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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