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ANALYSIS OF REGULATORY AND LEGAL FRAMEWORK TO ENSURE THE REALIZATION OF CANADIAN NATIONAL BIOSAFETY AND BIOSECURITY PROGRAM IN THE CONTEXT OF BIOTERRORISM

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ABSTRACT. *The article examines the regulatory and legal framework realization of Canadian National Biosafety and Biosecurity Program in the context of bioterrorism.*
Based on an analysis of Canadian law, it is shown that the creation of a regulatory system for this program is divided into several stages from the development of a general strategy to the creation and entry into force of specific legal acts that regulate in detail the order of research, storage and use of biologically dangerous agents and their toxins.
At present, activities in the field of biomedical research in Canada are conducted according to national standards, and monitoring of their implementation in order to counter threats to biological nature provided by specially created state agency that is responsible for the administration and implementation of legislated Biosafety and Biosecurity Program.
It is suggested to use the positive experience of Canada in Ukraine to create an appropriate national security system for countering bioterrorism, biological sabotage and other biological threats.
Key Words: *bioterrorism, biothreats, bio-risks, biological security, biological protection.*

Introduction. The Aim of the Article. Today, there are two mechanisms in the world to prevent threats to national security of biological character, in particular bioterrorist attack – an effective intelligence service and an effective system of biological security and biological protection of the country. The intelligence service aims to prevent these threats, and the biological protection system aims to minimize the negative effect, if the attack does occur [1].

The concern of the international community about the inappropriate use of pathogens and products of their pathogenic organisms and products of their livelihoods or processing dates back to ancient times, when people noticed the toxicity of some biological materials that led to the humans and animals' deaths. Thus, in the political and economic treatise of ancient India, "Arthashastra" or "The Science of Politics", attributed to the wise Brahmin Kautilya, also known as the scientific name of Chanakya, refers to the possibility of using biologically dangerous poisons against humans and animals [2]. In the seventeenth century, the scientist Francis Bacon, for the second time, draws the attention of mankind to the reality of threats to biological health and life [3].

The very terms biological safety and biological protection have become widely used both in scientific publications and directly in the field of biomedical activity in the late twentieth century. The rapid development of information technology in the second half of the last century became a catalyst for the development of biological science. In the late twentieth century, in the field of biomedical research, scientists have been able to develop a number of new methods that have enabled humans to manipulate the heredity of living organisms at the genome level. This has opened up new opportunities not only for peaceful biotechnology but also for bioterrorism. Confirmation was not delayed. The fact of bioter-

rorism in 2001 by sending anthrax leaflets to the US forced many countries, including Canada, to respond to these threats in a new way [4]. This fact has accelerated the process of defining bioterrorism as a priority for this country, creating its own biosafety and biosecurity system.

Methods and Materials. The Canadian scientists and experts are studying the features creating and implementing a modern national program on biosafety and biosecurity in Canada. Among them there are Kirsten Almqvist[1], Julia Fernandez[2], Morgan Kafenzakis[3], Stacey Mantha[4] [4].

At the same time, it is necessary to recognize that foreign experience of regulatory support of bioterrorism, in particular Canadian, in the implementation of the respective national program in this country has not been studied by domestic scientists, so there is no scientific publication on this issue.

Results and Discussion. Canadian approach to resolving the issue of biosafety and biosecurity in the country is complex. One of the determining factors affecting its effectiveness is the establishment and compliance with regulatory requirements for research on human and animal pathogens. This is of paramount importance for the public health of the country. Considering the high bio-risks for health and safety of professionals in conducting relevant biomedical research and in delivering their results to the public, Canada recognizes the priority of creating necessary conditions for their safety. In general, addressing the issue of biological security and biological protection in this country is regarded as one of the most important tasks of the national level, taking the necessary measures to ensure its proper legal and regulatory support.

Formation of the legal bases for biosecurity and biological protection in Canada can be divided into two periods. *The first period began in 1990 with the publication of The Instructions for Working with Pathogens and Toxins (hereinafter – The Instructions)* [5].

It was a guidance document to clarify the importance of the safe use and safe storage of pathogens and toxic products of their viability or

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processing. Following the adoption by Canada in *1994 of The Regulations Respecting the Importation of Human Pathogens and Their Transfer* (hereinafter – The Regulations), regulatory control over legal entities wishing to import pathogens and toxins into the country with respect to three of the four bio-risk groups according to international classification is established, namely: BSL-2; BSL-3 and BSL-4 [5].

Since that time, the country has established legal supervision of those seeking to import these pathogens. Thus, in particular, *The Regulations* establish a mandatory procedure for informing legal entities of authorized state bodies about the intentions of importing pathogens and granting the consent of the importer to assume legal responsibilities in order to assist the control bodies in the case of need to check its activities (i.e., get documentary audits and inspections).

The Regulations also require that, prior to the importation of pathogens, employers to train their personnel on compliance with biosafety and biosecurity requirements when dealing with a group of pathogens to be imported into the country, and to explain to them possible legal (administrative or criminal) and moral liability commitments.

At the same time, the import conditions provide the compulsory adherence and requirements of the previously adopted guidance document, *The Pathogen and Toxin Instructions.*

Thus, thanks to *The Regulations* adopted by the Canadian Authorities, they were authorized to inspect laboratories for compliance with biosafety and biosecurity prior to granting them permission to import pathogens.

The beginning of the second period is the adoption of *The Human Pathogens and Toxins Act* (hereinafter – the Act) in 2009 [6]. By doing so, Canada is expanding its monitoring of biosafety and biosecurity to eliminate the risks associated with the use of human-made pathogens and toxins purchased and isolated or manufactured domestically. Certain provisions of the Act came into force immediately after its adoption, i.e., already in 2009. According to this law, Canada establishes control over the internal circulation of genetically modified organisms and the work on their creation. At the same time, special attention is paid to the need to ensure control over biomedical studies that involve the use of genetic engineering methods for both human and animal pathogens [6]. The relevant provisions of this regulatory legal act provide control entities with inspection powers, determine offenses and punish them; oblige to keep a mandatory record of all biomedical laboratories that store human pathogens and toxins, to take all necessary measures to protect the health and safety of society when dealing with hazardous biological agents (hereinafter – HBA); prohibit any activity with smallpox agents and intentionally distribute pathogens that are dangerous to humans.

In addition, there are requirements for accessing confidential information related to the *HBA* and their toxins. Thus, one of the mandatory requirements is the provision of fingerprints and the license holder's application for a scheduled person for biomedical research, which demonstrates the need to agree with the competent authorities to obtain their right of access to, or work with, the *HBA* storage site and their toxins. The requirement to obtain the right of access to classified material related to biomedical activities has a positive effect on significantly reducing the risk of anthropogenic factor – an internal threat due to the penetration of persons with criminal intent. This is accomplished in Canada by screening applicants for obstacles to access to biomedical activity through databases maintained by Canadian law enforcement agencies, special services, and creditworthiness. Thus, the selection of professionally fit and trustworthy personnel that forms the basis of biosecurity in Canada is ensured.

The implementation of the remaining sections of *The Act* required further work to develop a new biosafety program and regulatory framework that would include a licensing scheme and an explanation of biosafety requirements. It should be noted that Canada views biosafety as a biosecurity subsystem.

The process of creating and implementing a system of regulatory control for the implementation of the program of ensuring biological safety and biological security after the adoption of *The Act* can be divided into four stages.

The first stage was the development of a general content strategy for the implementation of *The Human Pathogens and Toxins Act.* For this purpose, preliminary consultations with local and territorial state agencies and leading national biotechnological associations were held. At that time, many Canadian biomedical laboratories

were working with both types of pathogens (human and animal) and were forced to contact two different government agencies to obtain authorization for the import of animal and human pathogens.

For reference: [dangerous only for humans (anthroponosis – infection is transmitted only from person to person, animals cannot be infected and become ill, as an example – cholera); dangerous only to animals (zoonoses – infection is transmitted only from animal to animal; humans cannot be infected and become ill, as an example – African swine fever); common, that is, dangerous to both humans and animals (zoanthroponosis – when infection is transmitted from person to animal, as an example – a sick person for anthrax can infect domestic animals), and anthropozoonoses – infection is mainly transmitted from animal to animal, but people can be infected and become ill, such as rabies, brucellosis, cattle tuberculosis, etc.). It should be noted that the last two ways of infection can be considered as one mixed type; however, many experts do not make this division at all.]

Therefore, in 2013, in order to reduce the regulatory burden on a single national focal point for the laboratories of departments and enterprises of the biomedical industry working with pathogens, working with pathogens for both humans and animals autochthonous for Canada, a separate entity is formed from the C*anadian Department of Health – a government entity – the Public Health Agency of Canada.*

The Canadian Science Centre for Human and Animal Health (CSCHAH) has become the main base of the *Public Health Office of Canada. CSCHAH* is the science center for infectious disease laboratories in Winnipeg, Manitoba, which reports directly to the Government of Canada. There are two laboratories in this modern facility: The National Microbiology Laboratory (NML) and *The National Centre for Foreign Animal Disease (NCFAD)* [7].

At the same time, *The National Program for Harmonization of Human and Animal Pathogens* are under the control of their circulation in the country is being developed and adopted, and a single list is created that prevents the need for double permits for the import of pathogens.

The effect of this initiative is the reduction of paper work, speeding up import licensing, streamlining national communication processes, improvement of system efficiency, and strengthening the pathogen control in Canada.

In the same year, Canada, by refining and updating old versions of standards and instructions, and preparing new ones, created national standards for working with the HBA, which were published in the first edition: *The Canadian Biosafety Standards and Guidelines (hereinafter – The Standards)* [8].

Furthermore, Canada has also created a free online and mobile application for *The Canadian Biosafety Standards and Guidelines* [8].

During the second stage, consultations were held on key elements of the national program, including: licensing of laboratories, defining the functions of responsible individuals for biological safety and biological security and their level of qualification, requirements for adherence to the approved schedule of hazardous biological agents inventory, procedure and nature of the case of an intra-laboratory infection, requirements and procedure for granting Canadian citizens working in the field of biomedical research, access to classified information and materials of the *HBA* provided by *The Act* [7].

In accordance with the requirements of *The Act,* the next step was to develop a new licensing scheme and recommendations for the organization of work on biohazardous facilities in order to ensure compliance with biosafety and biosecurity requirements during medical and biological activities. Accordingly, the license holder is obliged to notify *The Public Health Office of Canada* of any emergency at any level related to pathogens and their toxins, such as accidental release of *HBA* or toxin into the environment, unauthorized distribution, unintentional accumulation, an incident that was, or may be, the cause of an infectious disease, of human pathogens or toxins stolen or lost. In addition, in accordance with these regulatory requirements, it is necessary to inform *The Public Health Directorate* in the following cases: the loss of a dangerous active infectious material during the transportation and not finding it within 24 hours from the detection of the loss, when changing the name, the license holder, the prohibition of the holder of the license by the employee access to classified material by a licensed agency. Canadian law also requires that *The Public Health Agency* to be informed of any changes to the building where the *HBA* is operating or storing and their toxins, facilities, equipment or standard operating procedures (SOPs) that could affect the safety of storage in the pathogen laboratory and their toxins BSL-3 or BSL-4 risk groups, identified by sensitive, dangerous biological agents.

In addition, all individuals and organizations working with the *HBA* (i.e. owning, using, producing, storing, sharing, transmitting, importing, exporting, distributing or disposing) are required to be licensed by *The Public Health Agency of Canada.*

In the field of biomedical research, all licensed institutions are obliged to develop, implement, monitor, and analyze a biosecurity plan that outlines strategies in the event of an emergency response to mitigate the adverse effects of the *HBA* and their toxins. At the same time, the legislator emphasizes the need for mandatory inclusion of five sections in this plan: physical protection, professional suitability of personnel and its reliability, control of the circulation and inventory of the *HBA* and their toxins, measures for response to incidents and emergencies with the *HBA* and their toxins, information security of biosecurity measures at the site [5].

Individuals conducting biomedical research, in accordance with the regulations of Canada, are obliged to inform the license holder and the person responsible for biosafety and biosecurity of deliberate genetic modification of the pathogen dangerous to humans, which can increase its virulence, contagiousness, toxicity, lethality and resistance to existing drugs and preventive or therapeutic agents.

To implement these provisions, the existing supervisory bodies with expanded powers for state audits were reorganized and additional work was done to create an additional departmental regulatory framework to ensure their legal support.

During the third stage, the public health administration of Canada addressed the stakeholders on political approaches proposed by the government to address these issues, as well as to identify any potential problems with cross-cutting, as well as to prepare relevant regulatory drafts. legal documents. The purpose is to update existing standards and recommendations and to develop new ones, to harmonize them with the requirements of international laboratory practice in the system of biomedical research.

During the fourth stage, draft laws were published to discuss them during information sessions in various regulated sectors of the economy and science and among *HBA* users in *Canada*. The comments and suggestions made during the multilateral consultations were taken into account when developing the final version of *The Canadian National Biosafety and Biosecurity Regulatory Framework* for its implementation in the context of counterterrorism.

Thus, during the four stages mentioned above, legal regulations have been developed in Canada to enforce *The Human Pathogens and Toxins Act,* which came into force on December 1, 2015. The materials of this work are published as separate documents, namely: The Canadian Biosafety Standard; *The Canadian Biosafety Handbook* and a series of best-practice guidelines for developing a biosecurity plan for the facility; safe work with the *HBA* risk group BSL-1 and recommendations for veterinary practice [8]. They regulate the implementation of a national licensing program for Canadian laboratories working with the *HBA* and a program for providing classified materials and information to scientists and other individuals in the field of biomedical research who have personalized access to the specified activity within the Canadian pathogen registry category “vulnerable”. Thus, license holders, in accordance with *The Canadian Biosafety Standard* [8] and other legal acts adopted under The Act, are directly responsible for the organization and compliance with the biosafety and biosecurity requirements of the entity under their control. People, responsible for biosafety at the site, are directly assigned by the licensee under *The Human Pathogens and Toxins Act.* Their primary duty is to promote and control compliance with the subject matter of the biosafety and biosecurity subject to the written authorization (order, instruction, etc.) of the licensee, to communicate with *The Public Health Office of Canada* on such matters, and to perform other designated functions in *The Regulation on the Permanent Commission on Biosafety and Biosecurity.* It is prepared and approved at each institution working with the HBA, as a separate document for the immediate laboratory, according to the current level of bio-risks and biothreats. Individuals who have been granted access to HBA work under a license and are involved in the aforementioned field of activity are personally liable for violations of biosafety and biosecurity regulatory compliance.

Thus, the biosafety and biosecurity system in Canada primarily involves the application of a set of regulatory measures to directly protect hazardous biological agents from possible loss, theft, misuse, abuse or intentional spread of infectious material or toxins (bioterrorism) [9].

Conclusions. Canada had been building an effective biosafety and biosecurity system at the legislative level for a long time. The development of this system began in 2000 with bringing to the relevant biosecurity entities a recommendation document – The Instructions for Working with Pathogens and Toxins and ended in 2015 with the adoption of specific regulations on the implementation of The Human Pathogens and Toxins Act, which together have formed an appropriate national program.

Thus, from the voluntary implementation of the recommendations of *The Instructions for Working with Pathogens and Toxins,* Canada has gradually transitioned to a legally defined systematic state control over compliance with the biomedical and biosecurity profile. To date, activities in the field of biomedical research in this country are carried out in accordance with national standards, and control over its implementation in order to counter threats to biological nature is provided by a specially created *Public Health Agency of Canada,* which is responsible for administration and enforcement, legislatively of the relevant Biosafety and Biosecurity Program. Since 2015, with the beginning of the implementation, regular reviews are being made of the legal regulation effectiveness and the impact on Canada's biosafety and biosecurity system of various factors.

In general, based on the foregoing, we can reach the following general conclusions:

Canada's approach to addressing biosafety and biosecurity in the country is complex. To this end, a proper program of biological safety and biological protection and a proper system of regulatory support for its implementation have been established in this country.

The Canadian National Biosafety and Biosecurity Program is designed to prevent losses, thefts, misuse of the *HBA*, counter bioterrorism and bio-sabotage, intentional distribution of the *HBA* for other criminal purposes, as well as for the dissemination of regulated infectious materials and the values held by the institution (for example, non-infectious material, animals and confidential information of biological nature).

One of the determining factors affecting the effectiveness of biological safety and biological protection is the establishment and compliance with regulatory requirements for research on human and animal pathogens. The latter is of paramount importance for the protection of the public health of the country, which is the most important task of the national level, and the necessary measures are being taken to fulfill it.

In developing national biotechnology, Canada strictly adheres to the requirements of international law on the non-proliferation of weapons of mass destruction or its components, including biological ones, in particular *The Convention on Bacteriological (Biological) and Toxic Weapons.*

But today, there is a number of legislative and regulatory acts in Canada that regulate in detail the order of research on human and animal pathogens, storage and use of the *HBA* and their toxins.

Canadian positive experience in developing a biosafety and biological protection program and providing legal support for its implementation should be used in Ukraine to create an appropriate domestic system, use it further to effectively combat bioterrorism, biological sabotage, and other national security biological threats.

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АНАЛІЗ НОРМАТИВНО-ПРАВОВОГО ЗАБЕЗПЕЧЕННЯ РЕАЛІЗАЦІЇ НАЦІОНАЛЬНОЇ ПРОГРАМИ КАНАДИ З БІОБЕЗПЕКИ ТА БІОЗАХИСТУ У КОНТЕКСТІ ПРОТИДІЇ БІОТЕРОРИЗМУ

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РЕЗЮМЕ. *У статті досліджується нормативно-правове забезпечення реалізації національної програми з біобезпеки та біозахисту Канади у контексті протидії біотероризму.*

На підставі аналізу законодавства Канади показано, що створення системи нормативно-правового забезпечення даної програми поділяється на декілька етапів від розробки загальної стратегії до створення і набуття чинності конкретних нормативно-правових актів, які детально регламентують порядок проведення науково-дослідних робіт, зберігання і використання біологічно небезпечних агентів та їх токсинів.

На сьогодні діяльність у сфері медико-біологічних досліджень у Канаді здійснюється відповідно до національних стандартів, а контроль за її проведенням з метою протидії загрозам біологічного характеру забезпечується спеціально створеним державним агентством, яке відповідає за адміністрування і виконання законодавчо закріпленої Програми з біобезпеки і біозахисту.

Запропоновано використання в Україні позитивного досвіду Канади для створення відповідної вітчизняної системи національної безпеки з протидії біотероризму, біологічним диверсіям та іншим загрозам біологічного характеру.

Ключові слова: *біотероризм, біозагрози, біоризики, біологічна безпека, біологічний захист.*

АНАЛИЗ НОРМАТИВНО-ПРАВОВОГО ОБЕСПЕЧЕНИЯ РЕАЛИЗАЦИИ НАЦИОНАЛЬНОЙ ПРОГРАММЫ КАНАДЫ ПО БИОБЕЗОПАСНОСТИ И БИОЗАЩИТЕ В КОНТЕКСТЕ ПРОТИВОДЕЙСТВИЯ БИОТЕРРОРИЗМУ

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РЕЗЮМЕ. *В статье исследуется нормативно-правовое обеспечение реализации национальной программы по биобезопасности и биозащите Канады в контексте противодействия биотерроризму. Детальный анализ законодательства Канады показывает, что создание системы нормативно-правового обеспечения данной программы делится на несколько этапов – от разработки общей стратегии содержания до создания и внедрения конкретных нормативно-правовых актов, детально регламентирующих порядок научно-исследовательских работ с патогенами человека и животных, хранения и использования биологически опасных агентов и их токсинов.*

На сегодня деятельность в сфере биомедицинских исследований в этой стране осуществляется в соответствии с национальными стандартами, а контроль за ее проведением с целью противодействия угрозам биологического характера обеспечивается специально созданным государственным агентством, которое отвечает за администрирование и выполнение законодательно закрепленной соответствующей Программы по биобезопасности и биозащите.

Предложено реализацию использования в Украине положительного опыта Канады по созданию программы биологической безопасности и биологической защиты и нормативно-правового обеспечения для создания соответствующей отечественной системы по противодействию биотерроризму, биологическим диверсиям и другим угрозам национальной безопасности.

Ключевые слова: *биотерроризм, угрозы, биориски, биологическая безопасность, биологическая защита.*

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