PROBLEMS OF BIOSAFETY IN CURRENT INTERNATIONAL LAW

PROBLEMAS DE BIOSSEGURANÇA NO DIREITO INTERNACIONAL ATUAL

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Introduction

These days, new problems and threats to humanity have arisen at the global, international, regional, and national levels. Research and development in modern areas of biotechnology, including human enhancement (CRISPR-Cas9) and the use of genetic weapons, may change the nature of war and international politics. Genetic weapons should be classified as weapons of mass destruction, along with chemical, biological, bacteriological, and nuclear weapons. Molecular weapons are likely to become reality soon enough. According to 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 view of international humanitarian law. On top of it, technological developments will trigger the issues of fundamental principles in current international law (the principle of neither use of force nor threatening to use it, the right of States to self-defense 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). New types of sovereignty will surely appear.[1] These are biosovereignty,[2] cyber sovereignty,[3] and genomic sovereignty of States.[4] 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. We will have to think about the legal regulation of post-genomic

1 There is a very common view in theory and practice that any international obligation limits sovereignty, or even that international law and sovereignty are incompatible. According to H. Kelsen, states, which are bound by obligations under international law, are no longer sovereign by virtue of this fact (American Journal of International Law. 1950. No. 1. P. 276). An American lawyer M. Janis argues that sovereignty and international law are absolutely antagonistic (Janis M. An Introduction to International Law. Boston, 1993. P. 151). Human freedom can be ensured only within the framework of law. In the same way, sovereignty can be real for all states only within the international legal order.

2 Sovereignty and Law: Between Ethics and Politics A Conex Marie Skłodowska-Curie Research Project Critiquing Sovereign Violence: Law, Biopolitics, Bio-juridicalism. Edinburgh: Edinburgh University Press, 2019.

3 Lauren C. Richardson, Nancy D. Connell, Stephen M. Lewis, Eleonore Pauwels, Randy S. Murch. Cyberbiosecurity: A Call for Cooperation in a New Threat Landscape. URL: https://www.frontiersin.org/articles/10.3389/fbioe.2019.00099/full

4 Kalinichenko P. A., Nekoteneva M. V. Genomnyy suverenitet razvivayushchikhsya stran: prioritety pravovogo regulirovaniya [Genomic sovereignty of developing countries: priorities of legal regulation]. *Geneticheskie tekhnologii i pravo v period stanovleniya bioekonomiki* [Genetic technologies and law during the formation of bioeconomics], Moscow, Prospekt Publ., 2020. (In Russian).

technologies, the biobanks 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). Much attention must be paid to human rights protection (the right to life, the prohibition of torture, the right to private and family life, the prohibition of discrimination, etc.).

So far, the problem of banning certain types of biomedical research has not been solved in some States and at the international level.[5] In this paper, we interpret the concept of biosafety rather broadly, considering the issues typical of allied industries.

Today, we are witnessing a dynamic development of a multi-disciplinary field called cyberbiosecurity. It combines cybersecurity, biosecurity, and cyber-physical systems security in the context of biological systems.[6]

Biosecurity and biosafety are directly related to ensuring environmental security since 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 wastes left from one process become raw materials for another process. Meanwhile, the use of biotechnologies, rapid industrialization, and urbanization are extremely detrimental to the environment, contributing to natural resource depletion. There is a close link between environmental and food security. The latter has triggered increasing concerns about the use of GMOs. In the international law of the sea, the novelty of recent years is the term *marine genetic resources*. Marine genetic resources have been the 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. Experts insist on international legal ban on the introduction of new species of organisms into the marine environment. Thus, marine biosecurity stands away from other types of security and safety because its purpose is to preserve biodiversity on our planet.[7]

States need to cooperate closely to prevent and suppress bioterrorism. Besides, they need to coordinate their joint efforts and actions in the fight against new types of biological threats. Otherwise, it will be impossible to maintain world peace and ensure international biosecurity and biosafety. 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. Currently, the efficiency of laboratories, detecting genetic modifications, is not always optimal, but the laboratory network can be strengthened through

5 Taras'yants E. V. Mezhdunarodnaya zashchita i pooshchrenie prav cheloveka v oblasti biomeditsinskikh issledovaniy [International Protection and Promotion of Human Rights in Biomedical Research]. Moscow BI Publ., 2011. 224 p. (In Russian).

6 Murch R. Cyberbiosecurity: An Emerging New Discipline to Help Safeguard the Bioeconomy DOI:10.3389/fbioe.2018.00039 URL: https://www.researchgate.net/publication/324224452_Cyberbiosecurity_An_Emerging_New_Discipline_to_Help_Safeguard_the_Bioeconomy.

7 Marnie L. Campbell, Kaeden Leonard , Carmen Primo and Chad L. Hewitt. Marine Biosecurity Crisis Decision-Making: Two Tools to Aid "Go"/"No Go" Decision-Making. URL: https://www.researchgate.net/publication/327849983_Marine_Biosecurity_Crisis_Decision-Making_Two_Tools_to_Aid_GoNo_Go_Decision-Making DOI:10.3389/fmars.2018.00331. This review assesses the efficiency of biosecurity-related biodiversity parameters obtained from eDNA/eRNA samples.

additional tools and technologies. In addition, the International Criminal Police (Interpol) report of 2021 pays attention to 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. Ultimately, a bioterrorism incident pre-planning and response guide has been issued.

There are still other urgent issues. 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) has not been adopted.[8] Nonetheless, the Bush Administration stated back in 2001 that the adoption of the Protocol poses a threat to confidential business information of American pharmaceutical companies.[9]

However, issues of developing joint practical measures to prevent threats to national, regional, and international security related to the impact of hazardous biological factors are being 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.[10] Within the framework of the CSTO, a draft Convention on Biosafety is being developed.[11]

Thus, at the end of 2020, Federal Law on Biosafety in the Russian Federation was adopted.[12] The law regulates activities aimed at ensuring biosecurity in Russia. Before the law was adopted, there were no conceptual tools in Russian legislation, defining what must be done to ensure the biosafety of citizens. The Law provides for measures to prevent terrorist attacks and sabotage through the use of biological weapons. There are at least 30 facilities in the Russian territory that potentially can pose chemical or biological hazards.

In 2021, the Russian scientific community enlarged the list of scientific specialties with four new groups of academic branches. These are computer science and informatics, biotechnology, subsurface use and mining sciences as well as cognitive sciences.[13] This proves that the issues of this type are especially significant for the foreign and domestic policies of the Russian Federation.

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8 *"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

9 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.

10 URL: https://iz.ru/1158527/2021-04-29/strany-odkb-dogovorilis-vyrabotat-mery-po-predotvrashcheniiu-biougroz

11 The Collective Security Strategy of the Collective Security Treaty Organization till 2025 was approved by the Collective Security Council of the Collective Security Treaty Organization 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_organizatsii_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.

12 The Federal Law on Biological Safety in the Russian Federation of 30 December 2020. URL: https://www.oreanda.ru/en/gosudarstvo/the-state-duma-of-the-russian-federation-adopted-a-law-on-biological-safety/article1351588/

13 URL: https://www.rbc.ru/society/10/04/2021/607167f39a794766130f7984?from=materials_on_subject.

On the issue of expanding the legal concept of biosafety

Maintaining biological security is an important task of the world community. With increasing globalization, it is becoming especially relevant due to the threats posed by infectious diseases and their pathogens. Hazards of this type are becoming comprehensive in the modern world. Until recently, the main content of biosafety was mainly related to the issues of sanitary and epidemiological welfare of the population. At the modern stage of the evolution of views, biosafety is characterized by a significant expansion of its main content.

The classification of biological threats currently includes a list of dangerous biological factors of natural origin. These are infectious diseases, which can be emerging, returning, new, emerging in new territories, and feral herd infections. There are also artificial threats caused by human professional activities, e.g. complication and intensification of research, 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 accidents at facilities where people are working with pathogens.[14]

Special importance is given to biological threats related to the deliberate use of pathogenic biological agents (bioaggression,[15] bioterrorism, ecological wars). It is the least controlled type of threat. That is why, according to many experts, such hazards constitute the greatest danger to humanity. 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.

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: criminalization 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 analyze 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.[16] To establish the identity 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

14 Biologicheskaya bezopasnost': analiz sovremennogo sostoyaniya sistemy podgotovki spetsialistov v Rossiyskoy Federatsii [Biosafety: the analysis of the current system of specialist training in the Russian Federation]. A team of authors from the Volgograd Research Anti-Plague Institute. *Zhurnal mikrobiologii* [Microbiology Journal], 2018, no. 2, pp. 5–18. (In Russian).

15 The definition of aggression has been fixed by the General Assembly Resolution 3314 (XXIX) of 14 December 1974. URL: https://legal.un.org/avl/ha/da/da.html.

16 URL: https://www.iarpa.gov/index.php/research-programs/felix.

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 big concerns due to the possibility of abuse by States or terrorist organizations. Many medical techniques threaten human biosafety and biosecurity. For example:

1. The creation of more dangerous pathogens and their use for criminal purposes. The unsafe studies of existing pathogens, which are dangerous to human health;
2. The risk of developing new pathogens or agents capable of causing cancer and other diseases;
3. 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;
4. 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 an international crime punishable through the universal jurisdiction.[17] That is because biological weapons (weapons of mass destruction) are considered to be *hostis humani generis* (the enemy of mankind). Moreover, the use of biological/genetic weapons by a State or a terrorist organization is subject to criminal punishment under international humanitarian law and international criminal law in the context of combating terrorism. If a State (directly or 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.[18] 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).[19] 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.[20] The right to self-defense should be used if necessary, 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

17 The Harvard Sussex Program on CBW Armament and Arms Limitation has put this idea forward in its draft convention criminalizing 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.

18 This conclusion stems from the principle of civilian population immunity from attack under international humanitarian law, but not from the principle of criminalizing the use of biological weapons.

19 The International Convention for the Suppression of Terrorist Bombings. URL: https://www.un.org/law/cod/terroris.htm

20 The UN Charter (1945). URL: https://www.un.org/en/about-us/un-charter/full-text.

UN Charter provisions is illegal. The Declaration 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".[21] 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 criminalize the use of biological weapons by States or terrorist organizations is based on the existing principles, which condemn and criminalize such behavior. The proponents of the proposal seek to directly and explicitly criminalize the use, possession, and unauthorized 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 organizations, 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 criminalizing certain governmental or individual behavior is very small.

International law and control over the non-spread of infectious diseases worldwide

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 specialized agencies of the UN (WHO, WTO) are revising international rules in the field of healthcare. They are also trying to establish 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.[22]

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 the persons who have consented to such manipulations with the genome. Such people are also responsible to future generations who will get an edited genome, which they will probably not be willing to have. 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). The court practice indicates that the desire to obtain the legally fixed status of the genome modification technology inventor is often not about scientific ambitions and a careful attitude to genomic sovereignty. It is mostly about commercial interests in promising technology. Given these circumstances, in the future, it may be necessary to revise patent legislation at national and international levels in order to protect public health.

21 The Declaration on the Enhancement of the Effectiveness of the Principle of Refraining from the Threat or Use of Force in International Relations. URL: http://www.worldlii.org/int/other/UNGA/1987/25.pdf

22 General Agreement on Tariffs and Trade. 1994, Marrakesh Agreement Establishing the World Trade Organization, Final Act Embodying the Results of the Uruguay Round, Annex 1A, art. XX (b).

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 organizations is a global threat.[23] Therefore, special safeguarding of biological and toxin materials, which can be used for making a weapon of this kind, is extremely necessary.

A bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants.[24] The biggest danger is that the inflicted damage is hard to control and reveal. With the massive deaths of animals and people from viruses and diseases, it may be difficult to identify the true causes since the strains of germs and viruses, existing objectively in nature, can be used for terrorist attacks. Distinguishing natural outbreaks from artificially created ones may take some time, and the subsequent identification of the perpetrators is therefore very complicated. In addition, the use of biological and toxin weapons was considered to be a highly unlikely threat until 2001, when terrorists spread anthrax spores by mail. As a result, 4 people died, 15 people were injured.[25] Not only the US government, but the whole world realized the danger of biological terrorism. Prior to this accident, the authorities did not believe that the damage inflicted this way could be so serious.

Another case of the biological material application for terrorist purposes was the use of ricin in the US in 2013.

Bioterrorism actors can be both terrorist groups and individuals ("lone wolves"). Bioterrorist attacks can be delivered in different ways: spraying pathogenic germs over pastures, infecting water, food, animals, pastures, etc.

Bioterrorism can be considered a threat or the use[26] of biological agents by a person or a group due to political, religious, economic, or other ideological motives. Bioterrorism may be very attractive to criminals because bioterrorist attacks are not so easy to detect since viruses and diseases generated by biological materials are quite natural. 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 can inflict very extensive damage. It is obvious that a person intentionally infected with a dangerous virus can easily infect a lot of other people because symptoms usually pop up only some time after the incubation period. The result is a delayed reaction of the governmental authorities responsible for public safety.

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23 Criminalizing Bioterrorism URL: https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2012/sloan_book/CH-03_Criminalizing%20BT_Preparing%20for%20Bioterrorism_Dec2012.pdf.

24 Department of Health and Human Services / Centers For Disease Control And Prevention / Bioterrorism Overview (Corporate Authors: Centers for Disease Control and Prevention (U.S.)) February 28, 2006. P. 1. URL: https://stacks.cdc.gov/view/cdc/44106/.

25 The Producer Of Anthrax Spores, Used By Terrorists In The USA, Will Remain In The Shadow. URL: https://english.pravda.ru/news/world/23473-n/.

26 Hochschule für Angewandte Wissenschaften Hamburg / Fachbereich Ökotrophologie / Studiengang Gesundheit / Diplomarbeit / Die Bedrohung durch den Bioterrorismus und das Management „biologischer Gefahrenlagen" in Deutschland / Eingereicht am ..Vorgelegt von. Svetlana Zunder.. Katzberg 17. 21502 Geesthacht / Elbe .. Matrikelnr.: 1589048 .. Betreuender Prüfer: Prof. O.-W. Naatz .. Zweiter Prüfer: Prof. Dr. C. Canavas / Vgl. Stemmler, 2001. P. 19. URL: https://edoc.sub.uni-hamburg.de/haw/volltexte/2008/416/pdf/wis_y_6.pdf.

States are prohibited from developing, producing, and storing biological weapons because if they exist in a particular country, there is an obvious danger that a terrorist cell may gain access to pathogenic microbes.[27] Dangerous biomaterials can be stolen from the laboratory and further used for terrorist purposes. This reason along with other factors 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 organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery 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 that would regulate the means and methods of verifying the implementation of the Convention. This may lead to such a situation where State Parties will be founded only on their good faith when deciding to abandon biological and toxin weapons.

Moreover, the Convention is relevant only for those States that have ratified it. Consequently, its effect is limited; it is not universal. In fact, a State can develop, produce, and accumulate biological and toxin weapons, even if it has signed the Convention but has not ratified it. This is what the US and some other countries are suspected of.

According to the provisions of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, persons engaged in the development of biological and toxin weapons are exempt from criminal prosecution provided

27 David P. Fidler. Bioterrorism, Public Health, and International Law // Maurer School of Law: Indiana University. P. 8. URL: https://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1427&context=facpub.

that such activities are properly authorized by the US government.[28] This approach contradicts the goals and spirit of both the Geneva Protocol of 1925 and the Convention of 1971.[29] Thus, the US can engage in the development of biological weapons contrary to international law. Meanwhile, there are no tools that could help monitor the activities of States in the field of biosecurity and biosafety. That is why the international agreements on these issues are, for the most part, useless.

Thus, according to the data published by the Ministry of Foreign Affairs of the Russian Federation,[30] the US, represented by the Department of Defense and its affiliates, are operating on the territory of Georgia (the 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, nevertheless, there are facts, which indicate the involvement of American military units. Obviously, military assistance is not required for the development of health services. Note that the Convention of 1971 was ratified by Georgia, and, consequently, there are concerns that Georgia is violating the norms of international law by allowing the US actors to operate at the Lugar Research Center.

Another important factor is the lack of a precise list of biological materials covered by the Convention. Its provisions are too broad and it is unclear in what way and by what criteria one should determine the possible purposes of using the materials.[31] For example, when working with smallpox infection in the laboratory, it is possible to refer to the development of a vaccine. In fact, the modification of this virus may be carried out in order to develop biological weapons. It is difficult to determine what the minimum required volume is for conducting peaceful experiments in search of a vaccine. The danger is in the fact that a relatively small amount of infected biomaterials may pose a threat to people.

The development and adoption of a legally binding Protocol, supplementing the Convention has been hindered by the US since 2001. Russian representatives propose to adopt a Protocol in compliance with the Convention through an institutional framework for its implementation, but the UK and the US insist on involving existing international organizations (WHO and others) in monitoring the implementation of the Convention provisions. The adoption of the Protocol, which Russia insists on, would possibly make the activities carried out at biological facilities more transparent. Dangerous biological strains are rather unique. This fact makes it hard to trace operations with biologically hazardous materials since, unlike chemical weapons, firearms, and other types of weapons, biological strains are 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 happened

28 Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001. P. 115. URL: https://www.congress.gov/107/plaws/publ56/PLAW-107publ56.pdf

29 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. URL: http://www2.ecolex.org/server2neu.php/libcat/docs/TRE/Full/En/TRE-000159.txt.

30 The official website of the Russian Foreign Ministry. The comment from the Information and Press Department of the Russian Foreign Ministry in connection with the US report on compliance with agreements and obligations in the field of arms control, disarmament, and non-proliferation / 1027-04-07-2020 / https://www.mid.ru/web/guest/kommentarii_predstavitelya//asset_publisher/MCZ7HQuMdqBY/content/id/4207201#4

31 The International Legal Regime Affecting Bioterrorism Prevention / National Security Law Journal. University of Central Florida. 2014. 44 p. P.8. URL: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2478444.

in Sverdlovsk. Although anthrax spores were not used in the laboratory to create biological weapons, their leakage was extremely dangerous, 66 people died. [32]

Of particular importance is the Security Council Resolution 1540 (2004), which substantially complements and expands the provisions of the Convention in the field of non-use of biological weapons.[33] 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 related to combating terrorism, countering the threat of terrorism is implied. Non-State actors can be individuals ("lone wolves") and groups (terrorist organizations).

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). [34]
- Harmonization 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, Resolution 1977 (2011) was adopted.[35] Under Resolution 1977, international, regional, and subregional organizations are also involved in the fight for the non-proliferation of chemical, biological, and nuclear weapons by assisting the 1540 Committee.[36]

Interpol's Activities to Ensure Biosecurity

It is no secret that the process of globalization has lots of positive aspects. These are the reduction of costs and expenses, modernization and development of production, spurring and

32 Kupferschmidt K. Anthrax genome reveals secrets about a Soviet bioweapons accident. *Science*. 2016. *Social'nye i gumanitarnye nauki. Otechestvennaja i zarubezhnaja literatura* [Social Sciences and Humanities, Russian and Foreign Literature]. Series 8, Naukovedenie [Science studies], 2016, no 4. (In Russian). URL: https://cyberleninka.ru/article/n/2016-04-003-kupfershmidt-k-genom-sibirskoy-yazvy-raskryvaet-sekrety-intsidenta-s-sovetskim-biologicheskim-oruzhiem-kupferschmidt-k

33 Resolution 1540 (2004) adopted by the Security Council at its 4956th meeting, on 28 April 2004. URL: https://www.un.org/ga/search/view_doc.asp?symbol=S/RES/1540%20(2004)

34 The International Legal Regime Affecting Bioterrorism Prevention / 3 National Security Law Journal (2014) /44 Pages Posted: 11 Aug 2014 / Eric Merriam /University of Central Florida. 2014. P. 28. URL: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2478444

35 Resolution 1977 (2011) adopted by the Security Council at its 6518th meeting, on 20 April 2011. URL: https://www.vertic.org/media/assets/nim_docs/Treaty/resolutions/UNSCR1977_EN.pdf.

36 BioWeapons Monitor 2014. URL: http://www.bwpp.org/documents/BWM%202014%20WEB.pdf

development of advanced technologies, States and peoples are getting together, etc. But there are also negative points: environmental and demographic challenges, international crime, etc.

In the 21st century, there is a steadily rising trend towards the emergence of natural infectious agents with new properties. These properties are the result of frequent, extensive, and rapid natural genetic mutations, occurring due to various globalization processes: climatic disturbances, a significantly increased flow of people, biomaterials, agricultural products all over the world, etc.

Under these circumstances, international cooperation to combat criminal activities in the area has become especially relevant. One of the oldest examples of such cooperation is Interpol, uniting 194 countries.[37]

Since 2005, Interpol has been implementing a progressive Bioterrorism Prevention Program. Its main goal is to help all its 194 member countries realize the threats and risks associated with biological materials used as weapons. The initiative was the result of the anthrax attacks in the US in the fall of 2001.

The first global conference on the prevention of bioterrorism was held in March 2005 in Lyon (France). It 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 legal framework and the 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 the 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 because they can trigger panic among the population, enormous human casualties, and economic losses.[38]

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

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

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37 ICPO-Interpol's Constitution, enforced on 13 June 1956. URL: https://www.interpol.int/content/download/590/file/Constitution%20of%20the%20ICPO-INTERPOL-EN.pdf?inLanguage=eng-GB.

38 GOST P 22.0.04-95 Safety in emergency situations. Biological and social emergencies. Terms and definitions (in Russian). URL: https://gostexpert.ru/gost/getDoc/45471.

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. That is why the issue of ensuring the safety and security of biological materials seems more urgent than ever before. Terrorist groups have become more numerous and organized; they have stable funding.

In January 2014, a laptop was discovered that contained a detailed description of how to create bubonic plague bombs, which could be used in public places to kill and infect civilians.

In November 2014, in Guinea, a minibus, transporting blood samples infected with the deadly Ebola virus, was stopped by unknown armed persons. The container was stolen. The robbers had no idea what was inside, but the case indicated the vulnerability of infectious biological objects.

It is notable that the Ebola virus is a well-known biological agent, but it can be atypical. In this context, the outbreak of the Ebola virus infection in 2014 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, the danger of bioterrorism is not comparable to the use of explosives as well as chemical or nuclear weapons. This might lead to the 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 the coming years, due to the popularity of this hobby and the relative availability of scientific and technical equipment, the number of such laboratories may substantially increase worldwide. This fact will serve as a breeding ground for bioterrorists and various spontaneous discoveries that can result in human casualties. With the development of science, opportunities previously possessed only by large groups and companies are becoming available to small groups and even individuals.

Against this background, the Interpol member countries should make a list of those biological materials that, in their opinion, should be prioritized as representing the greatest risk with respect to possible misuse. It is necessary for further strengthening 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 synthetic biology methods make it possible to chemically reproduce the full-length genome of the virus and introduce it into a cell culture. Thus, the natural pathogen may be created. That is why such technologies are strictly prohibited by the World Health Organization.

Interpol has a special unit for the prevention of bioterrorism (INTERPOL Bioterrorism Prevention Unit), which aims to enable law enforcement agencies to prevent, prepare and

respond to the deliberate use of bacteria, viruses, or biological toxins that threaten or cause harm to humans, animals or agriculture.[39]

In addition to drawing up and publicizing 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 on telecommunication networks are increasing. This is especially true for the overlay Darknet network. 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. It is a reference document that outlines the basic concepts, 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 Biosovereignty of States

In the era of rapid progress in biomedicine and biotechnology, legal guarantees of the human being integrity 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).[40] Among them are the principles of biosafety and voluntary informed consent to any manipulation with human genetic materials, including for medical and research purposes.[41] 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, emphasizing that a personality cannot be reduced to his/her genetic characteristics. The Declaration stresses immutable respect for personal uniqueness. In the 21st century, everyone has a fundamental right to respect for their dignity and subjective rights, regardless of genetic characteristics, as well as the right to protect their genetic data.[42] Both principles of confidentiality and non-discrimination based on genetic characteristics are fixed in Articles 6 and 7 of the Declaration.

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39 Interpol CBRNE Bioterrorism Prevention Program. URL: https://www.interpol.int/Crimes/Terrorism/Bioterrorism.

40 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 (Oviedo, 4.IV.1997). URL: https://rm.coe.int/168007cf98. On 24 January 2002, the Additional Protocol on Transplantation of Organs and Tissues of Human Origin was signed in Strasburg. On 25 January 2005, the Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, was added. The Russian Federation is a party neither to the Convention nor to its Protocols.

41 Already at the Nuremberg trial where 23 German medical scientists were accused of conducting cruel and inhuman experiments on prisoners of war, the experiments on a person without his/her voluntary consent were strictly prohibited (the Nuremberg Principle).

42 Levoshchenko B. S. Novyj aspekt v mezhdunarodnoj zashhite prav cheloveka: etika i biomedicina [A new aspect in the international protection of human rights: ethics and biomedicine]. *Vestnik RUDN* [the RUDN Bulletin]. Legal Sciences Series, 2000, no. 2, P. 135. (In Russian).

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 technology of CRISPR-Cas9 genome modification promises a breakthrough in the treatment of these diseases. Using this technology, it is possible to modify any organism on Earth and edit any gene in just a few hours. On top of it, this will cost no more than fifty dollars. The new gene-editing technology is often called *gene scissors*.[43]

Potentially, a CRISPR attack can even stop the development of HIV. Today, scientists have started working on a CRISPR system aimed at countering COVID 19. Therefore, commercial and legal interests in this technology are only increasing. These interests triggered studies in the field of newly-appeared biolaw and became 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. From the view of biopoliticians[44] and lawyers, these aspects are getting additional ethical and practical legal shades.[45]

In the modern period, the legal doctrine has generated a new sub-branch of international biolaw. This is the legal regulation of genomic studies and the practice of referring to their results (genomic law). Genomic law may cover the following areas of legal regulation: 1) 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); 2) genomic registration and genetic testing, including gene screening, monitoring, DNA fingerprinting, and forensic genetic examination; 3) 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"; 4) 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, paleontology, genetic certification, gene therapy, biomedicine, sports, etc.

In general, it is believed that bioethics has been provoked by three aspects: 1) 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; 2) 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; 3)

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43 Clustered regularly interspaced short palindromic repeats, as a genome editing tool, make it possible to delete, add, or modify DNA sequences (Sontheimer, 2015:413–414).

44 Critiquing Sovereign Violence: Law, Biopolitics, Bio-Juridicalism Gavin Rae. 2019. Edinburgh University Press. P. 232. URL: https://www.jstor.org/stable/10.3366/j.ctvnjbfsx. The biopolitics of the State is related to the governmental task to promote the quality of people's lives. The anatomical policy of the human body is a global mass, which is influenced by common characteristics typical of life such as birth, death, production, disease, etc. In his lecture "Society Must Be Defended", Michel Foucault explores State biopolitical racism. The researcher describes the fundamental difference between biopolitics and discipline. To him, where discipline is a technology used to make people behave so that they are efficient and productive workers, biopolitics is used to manage the population (for example, to ensure a healthy workforce). Foucault, Michel (2007). Security, Territory, Population: Lectures at the Collège de France. Basingstoke: Palgrave. p. 1.

45 Denisenko Vladislav, Trikoz Elena. Biopolitics and legal issues of emergency situations in the context of coronavirus pandemic // E3S Web of Conferences. 2020. Vol. 175. № 14013. P. 1-7. doi: https://doi.org/10.1051/e3sconf/202017514013

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

It should be noted that a number of medical services are criminalized in various countries of the world (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, has to do with the guarantee and protection of somatic human rights. Criminal attacks on somatic rights endanger the biological well-being of the individual. For instance, E.V. Tarasyants studies in detail 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.[46]

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 reminds that, under Article 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950, the 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.[47]

In the 21st century, the problem of human genome modifications has become one of the most crucial issues.[48] Changes in germ cells (reproductive cells, including human embryos, eggs, spermatozoa, and their progenitor cells) will be inherited by the patient's descendants. This means interference in the lives of future generations who did not consent to such an invasion of their genome.[49] This is also an attack on the very principle of human biological diversity.[50]

In December 2018, 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).[51] 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

46 Taras'yants E. V. Mezhdunarodnaya zashchita i pooshchrenie prav cheloveka v oblasti biomeditsinskikh issledovaniy [International Protection and Promotion of Human Rights in Biomedical Research]. Moscow BI Publ., 2011. 224 p. (In Russian).

47 Trikoz E., Gulyaeva E., Belyaev K. 2020. Russian experience of using digital technologies in law and legal risks of AI. – E3S Web of Conferences. Vol. 224. No. 03005. DOI: https://doi.org/10.1051/e3sconf/202022403005. URL: https://www.e3s-conferences.org/articles/e3sconf/pdf/2020/84/e3sconf_TPACEE2020_03005.pdf

48 Montgomery J. (2018). Modification of the human genome: Human rights challenges raised by scientific and technical developments. URL: https://discovery.ucl.ac.uk/id/eprint/10057969/6/Oviedo%20Convention%20Anniversary%20Paper%20%20Final%208%20December.pdf

49 Krekora-Zając D. 2020. Civil liability for damages related to germline and embryo editing against the legal admissibility of gene editing. – Palgrave Communications. Vol. 6. Issue 1. P. 1-8. DOI: 10.1057/s41599-020-0399-2; Trikoz E. N., Mustafina-Bredihina D. M., Guljaeva E. E. Pravovoe regulirovanie procedury gennogo redaktirovanija: zarubezhnyj opyt [Legal regulation of the gene editing procedure: foreign experience]. *Vestnik RUDN* [the RUDN Bulletin]. Legal Sciences Series, Vol. 25, no. 1. (In Russian). DOI:10.22363/2313-2337-2021-25-1-67-86

50 Rogers A., De Bousingen D.D. 1995. *Bioethics in Europe*. Strasbourg: Council of Europe Press. 366 p.

51 WHO establishing expert panel to develop global standards for governance and oversight of human gene editing. URL: https://www.healthysoch.com/health/general/who-establishing-expert-panel-to-develop-global-standards-for-governance-and-oversight-of-human-gene-editing/.

and governance mechanisms both at the national and international levels. The purpose of this work is to understand how to promote transparency and trustworthy practices and how to ensure appropriate risk/benefit assessments are performed prior to any decision on the authorization of any gene modification technologies.

The European Union has adopted a number of Regulations, covering genome editing.[52] 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).[53]

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

Food and environmental protection issues are 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, eliminating potential environmental risks related to GMO production.

The EU and the US are still the main centers 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 is the area with the strictest legislation (including such countries as Norway, Iceland, and Switzerland). Nonetheless, GMOs are still used for agriculture, foods, and consumer goods production in those countries. In Europe, any foods, containing more than 0.9% of authorized GMOs are considered to be genetically modified. The limit of GMOs that have not been authorized yet is 0.5%. Before being placed on European markets, such foods must have a special package labeling, which is supposed to inform potential consumers about the genetically modified nature of a product.[54] The situation is quite different in the USA, Canada, and Argentina where labeling is required only if there is a significant change in the quality of the product or any health risk (e.g., allergies).[55]

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.

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52 Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. URL: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF; Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products; Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use (Art. 9 para. 6). URL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0020

53 Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. URL: https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

54 European Commission. Questions and answers on the regulation of GMOs in the EU (Memo/02/160-REV). Brussels, 2003.

55 *Kym A., Lee A.J.* Why Are US and EU Policies Toward GMOs So Different? // AgBioFo-rum. 2003. 6(3).

Moreover, the conventional (supranational) level of regulation and the ideological level of communitarian biopolitics development in the region are also being built up.[56] 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 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.

In fact, the EU has the strictest legal regulations and restrictions on GMOs in the world.[57]

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 be the main tool 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 assume that all GMOs are recognized as *novel foods*. The European Food Safety Authority (EFSA) conducts a comprehensive and scientifically based assessments of foods based on the following criteria: safety, freedom of choice, labeling, 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 the practice of the European Court of Justice in Luxembourg, the following landmark decision of July 25, 2018 is very well known. According to it, food suppliers in the EU, working with genetic engineering technologies, must strictly adhere to the Union's standards for the use of GMOs in the food industry. The case was about 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. The representatives of the French Association of Agricultural Producers were the first to sound the alarm and file a lawsuit. They were worried 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 have been possible to prohibit the cultivation of GM foods only if there was strong scientific evidence of their harm to human

56 *Denisenko V., Trikoz E.* (2020) Biopolitics and legal issues of emergency situations in the context of coronavirus pandemic // E3S Web of Conferences. 175, 14013. doi: https://doi.org/10.1051/e3sconf/202017514013

57 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.

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 to ensure a high standard of human health protection and the smooth functioning of the internal market. Consequently, according to the Justices' opinion, it is possible to completely prohibit GM foods only if there is indisputable evidence of the substantial health risk associated with them.

Computational selection is becoming a promising area of legal regulation, which in the near future may replace genetic modification of foods and other biotechnologies. By now, computational selection makes it possible to develop promising plant varieties without genetic modifications. The technique relies only on information from sensors and AI algorithms.[58]

Ensuring Biosafety in the Russian Federation

Currently, the main laws and regulations, covering biotechnology in Russia, are the following: the 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; the Federal Law "On Biological Safety in the Russian Federation" of 30 December 2020; the Forest Code of the Russian Federation; the 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; the new Strategy for the development of forestry complex in Russian Federation until 2030; the Federal Law "On Amending Certain Legislative Acts of the Russian Federation to Improve State Regulation of Genetic Engineering Activity" of 3 July 2016; the 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.

58 Trikoz E., Gulyaeva E. 2021. Ecological cases of the ECHR and the environmental risk of GMO. – E3S Web of Conferences. Vol. 244. No. 12024. DOI: https://doi.org/10.1051/e3sconf/202124412024. URL: https://www.e3s-conferences.org/articles/e3sconf/pdf/2021/20/e3sconf_emmft2020_12024.pdf; Trikoz Elena N., Gulyaeva Elena E., Belyaev Konstantin S. Russian experience of using digital technologies in law and legal risks of AI // E3S Web of Conferences. 224, 03005 (2020). doi https://doi.org/10.1051/e3sconf/202022403005

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 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.[59] 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 requirements for the principles of proportionality, minimization, and legality of the collection, processing and storage of personal data. A new category of sensitive data has been introduced, i.e. genetic data.[60] 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 authorized supervisory body about data leaks. A clear regime for cross-border data flows is also fixed therein.[61]

Conclusion

In current international law, the problem of adopting a Protocol, establishing an international control mechanism for verifying prohibitions on the development, production, and stockpiling of biological weapons is obvious. The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction adopted in 1993,[62] which contains a mechanism for verifying compliance with 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

59 URL: https://base.garant.ru/3101506/

60 Article 5 of the Russian Federal Law "On Personal Data". URL: http://www.consultant.ru/document/cons_doc_LAW_61801/

61 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.

62 The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction. URL: https://www.un.org/en/genocideprevention/documents/atrocity-crimes/Doc.42_Conv%20Chemical%20weapons.pdf

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 organizations constitutes a real threat to the States of the world. Combating bioterrorism is different from combating chemical and nuclear terrorism because in 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 prioritized for ensuring national security and defense of the country in order to combat bioterrorist attacks.

Nowadays, thanks to modern biomedical technologies that have become relatively accessible, a person gets the opportunity to recover from a particular disease (through the transplantation of a human organ, tissue, or cell) and even build up a family (in vitro fertilization). However, this sphere has also become a tool for obtaining illegal benefits and human rights violations. Social and individual biosafety is threatened because many scientific and biomedical achievements are not well regulated by law 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, nevertheless, there are no unified sources of law that could in a uniform way make it possible to combat international crime that threatens biosafety and biosecurity as well as reproductive and somatic human rights.

Effective mechanisms should be created and ensured at the global and regional levels within international collective security organizations. A Commission should be set up to investigate biosafety crimes.

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 Bacteriological (Biological) and Toxin Weapons and on Their Destruction to ensure a complete prohibition of biological weapons. The most important objectives of the Convention are also the investigation of cases related to biological and toxin weapons, prevention, localization, and elimination of emergencies in the sphere of ensuring bisafety and biosecurity all over the world.