciousness to integrate scientific ideas into deep underlying layers of pre-scientific thinking. The postmodern mixture of worldviews and values gives rise to ambiguity and uncertainty with regard to values in the era of discovery of the genetic mechanism of inheritance, creating additional difficulties for rule-makers (legislators) in course of forming a system for the legal regulation of genetic research. Finding a balance between prohibitions and permissions in the corpus of laws and by-laws regulating genetic knowledge development is all the more important given that the demarcation between representing and intervening in the research carried out by molecular biologists is losing its certainty (definiteness) even faster than in the physics of the microworld, let alone other subject areas of the modern science. Bioethics, which is currently providing a philosophical basis for the legal regulation of genetic research, requires theoretical elaboration and conceptualization. As one of the substantiation options, the article proposes the concept of supplementing instrumen-

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tal rationality with social communication put forward by Jürgen Habermas within the framework of his theory of communicative action.

Keywords: human genome, values, legal regulation, heredity, variability, interference

To cite this article: Przhilenskiy, V.I. (2022). The genetic knowledge: a gift or a curse? *Lex Genetica*, 2022;1(1):20–33. https://doi.org/10.17803/lexgen-2022-1-1-20-33

Received 15.11.2022
Review completed 16.12.2022
Passed for printing 03.01.2023

Introduction

It is not without a reason that the current epoch is called the molecular era. New knowledge about the mechanisms of human inheritance not only calls into question the boundaries of what is permissible in genetic research and manipulation, but also requires a critical reassessment of the systems of morality and law prevailing in society.

The proclamation of the molecular era implies that the previous historical period in the life of humankind should be called the pre-molecular era. Meanwhile, the pre-molecular era should be divided into two periods: archaic and modern. The archaic period features the formation of the worldviews and value systems characterized by the absolutization of heredity. However, the modernity that replaced it counterbalanced the importance of heredity according to the influence of variability, thereby lifting the 'genetic curse' from some people, and moderating the claims of some other people to 'genetic superiority'. The worldviews and value systems produced by modernity – which are spreading in successfully modernizing societies – do not annihilate the archaic worldview, but have to coexist and compete with their predecessors. The situation of postmodernity occurs when the archaic and the modern overcome the open enmity and move on to peaceful coexistence, mutual influence and even interpenetration. The discovery of genes and genetic mechanisms of heredity, as well as the scientific description of the causes of genetic variation, became a challenge both for the values of the archaic and for the ideals of the modernity *(McCuire et al., 2020)*. Each of the systems offered its own set of responses, each generating its own prohibitions and prescriptions, which are embodied in religion, bioethics and law in different ways. However, even greater importance is acquired by all sorts of combinations of the archaic and the modernity. Some of them represent the result of socio-political compromises, and others constitute the result of the postmodernist worldview prevalent in contemporary minds.

Blood and inheritance in the archaic era

The first historical period, called the archaic (from the Ancient Greek *ἀρχαῖος* meaning ancient), represents a time when the social life and human minds were totally dominated by tradition. Here, the very concept of tradition is organically linked to the concept of inheritance – both biological and social.

Knowing nothing about the molecular mechanisms of inheritance, people were per-

fectly aware of the fact of its existence and presence in everyday life. It might even be said that the experience of relations with blood relatives is the starting point of social formation. The experience of communicating with parents, then with other relatives, and then with children, gradually expanded and projected onto the rest of the world. The implications of such phrases as 'Mother Earth', 'Holy Father' or '…blood runs through my veins' – which filled the mythopoetic pictures of the world and magical practices with meaning – have come down to us from ancient times. Phrases like 'gypsy blood runs through my veins', 'blue blood flowed through his veins', or 'he suddenly heard the call of the blood', although belonging to the sphere of everyday consciousness and reaching us through literary images, were nevertheless clear and meaningful long before the emergence of genetics.

Biological inheritance precedes social inheritance. This is the manifestation of the ancient intuition perceiving everything social as a continuation of the natural, i.e., the biological. The initial form of social relations – tribal relations – places kinship in the very center, organizing morality and law, power and property, worldview and values, around it. It is not a mere coincidence that kinship is defined as blood relationship (or consanguinity): the ancient idea that a child receives its blood from the parents (from the father – through his semen, and from the mother – directly) had the same meaning as the scientific theories explaining the mechanisms of genetic inheritance today. The concern for procreation firmly occupied the central place in the system of values of the tribal society. The feeling underlying that concern has not faded away even today, although the era of social rationalization and individualization has put it to the test.

Meanwhile, the theory of inheritance from father to son of such personal qualities as courage, intelligence, honor and dignity imparted legitimacy to the institutions of inheritance of a social status, and – along with it – power (authority), property, rights, duties, claims and obligations. The glorious deeds of fathers allowed their sons to occupy a higher position in society than those whose parents had not gained glory for themselves. The descendants of those who brought disgrace and dishonor upon themselves and their families became outcasts, and were subjected to various forms of stigmatization. Thus, the idea of punishing children for the wrongdoings of their parents, or the idea of the need to recompense for other people's sins occupied a significant place in the archaic consciousness. Genetic mechanisms had yet to be discovered, but the concepts of consanguinity and the resulting rights and obligations had been forming a system of values since time immemorial.

The very fact of human birth and accompanying circumstances was perceived as fateful, encouraging a person to think in terms of the will of supernatural forces. Their entire future was predetermined by who their parents were (free people or slaves, rich or poor, noble or 'rootless'), and by who they were to their parents (firstborns or favorites, legitimate heirs or illegitimate offspring), as well as – of course – by the epoch and the society they were to live in. Ancient Greek philosophers, undoubtedly, challenged the public consciousness by daring to lead a lifestyle that assumed only one type of dependence – dependence on reason. Rejecting everything they acquired 'by inheritance', those lovers of wisdom performed actions measuring them only by the standard of the good that they determined for themselves.

One of the greatest works of world literature – the drama Oedipus Rex by Sophocles – fully reflects the whole importance of blood relations in an archaic society *(Sophocles, 1990)*. It is clearly kinship that underlies the conceptual structure within the framework of which the concepts of law and fate, chance and necessity, freedom and responsibility are correlated in the archaic consciousness. The knowledge of consanguinity comes to the protagonist (and the entire Theban society) along with knowledge of the most terrible crime – patricide. King Oedipus kills his father without knowing it, because he – just like the biblical Moses, as well as many other protagonists of legends and myths – had been removed from the family and handed over to chance (fate, gods). The centrality of the fact of birth and kinship in the value system and in the worldview of the archaic society is very accurately expressed in Sophocles' *Oedipus Rex (Sophocles, 1977)*:

"I, Oedipus, Oedipus, damned in his birth, in his marriage damned,

Damned in the blood he shed with his own hand," and

"Let every man in mankind's frailty
Consider his last day; and let none
Presume on his good fortune until he find
Life, at his death, a memory without pain".

Lévi-Strauss in his *Structural Anthropology* highlights that "the biological family is ubiquitous in human society. But what confers upon kinship its socio-cultural character is not what it retains from nature, but, rather, the essential way in which it diverges from nature. A kinship system does not consist in the objective ties of descent or consanguinity between individuals. It exists only in human consciousness; it is an arbitrary system of representations, not the spontaneous development of a real situation" (Lévi-Strauss, 1963, p. 50).

In an archaic society, a right is inseparable from law [legislation], and law can be either a codified custom, or the will of the legislator formulated and written down on paper. Thus, justice becomes a derivative of consanguinity. In this instance, a right [law] is determined based on the theory of justice, it does not yet become the object of a separate philosophical reflection. Two types of justice – egalitarian and distributive – fit fairly well into the logic and sociology of the archaic class-based society. At a time when the archaic period was still continuing, but with modernity already upon its heels, society remained class-based, but the concept of social justice was already emerging. This was a sign of weakening of the meaning of birth – heredity was giving way to variability.

Falling away from the 'wheel of births' in modernity

The situation changed with the onset of the modern era. Modernity brought about a new understanding of the phenomenon of inheritance and developed new ideas about the role and value of heredity. Even a moderate variant treating two factors of natural selection – heredity and variability – 'on equal terms' allows assuming that an individual is not dominated by either the unique biological features of their parents, or by their social, cultural or ethno-confessional background *(Lysenko, 2001)*. According to the narrative of modernity, the things that a person achieves in life and the place they occupy in society depend on themselves, whatever the circumstances of their birth. Some people are talented by nature, while some other people are born with average abilities (although in both cases it depends on a combination

of circumstances, rather than on their parents). Nevertheless, the natural talent needs to be developed, while patience and perseverance can compensate for the lack of talent *(Simonton, 2008; Shenk, 2011)*.

It is commonly understood that the ethics of modernity is formed on a foundation already prepared by ancient philosophers and devotees of the Christian religion. The ideas and concepts of these predecessors underwent a long evolution in order to lead the late Middle Ages into the birth of a humanistic system of values, which were then were proclaimed as the ideals of the Enlightenment. Both the reflections of ancient philosophers and the insights of medieval devotees contributed to the destruction of the archaic idea that one is born a human being [a person]. It was replaced by an alternative assumption: one is not born a human being [a person], one becomes a human being [a person]. Although Fyodor Kozyrev pointed out the lack of connection between such ideals of the Enlightenment as liberty and equality with the values of the Christian doctrine (Kozyrev, 2015), this connection undoubtedly exists. Nowadays, the Christian understanding of equality might be different from the political and legal interpretation of this concept prevailing in the era of modernity. However, before proclaiming the equality of all before the law in the 18th century, it was necessary to hear about the equality in Christ centuries before that. Suffice to recall the famous phrase from the Gospel, where 'there is neither Greek nor Jew, circumcision nor uncircumcision, Barbarian, Scythian, bond nor free: but Christ is all, and in all' (Bible, 1970). With this phrase, put into the mouth of Saint Paul the Apostle, Christianity abolished the previously immutable laws of the lineage, and rejected the worldview that explained the substantive mechanisms of inheritance inherent in archaism.

No less revolutionary were the speeches of the ancient philosophers who placed reason above any determinants – first and foremost, above the main one that could be called the determinant of birth. The Latin saying *Sapere aude*! ('Have the courage to use your own intelligence!') was considered by Immanuel Kant to be the motto of the Enlightenment. However, it can reasonably be called the motto of the philosophy of Socrates, and all the subsequent schools that emerged under his influence. When applied at the level of common reason, the Socratic method reveals the possibility of a free-thinking person to determining their own futures by making the right decisions. The same conclusion was reached by many others, including the Roman emperor Marcus Aurelius and the slave Epictetus, both recognised as teachers despite their very birth circumstances.

The philosophical doctrine affirming the omnipotence of reason that is capable of giving its owners liberty and equality, as well as the religious doctrine of the equality of all Christians before God, did not have a significant impact on the foundations and customs of the traditional societies which continued to exist in the environment of archaic thinking. It would take centuries for these two concepts to come together in a new worldview and a new system of social relations followed by the emergence of new values. Collectivism would give way to individualism, criticism and historicism, while customs were increasingly subordinated to supposedly moral reasoning according to a belief system that proclaimed individual human personality as its highest value.

No less interesting changes were brought about by modernity to the notion of the na-

ture and the essence of law [right]. Rather than being conditioned by someone's will, Law [right] is now expressed in an original and primary act of legislation. The understanding of its nature and essence, typical for Roman law, emerged, existed and developed in line with the archaic concept of ownership and inheritance. The right of inheritance in an archaic society was conditioned by the mechanism of transferring the rights to possession along with the blood, while the very fact of birth was interpreted within the context of realization of someone's will, be it the will of the father, the will of other relatives who make the decision about the choice of the bride for marriage, or even the will of the gods. However, within the worldview, all these connections, decisions and laws of inheritance were not interpreted in the context of the idea of law [right], which was the product of the ancient Roman and medieval European judicial practices. Therefore, it was in no way connected with the laws of nature or fate, but was interpreted exclusively as the result of someone's arbitrary [volitional] decisions and agreements. "Law is not simply the sum total of that which has been decreed and enacted; it is that which originally arranges things. It is 'ordering order' (ordo ordinans), not 'ordered order' (ordo ordinatus). The perfect concept of law presupposes without doubt a commandment affecting individual wills. But this commandment does not create the idea of law and justice, it is subject to this idea; it puts the idea into executio n, though the execution must not be confused with the justification of the idea of law as such" *(Cassirer, 1951, p. 240)*.

The meeting of the idea of law [right] with the worldview where an important role is played by the laws governing this world (God, fate, natural continuity) took place only within the framework of the Enlightenment.

'The perfect concept of law presupposes without doubt a commandment affecting individual wills. But this commandment does not create the idea of law and justice, it is subject to this idea; it puts the idea into execution, though the execution must not be confused with the justification of the idea of law as such... In enacting his various positive laws the legislator follows an absolutely universally valid norm which is exemplary and binding for his own as well as for every other will' *(Cassirer, 1951, p. 240)*.

All of that is most directly related to modernity, where the modernist understanding of the world requires to harmonize all regulatory and legislative acts with the fundamental concept of human rights. The entire theory of modern law can hence be asserted as the concentrated expression of the concept of natural law, universal and inalienable human rights.

The intertwinement of the archaic and the modern in postmodernism

The continuing popularity of ancient fortune-telling and prophetic practices in the modern era remains a mystery to researchers into mass consciousness. One might think that acquaintance with scientific explanations of natural phenomena, even those acquired within the framework of a general school education, should result in 'breaking the magic spell' of the world and squeezing out the ancient magical knowledge into the purely fictional spheres of fairy tales for children or the fantasy genre. Nevertheless, many superstitions demonstrate not only the miracle of their survivability, but even the capabilities to mount a counterattack. Sociologists, psychologists, and science theorists provide a whole variety of explanations

for the popularity of what is commonly called parascience, anti-science, or pseudoscience.

All the aforementioned types of knowledge, as well as the practices based on them, usually attach great importance to their antiquity and authenticity. The simple idea that the performance of a magic spell will be more effective the more accurately the corresponding ritual is observed, and the less such a rite/ritual contains anything alien to itself or connected with modernity, seems simple and convincing. However, life turns out to be more complicated: contemporary magical consciousness demonstrates an enthusiasm to use scientific discoveries for purposes far from those originally intended. The most obvious example is the use of computers and other IT technologies in astrological calculations.

One of the most impressive instances of the symbiosis between the prescientific archaic practices and modern scientific knowledge in the life of the present-day societies is the popular Japanese belief about the role of blood types in the formation of key human qualities, and the link between the blood type and such important features of individuals as their character, temperament, intelligence *(Ando et al., 2002)*.

The theories and teachings about the influence of numbers (numerology) or hand lines (palmistry) on human fate emerged in ancient times, when any person was able to look at lines and features on the palm or count objects. However, blood types were discovered a little over a century ago – i.e., at the dawn of the molecular era. They were identified and described using the means and methods of science – therefore, they appeared to be an integral part of scientific knowledge. Not only back then, but today as well, special medical devices developed by engineers and technologists are required to determine the blood type in each specific case. However, following its acquisition, the knowledge itself turned out to be suitable for application far beyond the boundaries of science, as part of practices whose origins are outright magical *(Nakamine, 2017)*.

The whole world knows about the scientific and technological achievements of Japan, due to which it has been perceived as a technologically advanced country for over a century. Several successful modernizations have contributed to Japan's ongoing firm position among the world leaders in high-tech industries. At the same time, the blood type theory developed by analogy with the ancient magical and astrological teachings – although using the data from science – has a significant impact on all spheres of social life without exception. There exist entire communities of followers of this theory, some of whose adherents can be described as fanatical. However, many Japanese are inclined to consider blood types when it comes to employment, promotion, the choice of a life partner, or a tutor for their children. Some experts even use the term 'obsession' to describe the belief that the blood type determines the fate of a person, and may influence those who happen to be around. In cultural terms, a lot of books are published describing the physiological and behavioural features of people based on their blood types, as well as films, shows and anime devoted to this issue.

This is just one of many examples demonstrating how the latest knowledge may be used by an archaic consciousness to achieve its own goals, rather than for the intended purpose of such knowledge. As an indicator of the peculiarities of the molecular structure of living matter, the blood type is separated from the rest of the body of special knowledge, as well as from the conditions of scientific

knowledge operation, use and interpretation. Thus, objects discovered and explored using scientific methods are endowed with magical properties other than according to the principles of genetics or science in general.

Reconfiguration of society in the era of genetic knowledge

Genetic knowledge has significantly changed the life of people and society. It would be no exaggeration to say that the information about genes and the related knowledge has revolutionarised many common social practices associated with inheritance. One of the key social institutions where the influence of molecular biology became most noticeable was the institution of family. In archaic societies, whole systems for ensuring the purity of inheritance developed, the essence of which boiled down to significant restriction of the freedom of women with the elimination of any risk of contacts with strangers. Customs prescribing wearing clothes that hide the face and body as much as possible, bans on going out without being accompanied by a male family member, prevention of any communication with the opposite sex are still valid for all women in some Muslim countries (many people in the regions where the majority of the population traditionally follows Islam also see this as an ideal of behaviour). However, here it should be acknowledged that the desire to control the transmission of kinship in course of biological reproduction has been characteristic of other cultural and religious traditions, albeit to varying extents. Meanwhile, the current genetic studies demonstrate that these measures, despite all their severity, did not always allow the set goal to be achieved. Even under conditions of total control or under the threat of severe punishment, people by no means are always able to follow the strict requirements of the archaic social order. This results in various deviations of actual reproductive behaviour from social norms and socially approved patterns.

Genealogical DNA tests aimed at finding or verifying ancestral genealogical relationships entered our life fairly recently. But how dramatic are sometimes the stories when the results of such tests do not confirm the fact of paternity or even kinship in general. Some people find out that they were mistakenly given to wrong parents in the maternity ward, while some fathers discover that the child whom they had considered to be their own was born as a result of the wife's infidelity. Fates are inexorably determined, families are torn apart, the whole way of life changes – even for those who did not want to change it at all. These processes are superimposed on other ones – social rationalization and social individualization – adding new factors of influence to the relations between individuals, as well as contributing to the evolution of the institution itself.

The impact of genetic knowledge on society is not limited to the institution of family. Almost all social systems, structures and institutions are affected by what Helga Novotny and Giuseppe Testa call the molecular gaze on life *(Nowotny & Testa, 2011, p. 1)*. These new optics – associated not only with knowledge about genes, but also about other cellular and molecular formations, genetic profiles, etc. – make the processes of interindividual, intragroup and intergroup interactions visible. The possibility to know much more about life than before brought about the temptation to actively interfere with its natural course. Moreover, the fact that the mechanisms of living things functioning and the reproduction of life as such became visible, had

a system-forming influence on social discourse, and, consequently, on the continuing formation of the basic value system. The correspondence of the accepted norms to these basic values is an essential aspect of bioethics and legal regulation of genetic research. At the same time, the values themselves also become structurally and substantively dependent on genetic knowledge.

Novotny and Testa make a good point saying that one of the main vectors of the genetic knowledge influence on society is that it is 'making things visible'. They use the example of an advertising campaign for a Philips 3D ultrasound scanner for prenatal diagnosis with the following slogan: 'Technology should be as simple as the box it comes in'. The viewer watching the advertisement first sees the conventional two-dimensional image in shades of grey in which only the gynaecologist can discern the relevant picture (although even the gynaecologist cannot easily make out the contours of the foetus). This is followed by an image processed using some kind of technology, where anyone can see the foetus, although this image is far from the usual pictures of everyday life.

Finally, the third stage comes when the three-dimensional image on the screen of the device allows seeing the child's head and body as if there were no mother's body hiding it from the naked eye.

'Then, – Novotny and Testa point out, – the third image delivers the advertisement's promise – simplicity. This is the 3D ultrasound scan that uses an algorithm to transform the meaningless segments of the grey surfaces into the familiar 3D image of a baby sucking its thumb. The image 'speaks' for itself; the baby's head is now recognizable even for laypeople' *(Nowotny & Testa, 2011, p. 2)*.

The authors recall *D'Alembert's Dream* – the famous work by Denis Diderot (1986) – in which the author claims that it is enough for him to see life appearing in an ordinary egg to topple all the creationist arguments of theologians. To clarify consciousness is to free the world from a magic spell: this is both one of the intentions and consequences of the Enlightenment. This is what gives hope for the profound transformative effect that genomic knowledge can bring about.

Randomness and predictability of genetic interference

In his book *Representing and Intervening*, Canadian philosopher Ian Hacking (1983) demonstrated that these two concepts equally characterize the two sides of the process of scientific knowledge [cognition]. Representing without intervening will never provide the knowledge needed by science. Different philosophical, scientific, and methodological schools have differently distributed the functions, the power and the order of these two aspects of research. In present-day genetics, and in the accompanying bioethical and legal studies, the question has arisen how to limit the intervening, or at least make it as safe as possible.

Although genetic knowledge creates tremendous opportunities for intervening, this intervention does not appear to be predictable. Research aimed at saving the lives of patients, which led to the discovery of antibiotics, had an impact on Europeans (and, thereafter, on the rest of humanity) which was equally large in scale, but much more distant in time. This has impacted on lifestyle changes in rationalized Western societies, where the decreasing desire to have as many children as possible partly due to the sharp decrease in child mortality and the ever-in-

creasing possibilities of birth control. Families with one child or two children have become more common along with the number of people who plan never to have a family. Thus, the countries with the most highly developed technology and economy are those whose rapidly aging population is being increasingly replenished by migrants.

At the same time, in the traditional societies of Asian, African, and Latin American countries, the availability of antibiotics together with other advances in medicine, has resulted in an unprecedented increase in population, whose cultural roots may still lie in the pre-molecular era. Meanwhile the long-term consequences of genetic knowledge collection and application are yet to be seen.

"...the familiar distinctions – Novotny and Testa point out, – between knowledge and application, between science and technology – are outdated. Under the hegemony of the molecular glance, knowledge has become action. Today the fact is that understanding life means changing life. The molecular life sciences' glance from within has replaced the external view – the famous 'view from nowhere'" *(Nowotny & Testa, 2011, pp. 5–6).*

While trying to understand the possibilities and boundaries of modern genetics, some anthropologists reflect on how rational it would be to interfere with natural phenomena in the course of human genome sequencing. Even Goethe reproached Galileo for the fact that the mathematical natural science created by the latter, unlike Aristotelian physics, did not explain nature, but only set out to conquer it. In accordance with the Bacon's famous dictum 'Knowledge is Power', such knowledge is invariably intended for using and transforming in one's own interests. However, interests have always been substantially different from ideals. Thus, genetic research should be subject to legal regulation for protecting human rights, including the right to information about the dangers and possible consequences for health in case of participation in an experiment.

As is commonly known, the beginning of genetic research regulation was marked by the Nuremberg Code (BMJ, 1996). Article 1 of the Code prohibits interfering with the natural course of a person's life without the voluntary consent of such person based on full knowledge of the potential consequences: 'The voluntary consent of the human subject is absolutely essential'. Russian legislators have reflected this principle in Part 2 Article 21 of the Constitution of the Russian Federation, as well as in Articles 32 and 43 of the Fundamentals of Legislation of the Russian Federation 'On Citizens' Health Protection' where some further specific details are added:

'Any biomedical research involving a person as a subject can be carried out only after obtaining such person's written consent. A citizen cannot be forced to participate in biomedical research... When obtaining consent for biomedical research, the citizen must be provided with the information about the goals, the methods, the side effects, the potential risks, the duration and the expected results of the research. A citizen has the right to refuse to participate in research at any stage'.

The Universal Declaration on the Human Genome and Human Rights adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization specifies the above-mentioned principle of the Nuremberg Code in terms of genetic research. Among other things, it touches upon the val-

ue of biological diversity and the interpretation thereof.

'Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and emphasizing in that connection that the recognition of the genetic diversity of humanity must not give rise to any interpretation of a social or political nature which could call into question 'the inherent dignity and (...) the equal and inalienable rights of all members of the human family', in accordance with the Preamble to the Universal Declaration of Human Rights'.

This provision is extremely important, as, in addition to the need to protect human rights, there exists another object of protection – the gene pool of humanity. It was only the development of genetic science that made it possible to realize the scale of the danger of interference with natural processes at the molecular level. However, at the same time arose many justifications of the impossibility of imposing a total ban on such research. 'We have never done anything', – David Baltimore, a biologist and former president of the California Institute of Technology, said, – 'that will change the genes of the human race, and we have never done anything that will have effects that will go on through the generations' (Regalado, 2018). In 2017, the international science and research community, led by the US National Academies of Sciences, Engineering and Medicine (NASEM), defined the conditions that need to be met before editing the human embryo genome meant for implantation. One of these conditions is that DNA sequences obtained as a result of editing must be already prevalent in the population and must not carry any known risk of disease.

The aforementioned requirement voiced by the NASEM actually forbids any innovation in the sphere of human genome. The probability and feasibility of codifying this requirement in legislation without discontinuing any research is a separate question. Moreover, modern researchers are discovering more and more new facts indicating that the human genome evolves under the influence of completely random circumstances, and it is not within the human power to keep it immutable *(Moraes & Góes, 2016; Shapiro & Noble, 2021)*.

Today, when the SARS-CoV-2 virus has brought innumerable adversities to the entire population of our planet, most people view viruses only as something evil. At the same time, scientists and researchers are increasingly realizing the high importance of the functions of viruses in nature and the significant role they may have played in human evolution. According to Kojima, Kamada, and Parrish (2021),

"Union of genomes from discrete biological entities is a major engine of genetic diversity. Fusion of gametes, each bearing a set of recombinant chromosomes, is the immediate source of the genetic material that uniquely identifies each human. Taking a wider viewpoint, much of a human genome can be recognized to have been acquired from a source other than modern humans".

This example clearly demonstrates the growing difficulties of determining the possible consequences, even if assuming that today's interventions into the genetic structures of individuals are absolutely safe for such individuals' personal health. At the same time, any addition of foreign insertions into an individual's genes appears to involves random and essentially uncontrollable process, upon which the illusion of safety – or, at least, of the possibility of purposefully influencing the human genome – is based. However, technologies such as CRISPR

are already demonstrating an ability to transform an uncontrollable [unmanageable] process into a controllable [manageable] one *(Noman, Aqeel, & He, 2016)*. While the use of such technologies is aimed at improving the health of certain individuals, its effects in relation to the human race as a whole remain uncontrollable. According to some authors, it is with this question that bioethics should primarily concern itself about at the current stage *(Zhang, Wen, & Guo, 2014)*.

According to the anthropologist Paul Rabinow (1992), the object to be known – i.e., the human genome – will inevitably become known in such a way that it can be changed. This approach fully involves what philosophers call instrumental rationality, which is characterised by the transformation of values into ends, and ends into means. The representation of the object is done in a way ensuring the most effective intervention, as this is how the mutual conversion of knowledge and power is achieved. Instrumental reason or instrumental rationality is the modern way of using descriptive knowledge as a means for transforming the world. Jürgen Habermas in his work entitled 'The Theory of Communicative Action' opposed this type of rationality to another one, more ancient and perhaps more human, which he called communicative rationality.

'If we start from the non-communicative employment of knowledge in teleological action, we make a prior decision (Vorentscheidung) for the concept of cognitive-instrumental rationality that has, through empiricism, deeply marked the self-understanding (Selbstverstundnis) of the modern era. It carries with it connotations of successful self-maintenance made possible by informed disposition over, and intelligent adaptation to, conditions of a contingent environment' *(Habermas, 2007)*.

Thus, communicative rationality, together with instrumental rationality, creates an effective decision-making system that balances the various goals, values and meanings generated in social practices.

Conclusion

The theory of communicative action lays the conceptual foundations of bioethics which need to be taken into account when building a system of administrative and legal regulation as well as socio-communicative regulation of genetic knowledge development. The distinction between communicative and instrumental rationality traces itself as far back as the Kantian doctrine of practical reason and the categorical imperative. Kant's ethics contains one of the interpretations of the categorical imperative forbidding treating others solely as a means to achieve one's own ends. This is exactly what characterizes the instrumental rationality which prompts seeing only a potential to serve actual means in all things existent.

It is not a mere coincidence that the main criterion of success within the framework of instrumental rationality is the concept of efficiency. Unlimited (unrestricted in any way) instrumental rationality is capable of resulting in moral degradation of society and in maximum dehumanization of the existence of human beings as such. That is why instrumental rationality must be subordinated to and supplemented by another kind of rationality – communicative rationality. Communicative rationality presupposes the presence of two entities (parties) and a dialogue between them, which prevents instrumentalization of interindividual, intragroup and intergroup interactions. Normal communication is supported not only by ends, but also values, on which basis the transformation

of any into means can be reliably prevented. It is extremely important to take this conceptual structure into account when making laws and performing other actions aimed at creating a system for regulating genetic research. In this connection, it would certainly be advisable to start taking this into account already at the level of declarations adopted by the global and regional communities of legislators, researches and public figures.

Thus, we see that it is impossible to choose one of the two drivers of natural selection – heredity or variability – as the main value. The human genome is naturally affected by each of these factors, which makes potential interventions either proactive, or reactive. Proactive interventions are aimed at changing the human genome, while reactive interventions are generally aimed at removing the causes of 'genetic damage', such as, for example, random mutations resulting in genetic diseases of some individuals. While reactive interventions as such are undoubtedly permissible and even desirable (if indeed the absence of any negative consequences is guaranteed), proactive interventions aimed at improving the human genome need to be reliably excluded today by means of legal regulation. Here it is accepted that proactive interventions may also become acceptable in the future if their influence on the genome can be reliably controlled and predicted. But even then, each such 'innovation' should be based on the results of a broad public discussion, multi-stage expert review and other means of communicative rationality.

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https://doi.org/10.17803/lexgen-2022-1-1-34-55

Original article

International legal issues on biosafety: general overview

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Abstract

Objective: The legal concept and content of biosafety is discussed in the context of International Law. Biosafety issues are enumerated as part of a definition of concrete aspects related to responsibility of the states for using biological weapons. The latest trends in international law on ensuring the international biosafety are analysed. Legal issues concerning the definition of a just war are discussed in terms of international humanitarian law, the issues of fundamental principles in current international law (the principle of necessity governing the use of force, the right of states to self-defence in case of a bioattack, the principle of the peaceful settlement of international disputes, the principle of non-interference in the internal affairs of states, arms control, and responsibility). The article presents an overview of new types of sovereignty such as biosovereignty, cyber sovereignty, and genomic sovereignty of states, along with the legal concept of international biocrime (genomocide), as well as classifications of bioterrorism, bioaggression, biopolitics and bioeconomics. Under current conditions, the importance of facilitating a broad interpretation of the concept of biosafety is emphasized.

Methodology: The research uses general scientific and special cognitive techniques wherein legal analysis and synthesis, systemic, formal-legal, comparative-legal, historical-legal and dialectical methods are applied.

Results: Despite the prohibition of biological weapons, urgent issues, such as establishing an international control mechanism for monitoring the non-proliferation of biological weapons, remain. Moreover, the Protocol to the Biological and Toxin Weapons Convention (BTWC), which entered into force in 1975, is yet to be fully adopted and / or ratified by all member states. Identifying certain types of biomedical research that should be banned according to generally accepted principles, the study concludes that the problem of banning these research activities has yet to be solved by some states. The concept of biosafety is interpreted broadly in terms of issues arising in relevant industrial processes. Biosecurity and biosafety are directly related to ensuring environmental security, marine security, food secu-

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rity and the security of outer space. Principles governing effective legal regulation for ensuring environmental, biological, and food safety are presented.

Keywords: biosafety, cyberbiosecurity, molecular weapon, genomic sovereignty, biobanking, biocrimes, genomocide, bioterrorism

To cite this article: Gulyaeva, E.E. (2022). Problems of biosafety in current international law. *Lex Genetica*, 2022;1(1):34–55. https://doi.org/10.17803/lexgen-2022-1-1-34-55

Received 15.11.2022
Review completed 16.12.2022
Passed for printing 03.01.2023

Introduction

In recent times, new problems and threats to humanity have arisen at the global, international, regional, and national levels. Research and development in contemporary areas of biotechnology, including human enhancement (CRISPR-Cas9) and the possible use of genetic weapons, may change the nature of war and international politics. In terms of their possible effects, genetic weapons can be classified as weapons of mass destruction, along with chemical, biological, bacteriological, and nuclear weapons. The additional category of molecular weapons may become relevant in the future.

According to some experts, the biotechnological revolution in military affairs will bring immense power to technologically advanced states, but it will also raise many questions about what should be considered a just war in the terms of international humanitarian law. Technological developments will trigger issues of fundamental principles in current international law (the principle of neither using force nor threatening to use it, the right of States to self-defence in case of an attack, the principle of the peaceful settlement of international disputes, the principle of non-interference in the internal affairs of States, arms control, and responsibility). New types of sovereignty will surely appear *(Kelsen, 1950; Pratter, 1989)*. These include biosovereignty *(Rae, 2019)*, cyber sovereignty *(Richardson et al., 2019)*, and genomic sovereignty of states *(Kalinichenko & Nekoteneva, 2020)*. It will be necessary to fit international biocrimes (genomocide) into international criminal law and build up the legal classification of bioterrorism, bioaggression, biopolitics, and bioeconomics. It will be necessary to consider the legal regulation of post-genomic technologies, the biodata of States' populations, ensuring individual biosafety, and the biosafety of the State. It is also urgent to ensure the safety of genomic research and confidentiality of genetic data, as well as to codify international law in the field of bioethics (e.g., to adopt a bioethical code). Here attention must be paid to human rights protection legislation (the right to life, the prohibition of torture, the right to private and family life, the prohibition of discrimination, etc.). While concerns do exist in the neurotechnology context, they apply to the existing artificial intelligence, including ((i) privacy and consent; (ii) identity and the meaning of subjective consciousness/free will; (iii) human enhancement/controlled growth; and (iv) bias. Four areas of potential

threats to individual rights can therefore be identified that require urgent attention from the legal community.

The use of electrical brain stimulation techniques, the electrode implantation in the brain, have raised concerns about the impact of these practices on the patient's personality. Topicality of the issue at hand is dictated by the following factors. The first, international research projects (BRAIN, BIOS, Blue Brain Project, Human Brain Project, etc.) are being actively implemented all over the world nowadays, aimed at collection, research, storage and transmission of neural information about human brain, as well as further application of data acquired in daily life. Technologies related to brain neural connections are widely employed in such sectors as the military, banking, medicine, commercial biotechnology, manufacturing, marketing, game industry, forensics, and criminalistics. At the same time, the international community lacks control over the state of the bioresource medical data collections and biomaterials for medical research. Improvements in these technologies necessitate a search for new ways and methods to ensure the personal and public safety of both the individual and society as a whole.

The problem of effectively banning biomedical research associated with the development of bioweapons is yet to be solved in some States or at the international level (Tarasyants, 2011). In this paper, we interpret the concept of biosafety rather broadly, considering the issues that typically arise in the relevant industries.

Today, we are witnessing a dynamic development of a multi-disciplinary field called cyberbiosecurity. This field combines cybersecurity, biosecurity, and the security of cyber-physical systems in the wider context of biological systems *(Murch et al., 2018)*. Biosecurity and biosafety are also directly related to ensuring environmental security. Environmental biotechnology aims at the optimal use of nature in the form of plants, animals, bacteria, fungi, and algae used to produce renewable energy, foods, and nutrients through a synergetic integrated cycle when waste materials generated by one process become raw materials for another. Meanwhile, the many uses of biotechnologies associated with rapid industrialisation and urbanisation can be extremely detrimental to the environment, as well as contributing to wider natural resource depletion. The close link between environmental and food security is a focus for increasing concerns about the use of GMOs.

In the international law of the sea, there have been recent developments in terms of marine genetic resources. Marine genetic resources have been a topic for discussion at the UN forums. Participants have noted that large private pharmaceutical companies extract and exploit natural resources not for scientific research aimed at the benefit of mankind, but for commercial purposes and profits. Thus, marine biosecurity can be distinguished from other types of security and safety because its purpose is to preserve basic biodiversity on our planet *(Campbell et al., 2018)*.

In order to prevent and suppress bioterrorism, close cooperation between States is necessary. In order to maintain world peace and ensure international biosecurity and biosafety, state actors need to coordinate their joint efforts and actions in the fight against emerging types of biological threats. Under the auspices of the UN Secretary-General, a mechanism has been established to investigate alleged biological attacks. Alongside this, efforts are being made to create a reliable international laboratory network that

will provide forensic support (forensic biotechnology) to such investigations. While the current efficiency of laboratories working to detect genetic modifications is not always optimal, the laboratory network can be strengthened through additional tools and technologies. The International Criminal Police (Interpol) report of 2021 considers COVID 19 and biomedicine factors while assessing threats to the international community. Considering the possibility of significant casualties, Interpol has developed a strategy to prevent crimes, involving biomaterials in the field of biosecurity and biosafety, which resulted in the issue of a bioterrorism incident pre-planning and response guide.

Other urgent issues remain outstanding. An international control mechanism for monitoring the non-proliferation of biological weapons has not been established yet. The Protocol to the Biological and Toxin Weapons Convention (BTWC), technical in force since 1975, has not been adopted and / or ratified by all member states[1]. Although the original instruments of ratification of the BTWC and the 1925 Geneva Protocol were signed by the USA on 22 January 1975. In 2001, the Bush Administration stated that the adoption of the Protocol poses a threat to confidential business information of American pharmaceutical companies[2].

However, issues connected with the development joint practical measures to prevent threats to national, regional, and international security related to the impact of hazardous biological factors continue to be discussed at the intergovernmental level. For example, the Secretaries of the Security Councils of the Collective Security Treaty (CSTO) countries at a meeting in Dushanbe agreed to develop measures to prevent biological threats. A draft Convention on Biosafety is in the process of being developed within the framework of the CSTO[3].

At the end of 2020, the Federal Law on Biosafety was adopted in the Russian Federation. This law regulates activities aimed at ensuring biosecurity in Russia. Prior to its adoption, there was no conceptual definition in Russian legislation defining measures to be taken to ensure the biosafety of citizens. The Law provides for measures to prevent terrorist attacks and sabotage involving the use of biological weapons. There are at least 30 facilities in the Russian territory that potentially can pose chemical or biological hazards.

[1] "Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict." URL: https://ppt.ru/newstext.phtml?id=15673

[2] Testimony of Ambassador Donald A. Mahley, House Government Reform Committee, Subcommittee on National Security, Veterans Affairs and International Relations, The Biological Weapons Convention: Status and Implications, July 10, 2001. U.S. Government Printing Office, 2002. 93 p.

[3] The Collective Security Strategy of the Collective Security Treaty Organisation till 2025 was approved by the Collective Security Council of the Collective Security Treaty Organisation on October 14, 2016. The instrument contains provisions aimed at strengthening the regime of the Biological and Toxin Weapons Convention, including the promotion of the initiative to make all the member states ensure full transparency of their biological activities outside their national territories. URL: https://odkb-csto.org/documents/statements/strategiya_kollektivnoy_bezopasnosti_organisatsii_dogovora_o_kollektivnoy_bezopasnosti_na_period_do_/. As an example, it should be mentioned that on May 6, 2021, the Government of the Russian Federation and the Government of the Republic of Armenia signed an intergovernmental memorandum on biosecurity issues in order to strengthen the common biosecurity space

In 2021, the Russian scientific community enlarged the list of scientific specialties to define four new branches of academic research. These are computer science and informatics, biotechnology, mining sciences and the use of subsurface space, as well as cognitive sciences *(Lisitsyna, 2021)*. This demonstrates that the issues discussed in this work are considered to be particularly significant for the foreign and domestic policies of the Russian Federation.

On the Issue of Expanding the Legal Concept of Biosafety

Maintaining biological security is an important task facing the world community. With increasing globalisation, it becomes especially relevant due to the threats posed by infectious diseases and their pathogens. Hazards of this type are becoming comprehensive in the contemporary world. Until recently, the main content of biosafety was mainly related to the issues of sanitary and epidemiological welfare of the population. Thus, at the present stage of their evolution, understandings on biosafety are characterised by a significant expansion of their primary content.

Any classification of biological threats includes a list of dangerous biological factors of natural origin. These are infectious diseases, which can include emerging, returning, new, emerging in new territories, and feral herd infections. There are also artificial threats caused by human professional activities, e.g. complications involved in the intensification of research involving the uncontrolled release or spread of living organisms that can affect ecosystems in unknown ways, an increase in the number of biologically hazardous facilities with maximum permissible or completely exhausted technical and technological resources, as well as various accidents occurring at facilities where people are working with pathogens *(Merinova et al., 2018)*.

Special importance is given to biological threats related to the deliberate use of pathogenic biological agents (bioaggression, bioterrorism, ecological wars). According to many experts, such hazards constitute the greatest danger to humanity due to being the least controlled type of threat. Leading experts in the field of biosafety and biosecurity also predict the emergence of fundamentally new threats associated with advanced biotechnologies and the creation of biological (molecular) weapons.

In this context, the need for continuous development of the biosafety system noted by many experts is obvious. Thus, biosafety, being an extensive field of activity in the current context, has also become a separate field of knowledge, which combines practice and theory of human protection against dangerous biotic factors.

International Criminal Law: Criminalisation of Bioterrorism in International Law

According to UN international experts and the Biological and Toxin Weapons Convention of 1971, modern genetic engineering is deemed to be a threat in terms of genome editing. To detect a genome editor, tools are being developed that can analyse the pathogen genome for indicators of genetic engineering. The IARPA Finding Engineering-Linked Indicators (FELIX) project aims to develop new experimental and computational tools for this purpose[4]. To establish the identity

[4] URL: https://www.iarpa.gov/index.php/research-programs/felix

of the genome editor is another problem since finding out that the organism has been created through genetic engineering and a certain kind of modification does not mean that it is also easy to detect the one who has done it. Different specialists can be involved in the process: from people working in medical laboratories to university research teams, industrial laboratories, and state-owned enterprises, producing biological weapons.

Modern scientific methods of genome editing provoke significant concerns due to the possibility of their abuse by States or terrorist organisations. Many medical techniques threaten human biosafety and biosecurity. For example:

The creation of more dangerous pathogens and their use for criminal purposes:

Unsafe studies of existing pathogens, which are dangerous to human health;

The risk of developing new pathogens or agents capable of causing cancer and other diseases;

New directions in immunotherapy, cell therapies, and enhanced viral clearance. The improved manufacturing of biologically active substances in biopharmaceuticals, biosynthesis, and bioproduction, which can potentially be used as weapons of mass destruction;

Changes in the personality traits of future mankind's generations that are not consistent with the goals of the healthcare system.

Extension of the Universal Jurisdiction of the International Criminal Court in Case Biological and Genetic Weapons Are Used

In the international law theory, the use, development, production, or stockpiling of biological weapons by any person, including diplomatic agents and heads of States, is considered as an international crime punishable through the universal jurisdiction[5]. That is because biological weapons (weapons of mass destruction) are considered to comprise a *hostis humani generis* (enemy of mankind). Moreover, the use of biological/genetic weapons by a State or a terrorist organisation is subject to criminal punishment under international humanitarian law and international criminal law in the context of combating terrorism. If a State (whether directly or indirectly through financing terrorist attacks) uses biological weapons against the civilian population, it is considered a war crime and, depending on the nature of the biological attack, potentially a crime against humanity[6]. However, the use of biological weapons by terrorists is already a crime under the criminal legislations of all the State Parties to the UN Convention for the Suppression of Terrorist Bombings (1997). The current international legal order is based on the fundamental international law principles (*jus cogens* norms). In practice, if biological weapons are used, this may be perceived as the violation of the prohibition on the use of force or the threat to use it in accordance with Article 51 of the UN Charter (1945). The right to self-defence should be used if necessary,

[5] The Harvard Sussex Program on CBW Armament and Arms Limitation has put this idea forward in its draft convention criminalising the development, acquiring, stockpiling, storage, transfer, possession, and use of biological or chemical weapons. The use, development, or possession of biological weapons might be considered as a crime under international law, taking into consideration the universal jurisdiction principle.

[6] This conclusion stems from the principle of civilian population immunity from attack under international humanitarian law, but not from the principle of criminalising the use of biological weapons.

and the measures taken should be proportionate, i.e. they should not go beyond what is required to repel aggression. The use of force or the threat to use force in violation of the UN Charter provisions is also illegal. The Declaration on the Enhancement of the Effectiveness of the Principle of Refraining from the Threat or Use of Force in International Relation of 1987 proclaims that 'no consideration of whatever nature may be invoked to warrant resorting to the threat or use of force in violation of the Charter'. Article 5 of the UN General Assembly Resolution 3314 (XXIX) of 1974 states the following: "a war of aggression is a crime against international peace. Aggression gives rise to international responsibility".

Thus, the proposal to criminalise the use of biological weapons by States or terrorist organisations is based on the existing principles, which condemn and criminalise such behavior. The proponents of the proposal seek to directly and explicitly criminalise the use, possession, and unauthorised development of biological weapons by any person. Nevertheless, there is a question: will such a provision in international criminal law have a significant impact on the position of states and terrorist organisations, regarding their possession of biological weapons? The international criminal law practice in such areas as armed conflicts and the acts of torture shows that the deterrent effect of criminalising certain governmental or individual behavior is very small.

The issue of the potential proliferation of biological weapons and bioterrorism is a great concern at the international level as well as the crisis of the global healthcare system. In this regard, the international specialised agencies of the UN (WHO, WTO) are revising international rules in the field of healthcare. Agencies are also trying to establish certain prohibitions and restrictions in international trade law. Restrictions on trade between countries are allowed when there is convincing scientific evidence that the cross-border movement of certain goods is dangerous and infectious diseases can be spread *(Porges, 1994)*.

Currently, there is a sufficient body of legislation, protecting the genomic dignity of a person and establishing responsibility for the illegal behavior of genome editors, as well as such persons as have consented to such manipulations with the genome. In the case of germline genome editing, such people are responsible not only to themselves but also to any future generations who will receive an edited genome to which they have not consented. In recent years, courts have heard a number of well-known cases related to patent disputes over breakthrough biotechnology for human genome editing (CRISPR-Cas9). Given these circumstances, it may be necessary in future to revise patent legislation at national and international levels in order to protect public health.

Issues of Development and Use of Biological/Bacteriological and Toxin Weapons by States and Individuals in the Context of Terrorist Attacks

Terrorism is one of the most serious concerns, affecting most countries of the world. The use of non-conventional weapons by individuals and terrorist organisations is a global threat *(Gronvall, 2012)*. Therefore, the special safeguarding of biological and toxin materials having potential for use for making a weapon of this kind becomes extremely necessary.

A bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in peo-

ple, animals, or plants *(Centers for Disease Control and Prevention (U.S.), 2006)*. The biggest danger here is that the inflicted damage can be hard to detect, let alone control. With the massive potential for deaths of animals and people from viruses and diseases, it may be difficult to identify the true causes since strains of germs and viruses, existing objectively in nature can also be used for terrorist attacks. Distinguishing natural outbreaks from artificially created ones takes time, thus complicating the subsequent identification of perpetrators. The contemporary use of biological and toxin weapons was considered to be a vague threat until 2001, when terrorists in the USA spread anthrax spores via the mail system. As a result of this terrorist attack, 4 people died and 15 people were injured (Pravda.ru, 2001), alerting only the US government but the rest of the world to the danger of biological terrorism. Another example of the application of biological material in the US for terrorist purposes was the ricin sent in envelopes to President Obama and a U.S. Senator in 2013.

Any threat or use of biological agents by a person or a group, whether due to political, religious, economic, or other ideological motives, can be considered in terms of bioterrorism (Zunder, 2008). Bioterrorist attacks can be delivered via different means: spraying pathogenic germs over pastures, infecting water, food, animals, pastures, etc. Bioterrorism may be very attractive to criminals due to the difficulty of detection. Conventional strains of pathogenic germs and artificially modified ones can be used as weapons. The latter case is exceptionally dangerous because an artificially "improved" virus is strongly resistant to medicines and vaccines.

A biological attack using a pathogen vector can inflict extensive damage. Due to symptoms typically appearing only some time following the incubation period, a person intentionally infected with a dangerous virus can easily infect a lot of other people. The result is an inevitable delayed reaction of on the part of governmental authorities responsible for public safety.

Along with other factors, the prohibition against States from developing, producing, and storing biological weapons is due to the acknowledged risk that a terrorist cell may gain access to pathogenic microbes stored in a particular laboratory for subsequent use in terrorist attacks (Fidler, 2020). This prompted the world community to adopt the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. The Convention contains a number of important provisions, ensuring international biosafety:

– The State Parties undertake to refrain from a number of actions while dealing with microbial or other biological agents, or toxins (namely, they refuse from developing, producing, stockpiling, acquiring, or retaining such substances). This refers to quantities that may be used in armed conflicts or any other violent behavior (Article 1). In addition, the State Parties are prohibited from all the aforementioned things with respect to weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflicts (Article 1).

– The State Parties undertake not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organisations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of de-

livery specified in Article I of the Convention (Article 3).

– The State Parties undertake, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment, and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control (Article 4).

It should be noted that the Convention specifies only one way to influence a State Party in case its activities do not comply with the most important provisions. Under Article 6 of the Convention, the UN Security Council may take action against such a State only if another State has lodged a complaint with the Security Council. The complaint should include all possible evidence confirming its validity. However, there is no clear legal regulation of how such evidence can be obtained. Thus, there is neither a Protocol nor a Resolution regulating the means and methods of verifying the implementation of the Convention. This may lead to a situation where State Parties will be assessed solely on the basis of their good faith when stating their abandonment of biological and toxin-based weapons.

Moreover, the Convention applies only to those States that have ratified it. Consequently, it is not universal and its effect is limited. According to the provisions of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, those engaged in the development of biological and toxin weapons are exempt from criminal prosecution provided that such activities are properly authorised by the US government *(Act, 2001)*. This approach contradicts the spirit of both the Geneva Protocol of 1925 and the Convention of 1971 *(McElroy, 1991)*. Thus, the US can engage in the development of biological weapons contrary to international law. Meanwhile, there is a lack of tools and mechanisms for monitoring the activities of States in the field of biosecurity and biosafety. For this reason, the international agreements on these issues appear, for the most part, to lack utility.

Thus, according to the data published by the Ministry of Foreign Affairs of the Russian Federation, the US, represented by the Department of Defence and its affiliates, are operating on the territory of Georgia in the South Caucasus (US Army Medical Research Unit – Georgia). Although the American government claims that these activities are related to providing assistance in the development of health services in Georgia, certain facts indicate the involvement of American military units, which is not required for the development of health services. It is noted in this connection that the BTWC was ratified by Georgia; consequently, concerns have been expressed that the country may be violating the norms of international law by allowing US actors to operate at the Lugar Research Center in Tbilisi.

Another relevant factor is the lack of a precise list of biological materials covered by the Convention. Currently, its broad provisions fail to specify in what way and according to which criteria the possible purposes of using the materials should be determined (Merriam, 2014). For example, when working with smallpox infection in the laboratory, it is possible to refer to the development of a vaccine, when the modification of this virus may actually be carried out for the purpose of developing biological weapons. Not only is it difficult to determine the minimum required

volume for conducting peaceful experiments in search of a vaccine, but an additional danger arises due to the possibility of a relatively small amount of infected biomaterials posing a threat to a large number people.

The development and adoption of a legally binding Protocol supplementing the Convention has been hindered by the US since 2001. Proposals by Russian representatives concerning the adoption of a specific institutional framework for the Protocol to ensure compliance with the Convention were rejected, with the UK and the US insisting on involving existing international organisations such as the World Health Organisation in monitoring the implementation of the Convention provisions. Meanwhile, Russia insists that the adoption of the Protocol has the potential to increase the transparency of activities carried out at biological facilities. Operations carried out using biologically hazardous materials are inherently hard to trace due to the unique characteristics of dangerous biological strains: unlike chemical weapons, firearms, and other types of weapons, biological strains can be dangerous even in very small amounts.

The danger of developing and accumulating biological weapons and toxins is also manifested in the fact that pathogenic strains may leak from a laboratory. In 1979, this occurred in Sverdlovsk. Although the anthrax spores were not being used in the laboratory to create biological weapons, their leakage le ad to the deaths of 66 people *(Kupferschmidt, 2016)*.

Given the lack of international mechanisms for governing the use and development of bioweapons in international law, Security Council Resolution 1540 (UN, 2004) is of particular importance. This Resolution substantially complements and expands the provisions of the Convention in the field of non-use of biological weapons. According to the Resolution, States are responsible for controlling the risks stemming from biological and nuclear threats where non-State actors are involved. Although the Resolution is not specifically aimed at combating terrorism, measures for countering the threat of terrorism are implied. Non-State actors can be individuals ("lone wolves") and groups (terrorist organisations).

The Resolution implies the development of appropriate national regulatory legislation if it is still absent, or the improvement of the legislation if it already exists. The document calls for the cooperation of States in achieving the main goal that is to suppress crimes related to chemical, biological, and nuclear materials, which constitute a security threat. Thus, the Resolution contains three essential provisions:

– States are prohibited from providing support to non-State actors that attempt to illegally deal with nuclear, chemical, or biological weapons and their means of delivery (this is the first international instrument, establishing control over transporting biohazardous objects) *(Merriam, 2014)*.

– Harmonisation of national legislations on control over chemical, biological and nuclear weapons.

– Supervision and control over the circulation, transportation, and use of biological, chemical, and nuclear materials by non-State actors.

For the fullest implementation of Resolution 1540 *(UN, 2004)*, Resolution 1977 *(UN, 2011)* was referenced. Under Resolution 1977, international, regional, and subregional organisations are also involved in the fight for the non-proliferation of chemical, biological, and nuclear weapons by assisting the 1540

Committee *(BioWeapons Prevention Project, 2014)*.

Interpol Activities Aimed at Ensuring Biosecurity

Although the process of globalisation has positive aspects, including the reduction of costs and expenses, modernisation and development of production, spurring and development of advanced technologies, as well as potentially bringing together States and peoples in common purpose, negative aspects include environmental and demographic challenges, international crime, etc. A rising trend occurring in the 21st century involves the emergence of natural infectious agents having novel properties. These can be the result of frequent, extensive, and rapid natural genetic mutations occurring due to various globalisation processes: climatic disturbances, a significantly increased worldwide flow of people, biomaterials, agricultural products etc.

Under such circumstances, international cooperation to combat criminal activities has become especially relevant. One of the oldest examples of such cooperation is Interpol, uniting 194 countries (The ICPO-INTERPOL Constitution, 1956). Since 2005, Interpol has been implementing a progressive Bioterrorism Prevention Program. Its main goal is to assist its 194 member countries to combat threats and risks associated with biological materials used as weapons. The initiative was the result of the anthrax attacks in the US in the Autumn of 2001.

The first global conference on the prevention of bioterrorism held in March 2005 in Lyon (France) attracted a large global audience of high-ranking law enforcement officials. The problem faced by Interpol was how to ensure work on biosafety within the international legal framework and Interpol's Constitution. The first step was to assemble a group of experts from the countries where law enforcement agencies had gained sufficient experience in combating terrorism. The first meeting of these experts took place in 2006. There were representatives from the US, the UK, Australia, and Canada. The meeting was also attended by non-governmental experts from the American Centers for Disease Control and Prevention (CDC) and the Robert Koch Institute (RKI, Germany).

Bearing in mind the possibility of enormous human casualties, Interpol has developed a strategy to prevent biomaterial crimes, relying on biosecurity and biosafety techniques. As a result, the Bioterrorism Incident, Pre-Planning and Response Guide was issued. Biological weapons are classified as weapons of mass destruction due to the possibility of triggering panic among the population, as well as potentially involving enormous human casualties and economic losses (GOST P 22.0.04-95, 1995).

In the context of the involvement of Interpol in ensuring biosafety, the versions, publicised mostly by the media, concerning an alleged artificial origin of COVID 19 or "providing support" in jumping the species barrier and transmitting the disease from animals to humans, are generally perceived rather negatively. After all, based on such "news", it is possible to conclude that control over biological laboratories, transportation, and non-proliferation of biological materials for criminal purposes is currently far from sufficient.

Although the use of biological materials as weapons was previously very rare, the number of such cases has begun to increase. Even false threats can be an effective way to sow terror among a general public.

Future Threats and Basic Biosafety Principles

Currently, there is a significant increase in threats and risks associated with the use of biological materials for deliberate criminal acts. For this reason, the issue of ensuring the safety and security of biological materials seems more urgent than ever. Terrorist groups have become more numerous and organised; in some cases, they have stable funding.

In January 2014, an ISIS laptop was discovered by commander of a moderate Syrian rebel group in Syria containing a detailed description of how to create bubonic plague bombs[7], which could be used in public places to kill and infect large numbers of civilians.

In November 2014 in Guinea, Africa, a minibus transporting blood samples infected with the deadly Ebola virus was stopped by unknown armed persons[8]. The container was stolen. Although the robbers probably had no idea what was inside, the case indicated the vulnerability of infectious biological objects. While the Ebola virus is a well-known biological agent, it can have atypical consequences. In this context, the 2014 outbreak of Ebola virus infection deserves special attention. Previously, the outbreaks of the dangerous disease ended in the death of a significant part of infected people. Nonetheless, the epidemics were very limited in range and effectively blocked by preventive measures.

At present, while the danger of bioterrorism is not comparable to the use of explosives, chemical or nuclear weapons, this might lead to an underestimation of the threat in the future. Nevertheless, the threat, stemming from bacteriological and other biological weapons, is increasing along with the growth of instability and the spread of biotechnologies in States, which directly or indirectly support terrorism.

Regarding the challenges facing Interpol in this area, it is also worth focusing on the phenomenon of "homemade" biotechnology. In coming years, the number of such independent laboratories may substantially increase worldwide due to the popularity of this "hobby" and the relative availability of scientific and technical equipment. This fact will serve as a breeding ground for bioterrorists and various spontaneous discoveries that can result in human casualties. With the development of technology and scientific knowledge, opportunities previously possessed only by large groups and companies are becoming available to small groups and even individuals. Against this background, Interpol member countries should make a list of those biological materials that, in their opinion, should be prioritised as representing the greatest risk with respect to possible misuse in order further strengthen control over them.

Among viral infections, the most likely agents for a terrorist attack are smallpox germs. Although smallpox has completely died out in natural environments and smallpox germs are officially stored only in the USA and Russia, modern biology synthesis methods can be used to reproduce the full-length genome of the virus and introduce it into a cell culture[9]. For this reason, such technologies are strictly prohibited by the World Health Organisation.

[7] URL: https://foreignpolicy.com/2014/08/28/found-the-islamic-states-terror-laptop-of-doom/
[8] URL: https://www.theguardian.com/world/2014/nov/21/bandits-guinea-steal-blood-samples-possibly-infected-with-ebola
[9] URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819212/

Interpol has a special unit for the prevention of bioterrorism (INTERPOL Bioterrorism Prevention Unit), which aims to empower law enforcement agencies in preventing and responding to the deliberate use of bacteria, viruses, or biological toxins that threaten or cause harm to humans, animals or agriculture.

In addition to drawing up and publicising intelligence reports on the biological conditions, the officers of the unit assess the needs of a particular country or region, providing operational support for relevant law enforcement activities at the local levels.

In conclusion, it should be noted that criminal activities carried out over telecommunication networks are tending to increase, especially using various darknet overlay networks. In order to assist law enforcement officers to detect triggers and indicators of potential criminal activities related to the access and trade of biological and chemical materials using the darknet. The "Interpol Operational Manual on Investigating Biological and Chemical Terrorism on the Darknet" has been developed by a team of experts. This reference document outlines the basic concepts and best international practices, as well as techniques and procedures useful for both investigators and analysts when conducting investigations on telecommunication networks.

Legal Aspects of Ensuring Genetic Security and Safety Within the Bio-Sovereignty of States

In the era of rapid progress in biomedicine and biotechnology, legal guarantees of the integrity of the human being and the protection of patients' rights are enshrined in the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) of 1997 (the Oviedo Convention) *(Council, 1997)*. Among these are enshrined principles of biosafety and voluntary informed consent to any manipulation with human genetic materials, including for medical and research purposes. Guarantees of respect for human rights and fundamental freedoms and ensuring freedom of research were formulated in the UNESCO Universal Declaration on the Human Genome and Human Rights of 1997. This document went further than the Oviedo Convention, emphasising that a person cannot be reduced to his/her genetic characteristics. The Declaration stresses immutable respect for personal uniqueness. In the 21st century, everyone should have a fundamental right to respect for their dignity and subjective rights, regardless of genetic characteristics, as well as the right to protection of their genetic data *(Levoshchenko, 2000)*. Both the principles of confidentiality and non-discrimination based on genetic characteristics are fixed in Articles 6 and 7 of the Declaration.

Today, millions of people in the world are suffering from serious chromosomal diseases, genetic mutations, and monogenic disorders (disorders in the genome structure) such as muscular dystrophy, cancer, Down syndrome, cystic fibrosis, etc. New CRISPR-Cas9 genome modification technology promises a breakthrough in the treatment of these diseases. Using this technology, it is possible to modify any biological organism on Earth by editing any gene making up its chromosome in just a few hours. Moreover, the basic cost such procedures can be as little as fifty dollars. The new gene-editing technology is often called genetic scissors *(Nurton, 2020)*. A CRISPR intervention is even claimed to be capable of stopping the development of HIV. Scientists have already started work-

ing on a CRISPR system aimed at countering COVID 19. Therefore, commercial and legal interests in this technology only tend to increase. These interests have triggered a flurry of studies in the field of newly-appeared biolaw at the same time as becoming the ground for patent wars. Biolaw regulates an extensive system of legal relations in the sphere of ecology and sociobiology, biomedicine and neurophysiology, genetics and genomics, etc. In the view of politicians and lawyers involved in biolegislation, these aspects involve additional, rapidly burgeoning ethical and practical legal nuances (Rae, 2019; Denisenko & Trikoz, 2020).

In the modern context, existing legal doctrines have generated a new sub-branch of international biolaw involving the legal regulation of genomic studies and practices involved in referring to their results (genomic law). Genomic law may cover the following areas of legal regulation:

– human genetic identity, legal protection of personal data and anonymity of genomic information; the right not to know your genetic makeup; big data genomics; genomic security and legal responsibility; prohibition of genetic weapons (genomocide);

– genomic registration and genetic testing, including gene screening, monitoring, DNA fingerprinting, and forensic genetic examination;

– legal status of persons participating in genomic research; medical, technical, and bioethical aspects of genomic research, including genetic editing and genetic engineering; "Genomic Research Code", "Nuremberg Code";

– provision of services for processing, storage and implementation of the genomic research results; patenting and consumer market, circulation of genetic data; application of DNA technologies in genealogy, palaeontology, genetic certification, gene therapy, biomedicine, sports, etc.

In general, bioethics has been provoked by three aspects:

– the emergence of a new paradigm of human rights in the post-war world and the civil rights movement, embracing the field of medicine and health;

– the rapid development and moral uncertainty in scientific and technological progress, its consequences for the survival of the human race and human well-being as well as concern about the rights of future generations;

– problems of justice in biomedicine and the implementation of the right to judicial protection and access to medical services.

A number of medical services are criminalised by legislation applying in some countries (e.g., surrogacy, trafficking in human organs, tissues, and cells as well as induced abortions). When these services are provided illegally, they pose a direct threat to human biosafety. Taking this fact into consideration, human biosafety should be understood as the normal functioning of the human body from the point of physiology, the integrity, and inviolability of the human body. This might help protect people from various forms of exploitation directly related to medical interventions. Biosafety, in our opinion, should be based on the guarantee and protection of somatic human rights. Criminal attacks on somatic rights endanger the biological well-being of the individual. For example, E.V. Tarasyants presents a detailed study the international legal basis for the protection and promotion of human rights against the backdrop of biomedical research and its significance for the system of human rights generations *(Tarasyants, 2011)*.

Over the past decade, there has been a rapid development of bioethics at the international and regional levels. As a result, the ECHR has considered a number of corresponding cases. From time to time, the ECHR issues reminders that, under Article 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950, member States of the Council of Europe are obliged to protect everyone's right to life. Moreover, the dignity of the human being must be protected from possible misuse triggered by scientific progress *(Trikoz, Gulyaeva, & Belyaev, 2020)*.

In the 21st century, the problem of human genome modifications has become one of the most pressing issues, since changes in germ cells (reproductive cells, including human embryos, eggs, spermatozoa, and their progenitor cells) will be inherited by the patient's descendants *(Montgomery, 2018)*. This implies interference in the lives of future generations who did not consent to such a modification of their genome *(Krekora-Zając, 2020; Trikoz, Mustafina-Bredihina, & Guljaeva, 2021)*. At the same time, this also represents an attack on the very principle of human biological diversity *(Rogers & de Bousingen, 1995)*.

In December 2018, the WHO established a global multi-disciplinary expert panel to examine the scientific, ethical, social, and legal challenges associated with human genome editing (both somatic and germ cell) *(Galichet, Taylor, & World Health Organisation, 2021)*. The panel is engaged in reviewing the literature on the state of the research and its applications as well as societal attitudes towards different uses of the technology. The expert panel is supposed to prepare recommendations for WHO on appropriate oversight and governance mechanisms both at national and international levels. The purpose of this work is to understand how to promote transparency and trustworthy practices at the same time as ensuring that appropriate risk/benefit assessments are conducted prior to any decision on the authorisation of any gene modification technologies.

The European Union has adopted a number of Regulations covering genome editing. For example, Regulation No. 536/2014 of the European Parliament and of the European Council of April 16, 2014 on clinical trials on medicinal products for human use directly prohibits carrying out clinical trials through gene therapies if they result in modifications to the subject's germ line genetic identity (Article 90).

Ensuring Environmental, Biological, and Food Safety in the Context of GMO Foods in the EU

Food and environmental protection issues fall within the areas of shared competence of the EU and the member States. The EU environmental policy on GM grain crops combines production and consumption policies. The EU promotes new food technologies and instructions for food distribution, aiming at the elimination of potential environmental risks related to GMO production.

The EU and the US are still the main centres for shaping the policy to regulate the GM food markets and environmental friendliness of GM foods. With the growth of biotechnologies, the EU system of regulating the production and distribution of GM foods is also dramatically changing. The field of genetic research and genomic modifications of living organisms an the area with the strictest legislation, including in such countries as Norway, Iceland, and Switzerland). Nevertheless, GMOs continue to be used in agricultural practices in those countries, as well as

the production of foods and consumer goods. In Europe, any foods, containing more than 0.9% of authorised GMOs are considered to be genetically modified, while the permissible limit of GMOs that have not been authorised yet is 0.5%. Prior to being placed on European markets, such foods must have a special package labelling, which is supposed to inform potential consumers about the genetically modified nature of a product (European Commission, 2003). The situation is quite different in the USA, Canada, and Argentina where labelling is only required if there is deemed to be a significant change in the quality of the product or any health risk (e.g., allergies) *(Anderson & Jackson, 2003)*.

Most EU member States have adopted comprehensive legislation to regulate such issues as GMO licensing, handling of GM foods and safety requirements in the field of living organism genetics. Meanwhile, conventional regulation developed at the supranational level aims at underpinning the ideological development of regional and communitarian biopolicy (Denisenko & Trikoz, 2020). The 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) was the first to address biosafety issues at such a high level in the context of manipulations with genetic materials, including for medical and research purposes. The Convention granted the ECHR an authority to give advisory opinions on legal questions associated with the protection of the fourth generation of human rights. The EU is generally considered to currently have the strictest legal regulations and restrictions on GMOs in the world[10].

The unified rules based on Regulation (EC) 1829/2003 are especially important. This instrument, which takes into account the WTO rules and regulations as well as the requirements of the Cartagena Protocol on Biosafety of 2000, is considered to comprise the main legal instrument for regulating the production and distribution of GM foods in the EU. It is the basis for decisions on the placement of GMOs on the markets within the entire EU.

In general, pan-European ecological regulations define GMOs as novel foods. The European Food Safety Authority (EFSA) conducts comprehensive and scientifically based assessments of foods based on the following criteria: safety, freedom of choice, labelling, and place of manufacture. In addition, the European Parliament's Committee on the Environmental, Public Health, and Consumer Protection has approved the "safety first" standard for GMOs. That means responsibility for any detrimental health consequences, stemming from GMOs.

In terms of the practice of the European Court of Justice in Luxembourg, the landmark decision of July 25, 2018 has been much discussed. According to this decision, food

[10] The most important EU legal instruments, covering the sphere in question, are the following: Directive 2001/18/EC on the deliberate release of GMOs into the environment; Regulation (EC) 1829/2003 on genetically modified food and feed; Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory; Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms; Directive 2009/41/EC on contained use of genetically modified micro-organisms; and Regulation (EC) 1946/2003 on transboundary movements of GMOs. The Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

suppliers in the EU that work with genetic engineering technologies must strictly adhere to the Union's standards for the use of GMOs in the food industry. The case involved the use of directed mutagenesis techniques, which were based on artificial changes in the plant DNA and the removal of some of its parts. This was done to improve the economic and biological indicators and yields. However, representatives of the French Association of Agricultural Producers were the first to sound the alarm, filing a lawsuit based on concerns about the side effects of mutagenesis for humans, animals and the environment. According to the CJEU decision, all agricultural producers who distribute foods obtained through mutagenesis must label them as GM foods.

No less important is the precautionary principle proclaimed in the ECJ decision of September 13, 2017. The final verdict stated that it would only be possible to prohibit the cultivation of GM foods if there was strong scientific evidence of their harm to human health. In that case, the interests of the Italian Government and the Monsanto Company (US), which was producing genetically modified corn, came into conflict. According Italian scientists, the American genetically modified corn was harmful to human health. Nonetheless, the EFSA concluded that there was no scientific evidence of the danger. The ECJ found that the EU rules on the GM foods and GM feeds were aimed at ensuring a high standard of human health protection and the smooth functioning of the internal market. Consequently, according to opinion of the Justices, it is only possible to completely prohibit GM foods if there is indisputable evidence of substantial health risks associated with them.

Computational selection is becoming a promising area of legal regulation, which in may come to replace genetic modification of foods and other biotechnologies. Computational selection makes it possible to develop promising plant varieties without genetic modifications, relying instead on manipulating information obtained from sensors via AI algorithms (Trikoz & Gulyaeva, 2021). Ensuring Biosafety in the Russian Federation

Currently, the applicable laws and regulations covering biotechnology in Russia comprise the following:

– Presidential Decree "On Measures to Implement the State Scientific and Technical Policy in the Field of Environmental Development of the Russian Federation and Climate Change" of 8 February 2021;

– Federal Law "On Biological Safety in the Russian Federation" of 30 December 2020;

– Forest Code of the Russian Federation;

– Federal Law "On Amendments to the Law on State Regulation of Production and Sales of Ethanol, Alcoholic Beverages, and Alcohol-Containing Products" of 28 November 2018;

– Strategy for the development of forestry complex in Russian Federation until 2030;

– Federal Law "On Amending Certain Legislative Acts of the Russian Federation to Improve State Regulation of Genetic Engineering Activity" of 3 July 2016;

– Federal Law "On Biomedical Cell Products" of 23 June 2016 amended by the Federal Law "On Amendments to Certain Legislative Acts of the Russian Federation on the Issue of Circulation of Biomedical Cell Products" of 3 August 2018.

A landmark legal event is the adoption of the Federal Law "On Biosafety in the Russian

Federation" of 30 December 2020. The Law regulates biosafety activities in the Russian territories. Russia is planning to set up a state information system on biosafety. The system will help monitor biological risks as well as developments in the field of biology, biotechnology, and genetically modified foods. The Law introduces a wide range of terms related to ensuring the protection of Russian citizens against biological and chemical threats. Prior to the adoption of the Law, there was no conceptual framework in Russian legislation, defining activities for ensuring the biosafety of citizens. The substantive part of the Law defines the foundations of state policy and the powers of the federal and regional authorities in the area. In addition to the unified information system for monitoring and controlling the spread of infectious diseases, the Law introduces surveillance over the production, consumption, and cross-border movement of antimicrobial drugs that can provoke human resistance (insensitivity) to antibiotics. Such drugs will in future be available only on a doctor's prescription. The Law also defines measures to prevent terrorist attacks and sabotage through the use of biological weapons.

A draft federal law "On the Legal Foundations of Bioethics and Guarantees of Its Ensuring" has been introduced in Russia. The draft law establishes the legal foundations of State policy ethics in the field of healthcare. In addition, Russia has undertaken international obligations on personal data protection. This has been done by adhering to the Protocol, amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. The Protocol enshrines the protection of new human rights. It contains stipulations concerning the principles of proportionality, minimisation and legality of the collection, processing and storage of personal data. A new category of sensitive data has been introduced, i.e., genetic data *(Federal Law 'On Personal Data' in the Russian Federation, 2006, Art. 5)*.

The Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing has developed a draft law on the inclusion of genetic data into the concept of special categories of personal data. New definitions cover new citizens' rights to manage their personal data during their processing through mathematical algorithms, artificial intelligence, etc. Under the draft law, personal data operators are obliged to notify the authorised supervisory body about data leaks. A clear regime for cross-border data flows is also fixed therein[11].

Conclusion

In current international law, the need to resolve problems associated with adopting a Protocol for establishing an international control mechanism for verifying prohibitions on the development, production, and stockpiling of biological weapons is becoming increasingly urgent. The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction adopted in 1993, which contains a mechanism for verifying compliance with

[11] On October 10, 2018, the representative of Russia signed the Protocol, amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. The purpose of the innovations is to increase the degree of personal data protection at the international level. The Convention is currently the only legally binding fundamental international document on personal data protection.

the prohibitions of the Convention, can be considered a precedent for the effective regulation of the circulation of hazardous substances all over the world. In 2013, during the war in Syria, the international community resorted to this mechanism, using it as a peaceful means of resolving international disputes described in Article 33 of the UN Charter. Biological weapons are a fundamentally different challenge in comparison to nuclear and chemical weapons. Diplomatic attempts to create a Protocol to the BWC have encountered political and technical difficulties. This fact proves how difficult it is to exercise international control over biological weapons.

The use of new types of biological weapons by terrorist organisations constitutes a real threat to the States of the world. Combating bioterrorism is different from combating chemical and nuclear terrorism since, in the case of bioterrorism, the health of the nation and the integrity of the healthcare system are at risk. The quality of the national infrastructure and public health capabilities are prioritised for ensuring national security and defence of the country in order to combat bioterrorist attacks.

Independent States face new challenges and threats affecting their core sovereignty and national security as a result of a number of biosecurity issues. The most commonly cited challenges are phenomena directly related to human and social activities, which, alongside other challenges are indirectly related to the human activity, making it harder if not impossible to manage the risks. In this category can be mentioned the annually increasing migration flows, the growing wealth-gap between States, the global terrorist threat, as well as acts of collective xenophobia and intolerance. When talking about challenges that are weakly or not at all dependent on the will of individuals and States, researches tend to imply extraplanetary threats, viral and biological hazards, global warming and other natural disasters. As can be seen, the national security of many States currently depends on factors that need to be studied and analysed taking into account not only the rapidly changing political environment but also the introduction of the state-of-the-art technologies. While the citizens of contemporary States may benefit from the opportunity to recover from a disease (e.g., through the transplantation of human organs, tissues, or cells), or even build up a family (*in vitro* fertilisation) thanks to contemporary technologies, this sphere has also become a tool for obtaining illegal benefits and violating human rights. Social and individual biosafety is threatened because many scientific and biomedical achievements due to poor legal regulation in most countries of the world. Despite the fact that the international community has in one way or another regulated some aspects of services related to surrogacy, transplantation and abortion, there are no unified sources of law for uniformly combatting international crime threatening biosafety and biosecurity, at the same time as ensuring reproductive and somatic human rights. Therefore, there is a need in the international community to create a regulatory framework that includes the legal basis for limiting the use of neurotechnology, the legitimacy criteria for the use of modern medical technology on people, as well as providing full protection of the rights and fundamental freedoms of patients through the responsible promotion of neurotechnology, both in domestic and international law. Thus, effective mechanisms should be created and maintained at global and regional levels within in-

ternational collective security organisations. A Commission should be set up to investigate biosafety crimes.

The emergence of such neuro rights as (i) cognitive freedom; (ii) mental privacy; (iii) mental integrity; and (iv) psychological continuity is worth noting. Internationally and nationally, it is necessary to legally formalize such terms as "neuro-right", "cognitive freedom", "neurohacking", "neurodopping", "neurocide", human brain transplants", etc., as well as the terms "neuroculture", "cognitive freedom", "brain implant transplants" and others. Universally agreed upon and established behavioral rules and norms should be instituted that prove effective in preventing the manipulation of human thoughts, feelings, and neural information by modern digital, pass-through technologies. In the adopted Russian Federal Law "On Biological Safety in the Russian Federation", a separate provision is devoted to international cooperation in the field of biosafety. Russia's foreign policy is focused on strengthening the regime of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriolog-

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https://doi.org/10.17803/lexgen-2022-1-1-56-62

Original article

Genetic Information in the Light of Genetic Discrimination: the Experience of Foreign States

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Abstract

Background. Genetic information is often used for purposes of discrimination. For example, the results of genetic testing can demonstrate a high risk of developing a disease in an apparently healthy person, which will require expensive medical care. Such information may affect the decision on the employment of a candidate for a job or the conditions for concluding an insurance contract with him/her.

Objective. The article discusses major issues of legal regulation of public relations arising from protection against discrimination based on genetic status in the legislation and law enforcement practice of a number of foreign countries (Australia, Canada, the USA).

Design. 20 studies written in English were retrieved from Scopus and Web of Science databases.

Results. The research methodology is based on dialectical, logical, predictive methods, system analysis, content analysis, as well as private scientific methods (statistical, technical legal, comparative legal methods). The article provides an overview of the international legal framework for the regulation of public relations arising from countering discrimination based on genetic status, as well as key acts of leading foreign jurisdictions and law enforcement practice.

Conclusion. In conclusion, the author reflects on the advisability of implementing relevant foreign experience into the Russian legal system.

Keywords: discrimination, genetic information, legal regulation, protection of rights, indigenous peoples, informed consent

Acknowledgments: This article is based on the results obtained within the framework of the State assignment of the Ministry of Education and Science of Russia 730000Ф.99.1.БВ16АА02001 ('Scientific and methodological support', Kutafin Moscow State Law University); the Russian Foundation for Basic Research grants 18-29-14078 MK and 18-29-14054 MK.

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To cite this article: Ponomareva, D.V. (2022). Genetic information in the light of genetic discrimination: the experience of foreign states. *Lex Genetica*, 2022;1(1):56–62. https://doi.org/10.17803/lex-gen-2022-1-1-56-62

Received 15.11.2022
Review completed 16.12.2022
Passed for printing 03.01.2023

Introduction

Genetic information is often used for discrimination purposes. For example, the results of genetic testing can reveal a high risk of developing a disease in an apparently healthy person, which will require expensive medical care. Such information may affect decisions on the employment of a candidate for a job or the conditions for concluding an insurance contract (Gadzhiev & Gusov, 2017). Canadian media report frequent cases of discrimination against applicants by insurance companies, who base their calculations on test results predicting the potential for hereditary diseases. Some countries (the USA, Australia, EU member states) have adopted relevant legislative acts on counteracting discrimination on the basis of genetic status *(Feldman, 2012)*.

Methods and materials

The international legal framework for combating genetic discrimination is formed by the following documents:

– UNESCO Universal Declaration on the Human Genome and Human Rights, 1997;

– UNESCO International Declaration on Human Genetic Data, 2012;

– Council of Europe Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ("Oviedo Convention"), 1997;

– Additional Protocol to the Convention on Human Rights and Biomedicine on Genetic Testing for Medical Purposes, 2008.

These documents include a general prohibition of genetic discrimination and stigmatisation based on genetic status (Adams, Donnelly, & Macdonald, 2015). At the same time,

the difference between stigma and discrimination can be seen in the fact that stigmatisation is not necessarily associated with a restriction in the enjoyment of individual rights. Stigmatisation, in particular, can take the form of words or actions that impose a stigma on a person or a group of persons due to some of their known or supposed features *(Tiller, Otlowski, & Lacaze, 2017)*.

Specification of the spheres of dissemination of discriminatory practices was carried out at the level of domestic regulation. Genetic discrimination concerns three main areas: employment, insurance, consumer services. Issues related to combating discrimination based on the genetic status of the most vulnerable groups of persons (indigenous peoples, ethnic communities, etc.) require a special attention. At the same time, two main models of legal regulation of genetic discrimination, namely, American and Australian are presented at the national level *(Gerards, Heringa, & Janssen, 2005)*.

The American model of legal regulation of genetic discrimination presupposes the issuance of a single comprehensive legal act on these issues. In 2008, the USA passed

the Genetic Information Nondisclosure Act (GINA), which limits its considerations to genetic testing in the context of health insurance and employment *(Flynn, Cusack, & Wallen, 2019)*. At the same time, the provisions of law do not apply to life insurance, disability and long-term care insurance. This act is primarily aimed at determining the cases in which genetic testing for research purposes can be performed. In addition, it is stated that reference to 'genetic information of an individual' also includes a foetus or embryo for regulatory purposes *(Keogh & Otlowski, 2013)*. In addition, the law prohibits the adjustment of premiums in connection with certain genetic information as part of a collective insurance agreement. The act provides an opportunity for workers to lodge complaints against their employers in case of discriminatory treatment based on genetic status. At the same time, the document discloses cases and conditions when mandatory genetic testing may be required *(Motoc, 2009)*. In particular, it may be necessary for 'genetic monitoring of the biological effect of toxic substances in the workplace', subject to the requirement to ensure confidentiality *(Steck & Hassen, 2019)*.

The Australian Genetic Discrimination Legal Model is an interconnected system of regulations containing provisions to counter discrimination on the basis of genetic status for various social groups. In 1992, the Commonwealth of Australia passed the Disability Discrimination Act 1992 containing a similar provision. At the same time, the regulations allow for discrimination in relation to the insurance sector if there are sufficient grounds. Insurers have the right to use information on the results of genetic testing even in the absence of obvious signs of the disease in order to refuse insurance payments or increase insurance premiums in the case of life, income, travel insurance. However, the legislator emphasises that the discriminatory attitude must be reasonably justified *(Rothstein, 2018)*. The insurers are obliged to consider all possible measures to reduce the risk of an insured event, including constant medical supervision or surgery. This requirement distinguishes between legitimate (but ethically controversial) discrimination based on genetic status within the scope of applicable law, and unlawful genetic discrimination, which suggests that the insurer's behaviour violates regulations *(Chapman, Mehta, Parent, & Caplan, 2020)*.

Legal regulation is formed at three levels: federal, state, and local. The federal level is represented by the following main acts affecting aspects of discrimination in the field of insurance: the Sex Discrimination Act 1984, the Race Discrimination Act 1975 and the above-mentioned Disability Discrimination Act 1992. Moreover, the Acts of 1984 and 1992 include special provisions on the admissibility of discrimination in the field of insurance in the presence of certain circumstances. The 1975 Act does not contain such a provision. At the same time, it limits the information that insurers are allowed to use in underwriting applications in order to ensure that payments are received if an insured event occurs. Thus, insurers may not differentiate between applicants on the basis of race even though life expectancy of indigenous Australians is known to be noticeably lower than that of the Caucasian population as a whole *(Hao, Macdonald, Tapadar, & Thomas, 2016)*.

Regarding the legislation at the state and local level, in each case it is a separate regulation in the field of insurance and non-discrimination *(Lemke, 2005)*. Not surprisingly,

states and territories adopted the provisions of the 1992 Insurance Discrimination Act under certain conditions. However, this does not exclude the possibility of conflicts of laws adopted at various levels *(Dupras, Song, Saulnier, & Joly, 2018)*.

Results and discussion

Genetic discrimination concerns three main areas: employment, insurance, services. The issues of discrimination on the basis of the genetic status of the most vulnerable groups of the population, which include ethnic communities and indigenous peoples, form a separate category *(Gammon & Neklason, 2015)*. Special attention should be paid to the following aspects of discriminatory practices:

– use of the so-called 'incomplete' informed consent for biomaterials from ethnic communities;

– lack of consideration of traditions and customs of peoples in the implementation of manipulations with biomaterial and genetic data;

– protection of national identity and counteraction to the exploitation of the genetic material of ethnic communities by representatives of the scientific community;

– unfair distribution of remuneration (benefits, preferences) from the use of genetic information *(Underhill-Blazey & Klehm, 2020)*.

The practice of Australia is of particular significance in this context. Australian Aborigines have long participated in scientific research whose object was to obtain their genetic information. Moreover, the objects of research were not only limited to biomaterials of living people, it also included genetic information extracted from the remains of deceased representatives of indigenous peoples stored in museum collections. The case of Attorney-General v. The Trustees of the British Museum considered the issue of the possibility of transferring genetic material on display at the London National Museum of History to Australia for the purpose of burying the remains of Tasmanian aborigines in accordance with traditional rites *(Taylor, Treloar, Barlow-Stewart, Stranger, & Otlowski, 2008)*.

Representatives of the Historical Museum's board of trustees argued as part of the dispute that the return of Aboriginal remains after scientific testing should aim to strike a balance between what the trustees themselves believed were 'two opposing views on how to proceed. On the one hand, the museum considered the possibility of returning the remains to the country of origin; on the other hand, it seemed necessary to use this invaluable and unique resource for the purposes of scientific research'. The board of trustees were determined to extract DNA samples from the remains, as they "represent the human population at a time when Tasmania was isolated from the rest of the world, and such scientific information could allow future generations to learn more about how their ancestors lived, where they came from." At the same time, the board of trustees recognised the unlawfulness of the seizure of the remains from the Tasmanian aborigines, which created the legal basis for their return *(Taylor, Treloar, Barlow-Stewart, Stranger & Otlowski, 2008)*.

Due to the length of the proceedings and the increasing legal costs, the Museum's Board of Trustees agreed to use mediation to resolve the dispute, as suggested by a High Court judge. Each of the parties appointed a mediator who jointly tried to bring the parties to an agreement by balancing their interests. The Museum pursued

the need to protect scientific interests, considering the collection of data and the preservation of genetic material as fundamental for future research. According to Tasmanian traditions, the Aborigines, on the other hand, wanted the remains to be preserved in their original form, and opposed "any physical interference and the permissibility of desecration of the remains in the future". Ultimately, the mediator managed to convince the parties to agree to a mutually acceptable compromise. Aboriginal people recognised the importance of the Museum preserving the collected DNA collection, and the Museum staff, in turn, agreed that the remains and all related documentation should be transferred to the Tasmanian medical institution *(Otlowski, Taylor, & Bombard, 2012)*.

Thus, as well as raising the question of who owns the DNA collection, the process invoked a consideration of how to 'balance' the museum's ownership of biomaterials and the determination of the Tasmanian Aboriginal Study Center to protect "Aboriginal cultural and spiritual beliefs". Under Australian common law, human remains cannot be subject to ownership (the 'zero-ownership rule') unless the object has been transformed to the point where it can be considered a work of art. At the same time, at the international legal level, the importance of obtaining the consent of indigenous peoples when handling the human remains of their ancestors is recognised *(Otlowski, Taylor, & Bombard, 2012)*.

The 2007 United Nations Declaration on the Rights of Indigenous Peoples explicitly states that 'indigenous peoples have the right to respect and revitalise their cultural traditions and customs' and that 'states provide remedies through effective mechanisms, which may include restitution, developed in collaboration with indigenous peoples, with regard to their cultural, intellectual, religious and cult property, alienated without their free, prior and informed consent or in violation of their laws, traditions and customs' (Article 11). The internationally proclaimed need to ensure the protection of the rights and legitimate interests of indigenous peoples can become an effective tool in countering their discrimination, including with respect to the right to repatriate the remains of their ancestors, the right to use DNA materials, in particular to interfere with them for scientific purposes only with indigenous peoples' consent *(Slaughter, 2008)*.

Discriminatory practices often manifest themselves in relation to the use of 'incomplete' informed consent for biomaterials from representatives of ethnic communities. Noteworthy in this context is the American case 'Havasupai Tribe v. Arizona Board of Regents', which addressed the use of DNA samples from tribal representatives for purposes other than the initial collection of genetic data. The case was resolved in favour of the tribe: tribal members received $700,000 in direct compensation, funds for the tribal clinic and school, and the return of DNA samples. It was agreed that the genetic material was to be disposed of in a special ceremony *(Sorokina & Ponomareva, 2020)*.

The Havasupai case challenged the concept of informed consent, especially for vulnerable populations, pointing out that extended consent forms and incomplete disclosures did not lead to a full understanding of the research needed to make a truly informed decision to participate in health projects. It also raised the issue of the need to conduct research with the participation of indigenous peoples in a fair and non-dis-

criminatory manner, including addressing the issue of how to deal with 'old' DNA samples and 'old' informed consent when working with the modern generation of participants in genetic research. While DNA samples have unquestionable value, they become less usable as they 'mature', and long-time informed consent prevents the use of samples today. The Havasupai case also raises the question of how before legal community should treat the original, 'old', but valuable DNA samples.

Legal regulation of the use of genetic information of the most vulnerable groups of the population in scientific research requires a special approach from the point of view of ensuring a balance of regulation and traditions, ethics and law. The law enforcement practice of Australia and the United States in this matter clearly demonstrates the emerging tendency to take human rights (the rights of indigenous peoples) into account when deciding on the transfer of biomaterials and their re-use in scientific research (Sorokina & Ponomareva, 2020).

Conclusion

The development of legal regulation of genetic discrimination requires a special approach in terms of ensuring a balance between legal regulation and traditions, ethics and law. Considering the issue of the possibility of implementing the best foreign practices into Russian legislation, it is important to emphasise that the relations arising from countering discrimination on the basis of genetic status are not currently reflected in the realities of the Russian Federation's legislation. Amendments to the legislation should take account of emergent social relations and practical issues related to their regulation. Until such time, the legal community can limit itself to the formulation of norms and principles (including general prohibitions such as that of genetic discrimination) enshrined in a number of international treaties in the field of genomic research, which may in the near future be ratified by the Russian Federation (in particular, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: 1997 Convention on Human Rights and Biomedicine).

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https://doi.org/10.17803/lexgen-2022-1-1-63-74

Original article

Algorithmic Bias and Non-Discrimination in Argentina

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Abstract

One of the major research problems related to artificial intelligence (AI) models at present is algorithmic bias. When an automated system "makes a decision" based on its training data, it can reveal biases similar to those inherent in the humans who provided the training data. Much of the data used to train the models comes from vector representations of words obtained from text corpuses, which can transmit stereotypes and social prejudices. AI system design focused on optimising processes and improving prediction accuracy ignores the need for new standards for compensating the negative impact of AI on the most vulnerable categories of peoples. An improved understanding of the relationship between algorithms, bias, and non-discrimination not only precedes any eventual solution, but also helps us to recognize how discrimination is created, maintained, and disseminated in the AI era, as well as how it could be projected into the future using various neurotechnologies. The opacity of the algorithmic decision-making process should be replaced by transparency in AI processes and models. The present work aims to reconcile the use of AI with algorithmic decision processes that respect the basic human rights of the individual, especially the principles of non-discrimination and positive discrimination. The Argentine legislation serves as the legal basis of this work.

Keywords: algorithmic bias, discrimination, artificial intelligence, explainable AI, transparency, human rights

To cite this article: Farinella, F. (2022). Algorithmic bias and non-discrimination in Argentina. *Lex Genetica*, 2022;1(1):62–74. https://doi.org/10.17803/lexgen-2022-1-1-63-74

Received 15.11.2022
Review completed 16.12.2022
Passed for printing 03.01.2023

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Introduction

The development of technologies aimed at understanding the functioning of the brain paves the way to intervene directly in its processes, and consequently, to manipulate human brain activity. While such technologies may be claimed to be neutral, they may have both positive and negative consequences depending on how they are used. The claimed possibility of deciphering the neural code implies ethical challenges in terms of novel medical and technological applications that could be realised on the basis of such an informational infrastructure. Thus, the need to recognise new rights related to neuroscientific technologies is a topic of current discussion. While the various algorithms forming an artificial intelligence (AI) program may be transparent and specific, any AI or neurotechnological intervention in the brain's activities suffers from the same deficiencies as the humans who design them or intervene in their creative processes in terms of prejudices or biases. Banjali and Greenwald (2013) remind us that even the most ostensibly well-intentioned people may possess unconscious or implicit biases against other groups.

The present work discusses the problem of biases applying in AI and neurotechnology. In a postmodern age, such algorithmic biases can be used to surreptitiously perpetuate individual and social discrimination. Even unconscious personal biases can be easily transferred to products that make use of AI to generate discriminatory results. Reliance on data generated by AI does not give algorithms a presumption of veracity. This is so because in addition to the prejudices that may exist at the time of software design, we must consider that the data on which it is based may also be biased. If these data express a present reality that discriminates against certain groups, their use by AI is consequently likely to reinforce existing patterns of discrimination *(Mayson, 2018)*. Beyond the speed and efficiency with which a problem can be solved, neither AI nor neuroscience guarantee the justice of the decisions made through their use. The realisation of justice as a human value (even through the use of technology) requires some degree of human intervention.

In early 2016, Microsoft launched Tay, an AI chatbot that was supposed to mimic the behaviour of a curious teenage girl engaging in discussions with Twitter users. While the stated intention was to demonstrate the potential of conversational interfaces powered by AI, in less than a day, innocent Tay had apparently become a racist, misogynist Holocaust denier *(Metz, 2018)*. Thus, the myth of algorithmic impartiality failure was debunked, sparking discussions concerning potential solutions to the identified biases. Reasons behind biases in software can be found in machine learning and deep learning processes underpinning AI. Deep learning algorithms rely on very large quantities of data. The more tagged data an algorithm records, the better the result. However, as data are recognised, deep learning algorithms develop blind spots based on missing data or excess data relative to what is trained. This will be the beginning of its bias. Tay, for instance, did not have the opportunity to interact with respectful, non-discriminatory, open-minded or empathic people.

Non-Discrimination and Bias

The prohibition of discrimination is a vital pillar of international human rights law and can already be considered part of jus cogens. The right to equality before the law and the principle of non-discrimination are

provided in the Argentine Constitution (Argentine Const. art. 16, 19, 22, 23, 37, 75) and the American Convention on Human Rights, as well as in various international instruments that employ a constitutional hierarchy[1].

The Supreme Court of Justice of Argentina has ruled on numerous occasions on the scope of Article 16 of the National Constitution confirming that equality before the law involves the duty on the part of the State to 'treat equally those people who are in identical circumstances' (Supreme Court of Justice, Argentina, Sentences 16:118) and furthermore, that 'equality before the law (...) is nothing other than denying the creation of exceptions or privileges that exclude some people from what is granted to others under the same conditions' (Supreme Court of Justice, Argentina, Sentences 153:67).

Discrimination consists not only in making a distinction or difference, but implies the unfavourable treatment of a person in a particular circumstance as prohibited by law. Certain differentiated treatments are even legal. In this sense, when determining the scope of the Discriminatory Acts Law (Law No. 23, 592), the Supreme Court of Argentina argued that the Law:

(...) does not sanction all discrimination, but exclusively that which arbitrarily restricts in some way or undermines the full exercise on equal bases of the fundamental rights and guarantees recognised in the National Constitution' (Supreme Court of Justice, Argentina, Sentences 314:1531 and ss).

In the words of the Inter-American Court of Human Rights (IACHR):

'Not all different legal treatment is properly discriminatory, because not every distinction in treatment can be considered offensive to human dignity. There are certain inequalities in fact that can be translated into justified inequalities of legal treatment, which express a proportionate relationship between the objective differences and the aims of the norm' *(Inter American Court of Human Rights, Advisory Opinion OC-4/84 of 01/19/1984, § 56-58)*.

In this context, both private companies and state institutions increasingly rely on the automated decisions of algorithm-based systems, all of which could potentially involve the discriminative use of AI models and algorithms. As stated by the Inter-American Court, obligations in matters of equality and non-discrimination fall under the powers of the State, as well as applying to individuals, since the obligation:

'(...) extends as much with respect to those cases in which the discriminatory situation is the result of the actions and omissions of the public powers as when it is the result of the behavior of individuals' *(Inter-American Court of Human Rights, Consultative Opinion 18/03, § 4)*.

A study conducted by the Institute for Technology Assessment and Systems Analysis in Karlsruhe (Germany) on behalf of the German Federal Agency Against Discrimination, found that, although AI increases efficiency to save time and money, it also carries risks of discrimination against individuals or vulnerable population groups.

In an increasing number of categories, such as granting a loan, hiring new staff members, or making legal decisions, algorithms are applied to decision-making or helping human decision makers to come to a final decision. In both cases, this circumstance affects the lives of other individuals. Carsten Orwat, who works at the Institute for Technology Assessment and Systems Analysis, states that "situations become particularly critical when algorithms operate on inaccurate data and

are based on criteria that must be protected, such as age, gender, ethnicity, religion, sexual orientation and disabilities" (Karlsruhe Institute of Technology, 2019). Biased data samples can teach machines that women shop and cook, while men go out to work. This type of problem occurs when the training the data provided by scientists reflects their own prejudices *(Mullane, 2018)*.

The study of algorithmic bias focuses on algorithms that reflect some type of systematic and unfair discrimination and has only recently begun to be considered for the purposes of its legal regulation, for example with the General Data Protection Regulation of the European Union (2018).

Areas of protection against discrimination and biased algorithms

When talking about illegal discrimination, it is necessary also to note that the law seeks to protect vulnerable groups, which, depending on their characteristics, tend to be usual victims of discrimination. This circumstance gives rise to a list of "suspicious" or "prohibited" categories. Generally speaking, such categories include race, gender, religion, political opinions, national or social origin, economic status, as well as certain physical characteristics.

The standardisation of suspicious categories is useful in order to distinguish the work to be performed by the justice as well as to know the distribution of the burden of proof in a legal process. When differences in treatment are based on such "suspicious" categories, a rigorous test of reasonableness is required. On occasions, the norm or practice is analysed by means of a "standard scrutiny", which attempts to maintain a balance between the parties regarding the burden of proof, and where the applicant must prove that the differential treatment to which he or she was allegedly subjected is in violation of the principle of non-discrimination, as unconstitutionality is not presumed. In other situations, a "strict scrutiny" approach should be used: the contested rule or practice is presumed unconstitutional, and it is for the defendant to prove that it pursues a legitimate, relevant and imperative purpose, and that the means he/she chose is suitable, essential and constitutes the less harmful alternative in terms of the rights of those people affected.

European Union regulations distinguish specific areas of protection such as employment, welfare and social security, education, access to the supply of goods and services including housing, access to justice, private and family life, adoption, domicile and marriage, political participation, freedom of expression, assembly, association, free elections and criminal matters. It also protects against discrimination on various grounds, specially including: sex, gender identity, sexual orientation, disability, age, race, ethnic origin, colour and pertaining to a national minority, religion or beliefs, social origin, birth or property, language, and political or other opinions.

Article 14 of the European Convention on Human Rights and Fundamental Freedoms (ECHR) applies in relation to the enjoyment of the substantive rights recognised therein; while Protocol 12 to the ECHR protects all rights recognised at the national level, even those not protected by the ECHR. In contrast to this, the prohibition of discrimination emanating from the EU Directives applies only in three areas: (i) employment, (ii) the social welfare system and (iii) goods and services. The Racial Equality Directive also applies to such areas only. As regards the Directive, when it refers to equal treatment in employment, it is only applied

to labour matters, even though its extension to the other aforementioned areas is currently being debated. The Directive on equal treatment between men and women and the Directive on equal treatment between men and women in terms of access to goods and services only apply to the aforementioned contexts, but not in relation to access to the social welfare system *(de Europa & de Derechos Humanos, 2019)*.

In Argentina, the law penalises discriminatory acts, paying particular attention to 'discriminatory acts or omissions determined for reasons such as race, religion, nationality, ideology, political or union opinion, sex, economic position, social condition or physical characteristics' (Anti-Discrimination Law, 1988). The Office of the Public Prosecutor of the Nation distinguishes several types of discrimination: (i) against women; (ii) based on sexual orientation; (iii) based on disability; (iii) religious reasons; and (iv) other reasons *(MPF Argentina, 2012–2017)*. The regulations of the Autonomous City of Buenos Aires distinguish between discrimination in facts and in law, the latter being able to manifest itself directly or indirectly *(Law No. 5261, 2015)*.

There are some well-known examples of discrimination by algorithms. First, in the case of women, international obligations on non-discrimination require the State to adopt positive action measures to counteract gender segregation and reverse the sociocultural patterns that explain it *(Assembly, 1979, art. 2, 4)*. The Committee of the Convention emphasized that such measures are intended to accelerate the participation of women in the political, economic, social, cultural and civil spheres under conditions of equality. These measures may consist of outreach and support programs, reallocation of resources, preferential treatment, determination of hiring and promotion goals, and quota systems *(Assembly, 1979, General Recommendation 25, § 22)*.

The Committee for the Elimination of all Forms of Discrimination against Women warned that the States parties to the Convention must guarantee through the competent courts and the imposition of sanctions or other forms of reparation, the protection of women against discrimination committed both by public authorities and by organisations, companies and individuals (Assembly, 1979, art. 4). It also recommended that States should make greater use of temporary special measures in matters of employment aimed at achieving equality *(Assembly, 1979, General Recommendation 5, § 18)*.

Stereotypes and practices that devalue the feminine are found not only in real life but also in virtual life (*Consejo Nacional para prevenir la Discriminación*, 2016). The reinforcement of stereotypes and consequent deepening of silent discrimination against women is accentuated by the use of AI. For example, a algorithm-led search for cooking-related activity produces 33% more women than men in a normal internet search. If we add to the same activity, the training of the program from a continuous search, the figure grows from 33% to 68%. Researchers from Cornell University set out to correct this type of algorithm, but only with the hope of maintaining the deviation from the initial stage, since according to the current state of the art, it is not possible to correct it. To achieve this end, the authors designed an algorithm based on Lagrangean relaxation for collective inference *(Zhao, Wang, Yatskar, Ordonez, & Chang, 2017)*.

Second, the State and individuals are obliged to adopt positive action measures

to counteract gender segregation, as well as to reverse the socio-cultural patterns that structure segregation. Relevant human rights treaties expressly prohibit discrimination based on gender, economic position and origin, or any other social condition[2]. O'Neil (2018) refers to the setback suffered by Amazon when trying to hire staff through a learning machine. After testing the program, Amazon found that it only repeated the male bias of the technology industry to the detriment of women and other dissidences.

Third, a person's sexual orientation cannot constitute sufficient ground for restricting a right *(Inter-American Court of Human Rights, Judgment of February 24, 2012)*.

In 2009, Amazon removed 57,310 books from its ranking of best sellers, after an algorithmic change flagged as "adult content" books that dealt with sexuality issues (basically gay and lesbian issues). These titles disappeared from the site until the reason was known, upon which blame was apportioned to algorithms and the titles returned to their former ranking *(Kafka, 2009)*.

Fourth, people with disabilities shall enjoy the guarantee of the effective enjoyment of rights on equal terms with any other. For this to be possible, certain "reasonable adjustments" should be carried out to software programs. The new social model of disability implies making such adjustments and providing technical support, so that people with disabilities can fully exercise their rights. The so-called 'reasonable accommodations', according to the language used by the Convention on the Rights of Persons with Disabilities *(The United Nations, 2006, art. 2)*, are those necessary and adequate adaptations that do not impose a disproportionate or undue burden, when required in a particular case, in order to guarantee people with disability the enjoyment or exercise of all fundamental rights on an equal basis with the others.

Notwithstanding what has been said, software can also passively discriminate against certain people. For example, the algorithms of autonomous cars are trained to know what pedestrians look like so as not to run over them. If the training dataset does not include people in wheelchairs, the technology could become a life-threatening hazard. Algorithmic fairness to people with disabilities is a different problem than fairness to other vulnerable groups such as those based on race or gender. Many systems consider race or gender as simple variables with a small number of possible values. But as regards disability, there are several forms and grades of severity. Some are permanent, others are temporary. Thus, it is a dynamic group. Privacy of information and sensitive data are interrelated here. The first thing that comes into one's mind is that if the program does not know the user's disability, it will not discriminate against him/her. But in relation to disabilities, this is not the case. Information on disability should be provided as it often involves necessary information. Let's take the example of a person with visual impairment, who needs to use a screen reader to access the internet and takes an online test to access a job. If the test program is not

[2] Among the main documents we find articles 1.1, American Convention on Human Rights; 2, 3 and 26, International Covenant on Civil and Political Rights; 2 and 3, International Covenant on Economic, Social and Cultural Rights; 2, American Declaration of the Rights and Duties of Man; 2, Universal Declaration of Human Rights; and Convention on the Elimination of All Forms of Discrimination against Women.

well designed and is not accessible to the applicant, it will take longer for the applicant to navigate the page and answer the questions. Thus, people with a similar disability will face a systemic disadvantage (Hao, 2018).

Fifth, the right to freedom of religion and conscience encompasses, among other aspects, the right not to be discriminated against for one's religious beliefs. The Supreme Court of Justice of Argentina stated that:

'[freedom of religion and conscience is] (…) a particularly valuable right that includes respect for those who hold religious beliefs and for those who do not hold them' (Supreme Court of Justice of Argentina, Sentences 312:496).

According to the Argentine Constitution and other relevant international documents ratified by Argentina, freedom of religion and conscience has different aspects: the freedom to possess/not possess beliefs of one's own choice without suffering external interference, the right not to be discriminated against for religious beliefs, and the freedom to be educated according to one's own convictions.

In 2019, Facebook faced legal proceedings initiated by the US government for allowing advertisers to deliberately target advertising based on religion, race, and gender. Using this strategy, companies excluded people of a certain race, age, or gender from viewing housing advertisements, in violation of the Fair Housing Act. In another case, a group calling themselves "enlightened souls" that publish content related to spirituality, ancient practices, the worship of goddesses, etc., became a victim of biased Facebook ads. This occurred when the social network, which uses targeting algorithms, removed an ad that contained images of the goddess 'Kali' along with other goddesses, erroneously labelled as sexual content *(E-Hacking News, 2020)*.

Finally, with regard to discrimination for reasons different than those expressed, when the existence of a discriminatory circumstance is alleged, it is up to the defendant to prove that the allegedly discriminatory act was caused by an objective and reasonable motive, unrelated to any discrimination:

'…In cases in which Law 23,592 is applicable, and the existence of a discriminatory motive is disputed (…), it will be sufficient, for the party that affirms said motive, the accreditation of facts, prima facie evaluated, that result suitable to induce their existence, in which case the defendant who is accused of committing the contested treatment will be the proof that it was caused by an objective and reasonable motive unrelated to any discrimination (…)' (Supreme Court of Justice of Argentina, Sentences 334:1387).

Digital discrimination and responsible algorithms

We have seen that in certain cases programmers transfer their biases (even involuntarily) to the algorithms of the programs they create. The automatic training tools of a computer system expose it to the assimilation of a large and relevant amount of data, so that the program learns to make judgments or predictions about the information it processes based on the observed patterns. In a simple example, if someone wants to train a computer system to recognise whether an object is a book based on certain factors (e.g., texture, weight), such factors are provided to the system, and the software is programmed in order to recognise in which case the objects are books and in which they are not. After multiple tests, the system is supposed to learn what a book is and be able to predict without human help wheth-

er a certain object is/not a book, depending on the data received.

It has been demonstrated that when scientific or technological decisions are based on a limited set of systemic, structural or social concepts and norms, the created technology can privilege certain social groups and harm others. AI models are determined by different biases that reproduce and sometimes amplify the power relations that underlie reality. The examples cited above exemplify this statement.

We should also discuss so-called "sexist" or "racist" algorithms. In terms of everyday applications to complex algorithms, Ruha Benjamin (2019) describes how emerging technologies can reinforce "white supremacy" to deepen social inequity, arguing that automation has the potential to conceal, accelerate, and deepen discrimination. A similar issue arises in the application of AI in areas of criminal justice. In 2016, an investigation on judicial software conducted by a non-governmental organisation called ProPublica revealed that algorithms used by US law enforcement agencies erroneously predict that black defendants are more likely to commit repeat offenses than white defendants with similar criminal records *(Angwin, Larson, Mattu, & Kirchner, 2016)*.

Noble (2019) presents the idea that search engines like Google offer an ideal playing field for discrimination of ideas, identities and activities. Considering data discrimination as a genuine social problem, Noble (2019) argues that the combination of private interests in promoting certain sites, together with the status of a quasi monopoly enjoyed by a relatively small number of Internet search engines, leads to a skewed set of search algorithms that privilege "white" people and discriminate against people of colour, especially black women. Through an analysis of textual and media searches, as well as extensive research on paid online advertising, Noble (2019) exposes a culture of racism and sexism that is present in the way online search ability is built.

Fair or at least non-discriminatory search tools are scarce today. Whether searching for a job, applying from a university course, or predicting inmate recidivism, clear examples of discrimination through algorithms can be identified. In these situations, the AI used by search engines favours discriminatory patterns, generated by algorithms that are not programmed to compensate or correct human prejudices *(Gomez Abajo, 2017)* and consequently end up reinforcing them.

Amid discussions of algorithmic biases, companies using AI claim to be taking steps to use more representative training data, while regularly auditing their systems for unwanted biases and the eventual negative impact against certain groups. Harvard researcher Lily Hu says this is no guarantee that their systems will work fairly in the future *(Heilweil, 2020)*. While there is not a wide range of studies on the demographics of AI, currently the sector tends to be male-dominated, and the high-tech sector tends to overrepresent whites, according to the US Equal Opportunity in Employment Commission.

At this point, we should consider the relation between non-discrimination and affirmative action. Private companies and other users of algorithms are not legally obliged to take affirmative actions in the benefit of vulnerable groups, unless there are laws which bind them, even though they may stated it to be a desirable goal. The principle of non-discrimination is consistent with affirmative action *(Lawrence III, 2001)*. However, since they are designed for the specific inter-

ests of the user, algorithms may have different aims. This is where the legislator or the industry itself through must intervene in terms of applying the law to impose the necessary trade-offs to balance society's varying goals. As an example, some authors comment on the case of a university admissions procedure that priorities the admission of the most talented students but, at the same time, aims to represent a degree of diversity according to the composition of society. In this case, algorithms would help to obtain and compensate both goals at the same time, uniting private and public interests *(Kleinberg, Ludwig, Mullainathan, & Sunstein, 2018)*.

When we talk about users of AI, another important concept that is worth mentioning is explainable AI. When it comes to explain any algorithmic decision-making process, it is not enough to observe the classification result given one instance. To fully understand an automated decision, the whole process needs to be taken into account. If not, the explanation might not be representative and might not reflect all input factors and parameters which led to a particular decision (Fayyad, Piatetsky-Shapiro, & Smyth, 1996). A possible definition for explanation in the context of ADM could be:

'A formal and unambiguous descriptive representation of the output of a classifier based on the current and prior input represented as parameters' *(Waltl & Vogl, 2018)*.

Explainable AI looks for methods useful for analysing and/or complementing AI models with the aim to make the internal logic and output of algorithms transparent and easy to monitor and, eventually, correct, making these processes humanly understandable and meaningful. Gunning and Aha (2019) provide a basic set of questions in order to help assessing algorithmic decision making. The question concerns how to correct errors. They can be considered as guidelines which provide a stronger structure to the development of this kind of decision-making and improve their intrinsic explainability. On this basis, algorithms can be built to provide explanations for why specific instances or entire classes were classified in the way they were. This would greatly help to satisfy the need for more algorithmic transparency.

Conclusion

As search engines and their related businesses grow in importance, operating as information sources, social communities, and – especially in a time of pandemic – acting as vehicles of learning at all levels, the increasing threat requires understanding to reverse discriminatory practices. Discrimination does not only reveal itself in the form of violation of norms that prohibit some practices, but, more importantly, as obligations to take action in order to improve the situation of those vulnerable groups which are inherently unequal (so-called positive discrimination). No amount of increased accuracy or efficiency that a particular AI may add to the final result compensates for a model that is unfair or unethical. For example, the Chinese government uses AI to track its Uighur Muslim minority in Xinjiang, of whom around one million are believed to be living in re-education camps.

Of the various options that exist to counteract discrimination through algorithms, preventive measures appear to be the most reasonable. Businesses can seek assistance from anti-discrimination agencies to educate their staff and IT experts and raise awareness. These people will then use data sets that do not reflect discriminatory practices or unequal treatment. The goal is to make future

algorithms "free from discrimination by design". This circumstance implies that the programs are constantly verified along their initial development and then are continuously monitored. In any case, many authors affirm that defining justice in a mathematically rigorous way is very difficult, if not impossible *(Angwin et al., 2016)*.

Nevertheless, if we cannot make mathematics fair, at least we can make it less opaque. Therefore, we affirm that, in relation to AI models and algorithmic decision-making, transparency is paramount. If these processes become more transparent, their explainability would increase. Any algorithmic decision-making process should be able to explain its inputs, outputs and results, as well as be prepared to correct undesired errors. Moreover, it will also help to optimise these systems and understand the boundaries of AI and to assign responsibilities when we get an unwanted result.

Ultimately, this article deals with something more important than algorithmic bias. It is about the protection of supreme values of societies that respect human rights, such as equality and free development of the personality. Considering the rapid developments of big data and AI, it is necessary to urgently improve anti-discrimination legislation and data protection. These actions will help to eliminate or at least minimise algorithmic bias. Additional research should be carried out on the programmers themselves, including procedures for their selection and / or training.

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