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Article

Biosecurity of dual-use items

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Abstract

Most of biological warfare agents are simultaneously serious biological threats for public health. The way in which these factors are used is mainly determined by the anthropogenic factor. Accelerated progress in life sciences and biological engineering stopped the COVID-19 pandemic (mRNA vaccine), on the other hand, opened the way for advanced research using biological agents for unethical purposes. The paper provides an introduction to biological security issues. It presents the concept of biological security in a cross-cutting manner, in terms of international disarmament, non-proliferation agreements on biological and toxin weapons as well as the regulations referring to them. The author reviews and analyses measures to secure and protect biological agents and related technologies, with reference to activities particularly vulnerable to abuse in the area of such protection. Effective countering of biological threats requires an interdisciplinary approach to biosecurity. At stake is the prevention of the use of biological materials with dual-use potential as a weapon or terrorist agent.

Keywords

biosecurity, multilateral treaties, dual-use items

Biological hazard

It is generally accepted that biohazards are mainly caused by biological agents – bacteria, viruses, biological toxins[1]. Sources of danger can be, for example, the *Bordetella pertusis* bacterium, which causes whooping cough, a highly contagious disease that poses a public health threat, and the *Bacillus anthracis* bacterium, the cause of anthrax. Due to a number of factors (including environmental, biological, epidemiological, health, medical, social, community, behavioural, ethnographic, geopolitical) and their variables, anthrax can pose a threat at different levels. It can pose an epidemic or public health threat if it applies to human cases, and an endemic threat if it applies to a specific population or is common in a geographical region. In addition, anthrax may pose an epizootic threat if it affects animal infections, as well as a terrorist threat in the case of deliberately causing human and/or animal infections. Because of the possibility of different forms of anthrax among humans (pulmonary, cutaneous, gastrointestinal), requiring slightly different types of treatment and post-exposure measures, assessing the risk of contracting the disease is complex and beyond the jurisdiction of a single scientific discipline.

A consequence of the existence of a biohazard may be that the technology used for the selection, proliferation or modification of micro-organisms, apparatus for biological synthesis or biotransformation used in the production, isolation and purification of products of organic origin (proteins, including toxins) may be misused. For example, a bioreactor (fermentor) used for the production of bacteria under large-scale continuous culture conditions can be used in two ways depending on its intended use, i.e. as equipment prohibited by international law if used for the production of biological agents for warfare purposes, and as equipment permitted for use and dissemination if used for the production of biological agents for peaceful purposes, e.g. health care (production of vaccines, antibiotics, antiviral drugs, therapeutic proteins) or environmental protection (production of plant protection products). In both of these cases, the same technology and instrumentation is used during manufacture. Therefore, during the initial inspection of a site, it is often difficult to resolve whether an activity involving the production

[1] The article builds on issues analysed in the author's doctoral dissertation. The article has updated the text in relation to the dissertation. Moreover, it has been expanded to include threads on events that occurred after September 2018.

of microorganisms or biological toxins is being carried out for peaceful, hostile or both purposes. Because of the dualistic nature of technology using living biological systems in industrial production, it is referred to as dual-use technology. A slight modification of it can make it serve offensive instead of defensive purposes[2].

Ensuring effective biosecurity is a major challenge. This is due to the multitude of factors that influence it. These include, among others: the profile of human activity and its objectives, the diversity of biological agents, the possibility of modifying them at different stages of gene expression, the multiplicity of biotechnological processes and methods, the variability of environmental conditions affecting the distribution and availability not only of the agents themselves, but also of vectors (carriers) of infectious diseases, the different ways in which they are released, the specificity of individual conditions at the cellular level, which have a direct impact on susceptibility to disease.

International agreements on biosecurity

The broad spectrum of human activities and the biological threats that result from them means that, despite the common goal of effective biosecurity, the means to achieve it may be different. Stakeholders from a wide range of backgrounds debated approaches to such protection, including specialists in international law dealing with bioweapons and toxin prohibition, environmental and biodiversity protection, public health and epidemiology, animal health protection, phytosanitary protection, occupational safety and health protection in laboratory, health crisis response, as well as representatives from a wide range of academia. Each of these communities identified as leading those demands that coincided with its subjective objectives. These objectives included, among others: disarmament and non-proliferation of weapons of mass destruction (hereinafter: WMD), countering bioterrorism, protecting human health and emergency response to epidemics, protecting biodiversity, protecting

[2] With malicious intent, a biohazard can be created through equipment that is also used by other industries, such as fuel production equipment or installations designed to ferment food beverages. In addition, such apparatus can be cleaned or dismantled within hours, making it possible for criminals to quickly hide signs of their activities.

the health of animals and crops, occupational safety and health protection against harmful biological agents, raising awareness of biological risks.

The concept of biosecurity originates from international agreements on disarmament and non-proliferation of biological and toxin weapons. The first agreement banning the use of biological warfare agents was the *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare*, commonly referred to as the Geneva Protocol[3]. Poland was also involved in the work on this document. This was a huge step forward in sanctioning the ban, even though the protocol covered only the use of these agents in times of war. Nevertheless, if the biological weapons research, production and stockpiling were not oficially banned, they were allowed in silent consent. In addition, some signatories (France, the United States, the United Kingdom) reserved the right to use them in retaliation if the adversary used the agent first, which was an additional limitation of the ban. Despite this, the Geneva Protocol never lost its relevance, as evidenced by the reference to it in the preambles of two later agreements: the 1972 *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, commonly referred to as the Biological and Toxin Weapons Convention (hereinafter: BTWC)[4], and the 1993 *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, commonly referred to as the Chemical Weapons Convention (hereinafter: CWC)[5].

The BTWC is a key agreement concerning biosafety and biosecurity issues. This topic was also addressed in United Nations Security Council Resolution 1540 of 2004[6] on the global ban on all four types of WMD. International control regimes over biological and toxin weapons introduced by members of The Australia Group (AG)[7], including Poland, serve to

[3] *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare*, 1925.

[4] *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 1972*.

[5] *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, 1993.

[6] *Resolution 1540 (2004) / adopted by the Security Council at its 4956th meeting, on 28 April 2004*, 2004.

[7] *Fighting the spread of chemical and biological weapons*, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/index.html [accessed: 22 II 2025].

control the transfer and export of biological agents, toxins and dual-use technologies.

The topic of biological security is also addressed in other international agreements to which Poland is a state party. These include the Convention on Biological Diversity[8] and its two Protocols – on the supervision of living genetically modified organisms[9] and on the protection of biological diversity and the Earth's natural ecosystems[10], the International Health Regulations[11] established by the World Health Organization (WHO), and agreements on the transport of dangerous goods[12]. Handbooks and recommendations on biosafety and biosecurity in the laboratories, repositories, transport, research and development or in the event of the intentional use of chemical, biological, radiological and nuclear (CBRN) agents are also a valuable source of knowledge on biosecurity.

Biological and Toxin Weapons Convention (1972)

The text of the BTWC comprises 15 articles. It is the first multilateral legally binding agreement and currently the most important treaty in the field of non-proliferation of biological and toxin weapons in the world. It forms the basis for subsequent biosafety and biosecurity considerations and therefore requires more attention.

Representatives of the States Parties, including Poland, have been meeting every 5 years or so since 1980 and hold review conferences. The purpose of these deliberations is to review the operation of the BTWC to date and to develop a final document. It presents newly adopted arrangements to better interpret and understand the objectives of the Convention in the context of currently applicable normative documents, advances in knowledge and technology as well as activities undertaken in international fora in this area.

[8] *The Convention on Biological Diversity*, 1993.

[9] *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2003.

[10] *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, 2014.

[11] *The International Health Regulations*, World Health Organization 2005.

[12] *European Agreement Concerning the International Carriage of Dangerous Goods by Road* (ADR); *The Regulation concerning the International Carriage of Dangerous Goods by Rail* (RID); *The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways* (ADN); *The IATA Dangerous Goods Regulations* (IATA DGR).

In addition, the States Parties to the BTWC are required to submit so-called confidence-building measures (CBMs) in the form of reports each year. Their purpose is to eliminate possible doubts or suspicions about activities carried out for peaceful purposes in the field of biological sciences and to promote transparency and information sharing. The report includes below data:

1) information on research centres, laboratories and national biological defence research and development programmes;
2) information on outbreaks of infectious diseases and similar occurrences caused by biological toxins in the last year;
3) last year publication of results and promotion of use of knowledge in the coming year;
4) list of national legislation, regulations and other measures that have been established with reference to the BTWC;
5) information on past activities in offensive and/or defensive biological research and development programmes conducted after 1 January 1946;
6) data on national vaccine production facilities[13].

The BTWC was the first Convention to address the topic of biosafety and biosecurity, particularly in Articles I, III, IV, VII, IX and X. The review conferences over the past 44 years have successively detailed the provisions in this regard.

Article I

The BTWC does not specify biological agents and toxins that can be used as weapons, which is an advantage and disadvantage at the same time. This allows it to cover a wide range of biological agents that pose a risk to humans, animals and plants and that are acquired in different ways. For example, the final documents of the review conferences assume that Article I applies to all harmful microorganisms or other microbial agents or toxins occurring naturally and artificially produced or modified[14]. It also covers particles and cellular elements of agents and toxins, including synthetic equivalents obtained chemically or structural analogues of naturally occurring compounds, regardless of their source or method of production,

[13] *Confidence Building Measures,* United Nations, Office for Disarmament Affairs, https://disarmament.unoda.org/biological-weapons/confidence-building-measures/ [accessed: 13 X 2024].

[14] *Final Document of the Sixth Review Conference,* Geneva 2006. BWC/CONF.VI.I.1.

type and amount, the production of which has no prophylactic, protective or peaceful justification[15], as well as toxins of bacterial, animal and plant origin, including their synthetically produced analogues[16].

With regard to equipment and technology, the situation is identical. The Convention does not introduce equipment names or technical specifications, which makes it possible to prohibit all equipment and technology that could be potentially used for proliferation of biological warfare agents or their release[17].

Article III

It applies directly to biosecurity issues, as it obliges to refrain from transferring biological agents or their means of transfer for hostile purposes, assisting in and affecting their development work. The review conferences detailed this provision and obliged States Parties to ensure protection during transfer for all Article I agents. It was postulated that this should be done, inter alia, through national implementation of the BTWC, legal norms for the transfer of biological agents and the facilities that may be used for their production, the obligation to supervise and control these transfers. In 1996, ways to prevent the acquisition of these agents by a broad group of potential recipients (an individual, a state, a group of states or an international organisation) and their transfer within the national territory were discussed[18]. Unfortunately, this has proved problematic, since under the same convention, States Parties are obliged to allow the widest possible exchange of equipment, materials as well as scientific and technical knowledge for the peaceful use of biological agents, toxins and technology (Article X). For this reason, there have been repeated calls for the creation of instruments to establish a control regime over all biological agents, biological toxins, dual-use devices and their components for which there is a risk that they could be used for offensive biological and toxin weapons development programmes[19].

[15] *Final Document of the Third Review Conference*, Geneva 1991. BWC/CONF.III.I.3; *Final Document of the Fourth Review Conference*, Geneva 1996. BWC/CONF. IV.I.5.

[16] *Final Document of the Second Review Conference*, Geneva 1986. BWC/CONF.II.I.5.

[17] *Final Document of the Seventh Review Conference,* Geneva 2011. BWC.CONF.VII.I.1; *Final Document of the Eighth Review Conference*, Geneva 2016. BWC/CONF.VIII.I.1; *Final Document of the Ninth Review Conference*, Geneva 2022. BWC/CONF.IX/CRP.2/Rev.1.II.I.

[18] *Final Document of the Fourth Review Conference*... BWC/CONF.IV.III.3.

[19] *Final Document of the Third Review Conference*... BWC/CONF.III.III.1; *Final Document of the Fourth Review Conference*... BWC/CONF.IV.III.2; *Final Document of the Sixth Review*

It was proposed that export controls should issue licences or permits, which would be granted once there was assurance that the goods in question would reach a pre-approved consignee and be used for purposes consistent with the agreement[20]. It was recommended that States Parties create a system of safeguards and protection for each of the measures applying to the article[21], which was problematic given the absence for a long time of an arbitrary list of these measures.

After the terrorist attacks in 2001, the need to regulate the protection of agents included in the Article I of the BTWC has increased. It was concluded that the threat posed by biological terrorism should imply the need for more effective measures to control the carriage and transfer of these agents. This was particularly true for countries not party to the BTWC, regardless of whether the transfer would be to an individual or to members of groups representing the views of specific nationalities or other groups. This generated considerable debate, as it was feared that the proposed measures could harm traditional trade and impede cooperation between States Parties for peaceful purposes[22].

Polarisation of positions on this issue is still evident. A large divergence is observed between highly developed countries with adequate capacities, scientific and technical backgrounds, making extensive use of biological agents in the (commercial) health sphere, and countries without sufficient specialist knowledge and biological capacity. They call for unfettered access to biological materials and technology as well as the provision of far-reaching assistance rather than the prior introduction of control and surveillance mechanisms for biological agents[23].

Article IV

It obliges States Parties to take all measures to prevent the production of biological and toxin weapons, but does not specify these measures explicitly, thus allowing the possibility of introducing arbitrary tools

Conference... BWC/CONF.VI.III.8-9; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.III.9; *Final Document of the Eighth Review Conference*... BWC/CONF/VIII.III.9.

[20] *Final Document of the Sixth Review Conference*... BWC/CONF.VI.III.8.

[21] Ibid. BWC/CONF.VI.III.9.

[22] *Final Document of the Fifth Review Conference*, Geneva 2001–2002. BWC/CONF.V.COW/CRP.1.III – *Annex to the draft report of the Committee of the Whole*.

[23] *Biological Weapons Convention – Ninth Review Conference*, United Nations, Office for Disarmament Affairs, https://meetings.unoda.org/bwc-revcon/biological-weapons-convention-ninth-review-conference-2022 [accessed: 8 III 2025].

and measures. The final documents of the review conferences assumed that undertakings should derive from the legal instruments in force in the country, both from the penal provisions for the implementation on the territory of the country of the prohibition of the development, production, storage, acquisition and maintenance of biological agents and equipment listed in Article I, and from the provisions related to the prevention of such activities by exercising control over them[24].

In order to effectively fulfil Article IV obligations, the security of biological agents was repeatedly addressed at review conferences. For example, the implementation of international standards for biosafety management and biosecurity[25], the implementation of regulations for the physical protection of property and the safeguarding of facilities where particularly dangerous biological agents and toxins are used were considered particularly important. It was emphasised that the establishment of regulations in this area would significantly affect not only public health security in the event of epidemic threats, but also the safeguarding of infectious agents and toxins against their release or hostile takeover[26]. In enhancing the effectiveness of this article, the need to secure biological agents and biotoxins was pointed out, not only in laboratories or storage areas, but also during transport[27]. When in 2005 WHO published the International Health Regulations addressing the issue of building national preparedness for detecting, identifying and responding to cross-border health threats, the close correlation of this legal instrument with Article IV of the BTWC was recognised. The States Parties to the BTWC, which are to a large extent also WHO Member States, began to advocate for national measures towards improving diagnostic methods, strengthening epidemiological surveillance and the capacity to detect infectious disease

[24] *Final Document of the Second Review Conference*... BWC/CONF.II.IV.4; *Final Document of the Third Review Conference*... BWC/CONF.III.IV.3; *Final Document of the Fourth Review Conference*... BWC/CONF. IV.IV.1-4; *Final Document of the Sixth Review Conference*... BWC/CONF.VI.IV.11.i; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.11.i; *Final Document of the Eighth Review Conference*... BWC/CONF.VIII.IV.11.a-b.

[25] *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.13a.

[26] *Final Document of the Second Review Conference*... BWC/CONF.II.IV.4ii; *Final Document of the Third Review Conference*... BWC/CONF.III.IV.3ii; *Final Document of the Fourth Review Conference*... BWC/CONF. IV.IV.3; *Final Document of the Sixth Review Conference*... BWC/CONF.VI.IV.11.iii; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.11.iii; *Final Document of the Eighth Review Conference*... BWC/CONF.VIII.IV.11.b-c.

[27] *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.11.

outbreaks at the national, regional and international levels in order to simultaneously implement both agreements. In doing so, it was recognised that by continuously monitoring epidemiological trends through national disease surveillance system, the detection of atypical outbreaks or other biological threats would be much more efficient and faster. Especially the outbreaks, which could be a potentially result of works conducted in contrary to the BTWC[28].

Article IV also called for the implementation of legal instruments for the control and rationing of persons handling pathogens, the dissemination of knowledge among them and the promotion of ethical attitudes. It was considered that education and awareness-raising on the possibility of using particularly dangerous biological agents, biological toxins and devices as well as means of their transmission with the intention of contravening the provisions of the BTWC could enhance the effectiveness of Article IV activities. It was suggested that content about the BTWC and the Geneva Protocol should be included in training programmes and educational materials for medical, life sciences and military students[29]. In 2022, it was requested that the audience be expanded to include those in the public and private sectors as well as academia, and to become more actively involved in early identification of risks of non-compliance with the BTWC, including acts of bioterrorism. Particular scrutiny should be given to persons who have gained access to harmful biological agents and toxins applicable to the BTWC and to professionals who, through their knowledge and skills, are able to modify biological agents and increase the virulence of pathogens or exacerbate the course of diseases caused by them. This was considered as one of the possible measures to prevent the production of biological and toxin weapons[30].

[28] *Final Document of the Sixth Review Conference*... BWC/CONF.VI.IV.13; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.13vi; *Final Document of the Eighth Review Conference*... BWC/CONF.VIII.IV.13f.

[29] *Final Document of the Second Review Conference*... BWC/CONF.II.IV.4iii; *Final Document of the Third Review Conference*... BWC/CONF.III.IV.3iii; *Final Document of the Fourth Review Conference*... BWC/CONF.IV.IV.3iii.

[30] *Final Document of the Seventh Review Conference*... BWC/CONF.VII.IV.13ii-iv; *Final Document of the Eighth Review Conference*... BWC/CONF.VIII.IV.13b-d; *Final Document of the Ninth Review Conference*... BWC/CONF.IX/CRP.2/Rev.1.II.IV.

Article VII

It obliges treaty States Parties, international, governmental and non-governmental organisations to provide support to countries against which the UN Security Council has confirmed violations of the BTWC. The article compels mutual assistance in investigations in the event of the commission or suspected commission of an act prohibited by the convention. In order to effectively fulfil the provisions of this article, the review conferences recommended that the UN should play a coordinating role in the investigation, with the support of relevant international organisations, including the WHO, which is the international organisation with jurisdiction over global human health issues, including epidemiological investigations. It was felt that the involvement of epidemiologists, alongside other organisations, including those competent to investigate the commission and/or suspicion of an act prohibited by the Convention, would improve the detection and identification of the source of disease, describe the routes of transmission of the infectious agent and indicate the appropriate course of action if the agent were to be used as a weapon or a terrorist agent[31]. In 2006, the list of these organisations was expanded, as it was accepted that mutual assistance would strengthen global security and minimise the impact of similar incidents[32].

In addition, there was a call, similar to Article IV, for national efforts to strengthen surveillance of infectious diseases and the capacity to detect and identify biological agents that could be the source of infectious disease outbreaks[33].

Article IX

It commits to the establishment of a ban on chemical weapons and agents that may contribute to their production and proliferation, which on the face of it, correlates poorly with biosecurity issues. However, it should be remembered that during the deliberations on the BTWC, the issue of chemical warfare agents was repeatedly addressed and the need for

[31] *Final Document of the Third Review Conference*... BWC/CONF.III.VII.4; *Final Document of the Fourth Review Conference*... BWC/CONF. IV.VII.5.

[32] *Final Document of the Sixth Review Conference*... BWC/CONF.VI.VII.34; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.VII.36.

[33] *Final Document of the Sixth Review Conference*... BWC/CONF. VI.VII.35; *Final Document of the Seventh Review Conference*... BWC/CONF. VII.VII.38; *Final document of the Eighth Review Conference*... BWC/CONF.VIII.VII; *Final Document of the Ninth Review Conference*... BWC/CONF.IX/CRP.2/Rev.1.II.VII.

a Chemical Weapons Convention was raised. This resulted in the emergence immediately after its promulgation of 181 instruments of ratification and applications for accession[34].

It was in the context of Article IX of the BTWC that the issue of the increasing convergence of biology and chemistry and the challenges of their security began to be recognised. The 2011 review conference recognised that the risks at the interface between biology and chemistry, and the convergence of biological and chemical technologies applicable to biosafety and the protection of humans and the environment, should suggest a concerted effort to prevent biological and chemical risks in relation to both treaties, i.e. the BTWC and the CWC[35].

This is important insofar as the differences between chemically synthesised pathogens and chemical compounds produced using living organisms are very often blurred. Using chemical systems, a dangerous pathogen can be developed, and using bacterial cultures, the biological toxins, including their synthetically produced analogues, can be made[36].

Article X

It is primarily concerned on the broad cooperation of States Parties in scientific research, bioengineering work, specific knowledge and technology transfer. It commits to the development and use of bioscience and technology for the benefit of mankind and the environment. This obligation should be implemented by allowing the exchange of equipment, materials, scientific and technical information on the use of bacteriological (biological) agents and toxins to the fullest extent possible, provided they are for peaceful purposes. This article obliges cooperation in contributing to the further development and use of scientific discoveries in the field of bacteriology for disease prevention or other peaceful purposes.

It was requested that States Parties to the BTWC, especially developed countries, expand scientific and technological cooperation with developing countries. The cooperation would include, inter alia: transfer of knowledge, experience and technological solutions for peaceful uses of biological agents and toxins, transfer and exchange of information, training

[34] *Final Document of the Fourth Review Conference*... BWC/CONF. IV.IX.45; *Final Document of the Seventh Review Conference*... BWC/CONF. VII.IX.48.

[35] *Final Document of the Seventh Review Conference*... BWC/CONF. VII.IX.49.

[36] *Final Document of the Second Review Conference*... BWC/CONF.II.I.5.

of scientists and experts, as well as transfer of materials and resources[37]. Access to expertise would include bacteriology, biotechnology, genetic engineering, microbiology and related scientific and technical fields[38].

During the 2016 review conference, the issue of cooperation, viewed differently by Western and developing countries, was particularly debatable, in addition to the introduction of a legally binding verification mechanism. The need to strengthen it within the framework of Article X was particularly highlighted by developing countries (e.g. Iran, Venezuela, Cuba) grouped in the Non-Aligned Movement (NAM) and other States. They demanded wider access to modern biotechnology developments and equipment, know-how, training and scientific and academic exchange, which was not welcomed by other states (e.g. USA, UK, Sweden and Germany)[39]. It was only during the agreement of the final document of the last review conference in 2022 that it was decided to establish an expert working group. Its purpose will be, among other things, to develop a mechanism for reviewing and assessing scientific and technological developments relevant to the BTWC[40].

The concept of biosecurity

The terms *biosafety* and *biosecurity* have repeatedly been treated as either identical or synonymous definitions. The term *biosafety* appeared earlier than *biosecurity* and for a long time included biosecurity issues. As a result, in some countries (e.g. France, Germany, Russia and China), the term biosecurity did not function at all, which often caused practical problems.

In order to better understand the differences between these terms, the 2003 BTWC participants proposed their informal interpretation. They assumed that biosafety is the protection of humans from micro-organisms, while biosecurity focuses on the protection and containment of micro-organisms from hostile human activities. Five years later, it was clarified that biosafety should focus on measures to create safe working conditions with harmful biological agents and to protect people and

[37] Ibid. BWC/CONF.II.X.3ii-iv; *Final Document of the Third Review Conference*... BWC/CONF. III.X.3ii-iv; *Final Document of the Fourth Review Conference*... BWC/CONF.IV.X.12ii-iv, viii.; *Final Document of the Sixth Review Conference*... BWC/CONF. VI.X.49; *Final Document of the Seventh Review Conference*... BWC/CONF.VII.X.58.

[38] *Final Document of the Second Review Conference*... BWC/CONF.II.X.2.; *Final Document of the Third Review Conference*... BWC/CONF.III.X.2; *Final Document of the Fourth Review Conference*... BWC/CONF.IV.X.2.

[39] *Final Document of the Eighth Review Conference*... BWC/CONF.VIII/4.X.59.

[40] *Final Document of the Ninth Review Conference*... BWC/CONF.IX/CRP.2/Rev.1. X.71.

the environment from accidental releases. Biosecurity, in turn, should be understood as the various means and ways of protecting biological agents and dual-use technologies from theft or unauthorised acquisition or acquisition and their use to cause harm. It comprises: physical protection of premises and facilities where particularly dangerous pathogens and toxins are stored, control of the transfer of dual-use products and technologies, proper packaging, labelling and secure during the transport of consignments containing infectious material, secure of knowledge, technology and the results of scientific and research work that could be a potential source of information on how to produce biological and toxin weapons, counteracting biological terrorism. Biosecurity also addresses issues of enforcing compliance with international agreements, countering agroterrorism (protecting the environment from the deliberate release of alien or invasive species to cause damage to agricultural crops), conducting investigations using biological traces as evidence and investigative efforts to apprehend perpetrators of bioterrorist acts[41].

The UN Security Council Resolution 1540 (2004)

The UN Security Council Resolution 1540 (hereinafter: Resolution 1540)[42] is the first international legally binding instrument comprehensively addressing all three types of WMD. The implementation of this resolution implies the need for national implementation of the provisions of the three agreements: the BTWC, the CWC and the Nuclear Non-Proliferation Treaty (NPT)[43].

The intent of Resolution 1540 directly supports the implementation of the obligations under the BTWC, as it details and specifies biosecurity measures to counter the illicit possession, manufacture, storage, transport, transit and trade in biological and toxin weapons materials and technologies. Measures are implemented in four areas:

1) adoption and enforcement of criminal law regarding non-compliance with the ban on the production of biological and toxin weapons and their means of proliferation,

[41] *Biosafety and Biosecurity – Submitted by the Implementation Support Unit*, 24 June 2008, BWC/MSP/2008/MX/INF.1; A. Bielecka-Oder, *Safety and Security Regulations Against Biological Threats*, in: *Defence Against Bioterrorism*, V. Radosavljevic, I. Banjari, G. Belojevic (eds.), Springer Netherlands 2018.

[42] *Resolution 1540 (2004)*...

[43] *The Nuclear Non-Proliferation Treaty* (NPT), 1968.

2) adoption of measures to reduce or eradicate illicit trafficking in WMD and materials used for their production,
3) not to hamper trade and the provision of commercial health services conducted in accordance with the applicable legislation,
4) to encourage dialogue and exchange of experiences between countries on security measures in place and on the protection of territorial borders and export controls.

In order to verify the effectiveness of national implementation of these assumptions, the 1540 Committee has developed the 1540 Matrices to describe the degree of implementation[44]. In the section on biological and toxin weapons and related materials, each country is obliged to:

- provide information on membership of international and regional agreements,
- provide information on national legally binding and non-binding instruments prohibiting the provision of services, assistance and funding activities listed in the matrix, including but not limited to production, extraction, storage, development, transport, transfer of ownership to other economic operators and/or individuals,
- provide information on the type of measures applied to national mechanisms for the control of compliance with biosafety and biosecurity regarding the production, use, storage, transport and other methods of obtaining biological agents, toxins and their means of dissemination, and the licensing of facilities involved in the abovementioned activities, the registration of persons handling the abovementioned materials, the verification of their trustworthiness, the use of physical protection, compliance with regulations on genetic engineering work and other regulations on biosafety and security,
- include national regulations, procedures, measures, including listing institutions responsible for, inter alia, exercising trade controls, negotiating the sale of goods and technology as well as brokering, conducting investigative and/or intelligence activities, verifying credentials and licences, conducting export controls based on control lists of biological agents, toxins and dual-use technologies and controlling their sources of funding.

[44] *Approved 1540 Committee Matrix of [State]*, https://www.un.org/en/sc/1540/documents/Matrix%20Template%202013%20(E).pdf [accessed: 17 XI 2024].

The Resolution 1540 is one of the main pillars of the international non-proliferation and WMD trafficking control order, as reflected in the 2022 EU Counter-proliferation Strategy Progress Report. It indicates that EU countries consider it as (...) *a key part of the global efforts to prevent the proliferation of Weapons of Mass Destruction, including to terrorists and other non-state actors*[45].

Australia Group (1985)

Currently, there are several multilateral export control regimes for security-sensitive materials and agents in the world (e.g. the Wassenaar Arrangement, the Zangger Committee, the Australia Group, the Nuclear Suppliers Group, the Missile Technology Control Regime). The most important body in the area of export control of biological warfare agents and dual-use technologies, significantly contributing to countering the proliferation and spread of biological and toxin weapons agents, is the Australia Group[46]. Its activities directly support the implementation of the provisions of the BTWC by coordinating the export policies of strategic goods by its members and enhancing the effectiveness of national dual-use licensing measures. The AG members, including Poland, are simultaneously States Parties to the BTWC and CWC[47].

As part of its control regime over biological and toxin weapons, the AG has developed three control lists: a) a list of biological dual-use equipment, technology and software, b) a list of human and animal pathogens and toxins, c) a list of plant pathogens that are subject to specific export controls because of their potential for use in the production of biological and toxin weapons. These are important lists as they are the first to indicate the specific species names and technical specifications of equipment with dual-use potential that should be subject to specific controls. These

[45] *Sprawozdanie roczne z postępów w realizacji strategii Unii Europejskiej przeciw rozprzestrzenianiu broni masowego rażenia (2022)* (Eng. Annual Progress Report on the Implementation of the European Union Strategy against the Proliferation of Weapons of Mass Destruction (2022)), Prawo.pl, https://www.prawo.pl/akty/dz-u-ue-c-2023-383,72216862.html [accessed: 28 IX 2024].

[46] *Introduction*, The Australia Group, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/introduction.html [accessed: 21 IX 2024].

[47] *Participants*, The Australia Group, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/participants.html [accessed: 21 IX 2024].

lists should become a point of reference for national regulations[48]. When examining the individual items on these lists, it should be borne in mind that, for example, the control regime does not apply to biological agents that are components of protective vaccines (peaceful purpose). It would apply if these agents were exported in the form of pure live cultures or, in the case of toxins, pure isolates (dual use possibility).

Both the BTWC Convention and Resolution 1540 have not lived up to such specificity. This can be presumed to be a consequence of the universality of these agreements, which necessitated a certain level of generality and the need for consensus. This does not apply to the AG, which is an independent grouping and thus perhaps more effective in implementing its resolutions.

It is worth mentioning that the AG members frequently address the topics of potential threats as a consequence of changing geopolitical and international conditions. For example, the 2022 Plenary discussed the possibility of the use of chemical and biological weapons agents by the Russian Federation. The possibility of attacks on Ukrainian civilian facilities where biological and chemical agents are used or deposited was not ruled out. The global threat posed by disinformation on the subject was also discussed[49]. This theme was also taken up in 2023–2024. It was emphasised that, because of the threat of chemical and biological terrorism, particular vigilance must be exercised with regard to ongoing procurements that could support hostile activities, and there is a need to guard against the misuse of chemical and biological technologies and equipment by non-state actors. Attention was also drawn to the risks posed by the transfer of intellectual resources and expertise in areas of science that may be applicable to non-proliferation agreements, or the sharing of such resources and knowledge through mass media or other channels of exchange, and the need for effective controls over intangible transfers of technology (ITT)[50].

[48] *Australia Group Common Control Lists*, The Australia Group, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/controllists.html [accessed: 30 XI 2024].

[49] *Statement by the Chair of the 2022 Australia Group Plenary*, The Australia Group, https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/2021-ag-plenary-statement.html [accessed: 22 IX 2024].

[50] *Statement by the Chair of the 2023 Australia Group Plenary*, Paris 2023; *Statement by the Chair of the 2024 Australia Group Plenary*, Paris 2024; K. Hyuk, *Intangible Transfer of Technology (ITT): Open-source Information Analysis for the Implementation of Sanctions on North Korea*,

The AG members attend meetings of BTWC States Parties and support the performance of its provisions. In 2024 it was indicated that they are looking forward to the development of two new mechanisms – concerning international cooperation and assistance and relating to scientific and technological development, as well as progress in the implementation of biosecurity measures[51].

Convention on Biological Diversity (1993)

The Convention on Biological Diversity (hereinafter: CBD Convention)[52] is the most important international agreement dedicated to the protection of environmental biodiversity from the risks posed by the use of modern biotechnologies. Its objectives, in addition to conservation, are the sustainable use of the elements of biodiversity, the fair and equitable sharing of the benefits arising from the use of genetic resources, the respect of rights over them and adequate funding[53]. Through the protocols arising from the implementation of its objectives, it indirectly addresses the issue of biosafety and security in the context of the BTWC.

Cartagena Protocol on Biosafety (2003)

It is a legally binding instrument that implements the first objective of the CBD Convention, namely the protection of biodiversity, including the protection of human, animal, plant and environmental health from the harmful effects of the products of modern biotechnology[54].

It is well known that, alongside the many benefits of the achievements of modern biotechnology, particularly molecular biology and genetic engineering techniques, there is a narrow margin of potentially hostile uses. Therefore, according to the BTWC, the production and use of bacteria, viruses and their toxins and the application of technology for purposes other than peaceful or protective are prohibited, and consequently the introduction into the environment and the spread of biological agents that could be used as weapons, cause human disease (bioterrorism), cause

38 North, 10 III 2023, https://www.38north.org/2023/03/intangible-transfer-of-technology-itt-open-source-information-analysis-for-the-implementation-of-sanctions-on-north-korea/ [accessed: 9 III 2025].

51 *Statement by the Chair of the 2024 Australia Group Plenary*..., para. 14.

52 *The Convention on Biological Diversity*, 1993.

53 Ibid., art. 1.

54 *Cartagena protocol on biosafety to the Convention on biological diversity*.

damage to the agricultural economy (agroterrorism) – whether through the deliberate contamination of food (food bioterrorism) or the deliberate destruction of environmental resources. Therefore, the deliberate modification of micro-organisms with dual-use potential for the purpose of releasing them into the environment or creating a threat to the health of humans, animals and wildlife is one of biosecurity aspects in the context of the BTWC.

The Cartagena Protocol was prompted by the need to establish rules for the safe use of living modified organisms (LMOs), including genetically modified microorganisms (GMMs), and to regulate international trade in them. The absence of these rules could have a negative impact on the conservation or sustainable use of environmental biodiversity and consequently pose a threat to public health[55]. The protocol also sets out the precautionary measures necessary to be taken in the event of a release of LMOs. Under this agreement, countries party to the protocol have the full right to restrict the import or use of these organisms, prohibit them if there is no scientific evidence or certainty about their safety[56].

Genetic modification of living infectious agents may create a weapon with new abilities, i.e. a known gene, but not present in the agent in question because it has been artificially incorporated into the genome, or an innovative payload, i.e. equipped with a newly created gene. Therefore, modifications such as transferring drug resistance genes to microorganisms previously lacking them in order to reduce the pathogen's sensitivity to the drug and deliberately altering the surface protein structures of pathogens responsible for antibody formation in the organism (defence), i.e. modifying the antigenic properties of pathogenic bacteria, are considered to require special attention. Work aimed at modifying the lipopolysaccharide structures of bacteria in such a way as to impede their early detection and recognition by the immune system and involving the addition of genes responsible for toxin production are also debatable. Potentially hazardous may be modifications of bacteria to increase their stability in the external environment, e.g. increasing their resistance to harmful atmospheric conditions (UV radiation) or mechanical stress (strength), resulting from their release into the environment and prolonged or vigorous mixing during bioreactor culture. The both transformation

[55] Ibid., art. 4.

[56] Ibid., art. 16–18.

of nonpathogenic micro-organisms into pathogenic by the deliberate transfer of genes responsible for pathogenic properties, as well as molecular changes programming micro-organisms to produce specific chemical compounds, including bioware toxins, which can be used as weapons, may be potentially dangerous[57].

Both the BTWC and the Cartagena Protocol regulate transfers. Article III of the Convention on transfer control of biological and toxin weapons agents and facilities, as well as Article X on the transfer of materials and technology and mutual cooperation for peace purposes. The Cartagena Protocol, on the other hand, on transboundary movements of LMOs as well as knowledge and technology transfer. Both agreements further emphasise the need to promote the exchange of information on experiments carried out and on national strategies implemented to counter the threats posed by biotechnology. In the case of the Protocol, this is the Biosafety Clearing-House[58], and in the case of the BTWC, it is the CBMs. However, it should be noted that the objectives of the two documents are different[59].

Despite the distant regulatory areas, the scopes of content of the two agreements – the BTWC and the Cartagena Protocol – converge in terms of assessing the effects of genetic modification. All biological agents subjected to modifications that alter their genotype qualify as agents covered by the prohibition expressed in the BTWC, as long as the purpose of the modifications is hostile use of the agents, since the prohibition covers all biological agents, including those produced by methods of modern biotechnology.

Nagoya Protocol on Access to Genetic Resources (2014)

The object of the regulation is to protect genetic resources from their illegal acquisition and use, which is referred to as biopiracy[60]. It mainly concerns the unlawful extraction and use of wild plants, exotic animals, endemic micro-organisms, their gene pools and the traditional knowledge

[57] K. Nixdorff, D. Schilling, M. Hotz, *Critical Aspects of Biotechnology in Relation to Proliferation*, in: *The Implementation of Legally Binding Measures to Strengthen the Biological and Toxin Weapons Convention*, M. Chevrier et al. (eds.), NATO Science Series II, vol. 150, 2004.

[58] *The Convention on Biological Diversity…*, art. 20.

[59] Ibid., art. 22.

[60] *Collins English Dictionary – Complete and Unabridged*, 12th edition, Collins 2014; E. Hammond, *Biopiracy Watch: A compilation of some recent cases*, vol. 1, Third World Network 2013.

associated with them[61] acquired from their region by pharmaceutical companies in order to research new medicines, patent them and then reap the material benefits.

The Nagoya Protocol implements the third objective of the CBD Convention, namely (...) *the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components*[62].

The States Parties to the Nagoya Protocol are mostly developing countries, for which the provision gives them the opportunity to legitimately raise their economic status by deriving material and immaterial benefits[63]. It states that genetic resources are pools of genes of species occurring naturally in nature (Latin: in situ), as well as man-made (Latin: ex situ) collections of resources – gene banks and microbial culture collections, including both living and dead biological material in the form of DNA or RNA.

And although the Nagoya Protocol does not cover human genetic material, it applies to micro-organisms or pathogenic micro-organisms isolated from human tissue, blood or body fluids. The analogy is with food commodities – the protocol does not apply directly to them, but it does apply to pathogens isolated from food[64]. In addition, it introduces concepts important for biosecurity and the protection of intellectual property[65].

The Nagoya Protocol is of indirect relevance to biosecurity, as its main purpose is to protect the rights of states to biological resources and intellectual property about them. It treats the protection of biological

[61] Traditional knowledge should be understood as folk, indigenous knowledge.

[62] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*, art. 1.

[63] E. Martyniuk, *Nowe uregulowania prawne dotyczące dostępu do zasobów genetycznych zwierząt i ich potencjalny wpływ na prace hodowlane i badania naukowe* (Eng. New regulations on access to animal genetic resources and their potential impact on breeding work and research), "Przegląd Hodowlany" 2016, no. 5, pp. 10–14.

[64] G. Verkley, M. Dunja, D. Smith, *The Nagoya Protocol and mBRCs: towards a MIRRI Best Practice for Access and Benefit Sharing (ABS)* – presentation at ECCO 34 Conference, Session 2 BRCs and Regulations, Paris, 28 V 2015.

[65] *Nagoya Protocol on Access to Genetic Resources...*, art. 2c and 2d.

collections, including agents hazardous to health, indirectly. However, its provisions translate into the need to establish safeguards in facilities where pathogen genetic resources and knowledge about them are collected and stored, in order to prevent their theft or other illegal use. This has indirect implications for reducing the risk of their unlawful use for hostile purposes as defined in Article I of the BTWC[66].

International Health Regulations (2005)

The International Health Regulations (IHRs)[67] are a legally binding instrument developed by the WHO to strengthen national capacities for prevention, epidemiological surveillance, detection and early warning and response to public health emergencies of international concern (PHEICs).

States Parties to this agreement, including Poland, are obliged to implement the IHRs and to build or improve national capacities for detection, identification, surveillance, prophylaxys, prevention of the spread of communicable diseases, biological risk assessment and preparedness to respond to major public health threats of international concern, with coordinated cooperation of national services involved in the response (in the absence of such capacities – in cooperation with the services of other states). However, IHRs should not disrupt cross-border passenger traffic and trade and should be based on national measures (legislative, legal, organisational, training)[68]. They include, inter alia, recommendations for the introduction of measures to safeguard human health when crossing border crossings, applying to travellers, their luggage, containers, means of transport, goods and consignments[69]. Each year at the World Health Assembly (WHA), progress in above mentioned aspects is discussed among Member States in relations to the implementation of IHRs[70].

The IHRs apply to infectious diseases and health threats that may spread beyond the administrative borders of countries, and whose control may require a coordinated response by several countries. This includes biological, chemical and radiological threats of unknown etiology that

[66] *The Workshop on Nagoya Protocol for "Collection Holders"*, Brussels 2017.

[67] *The International Health Regulations…*

[68] Ibid., art. 2, 12–13.

[69] *The International Health Regulations…*, art. 15–22, 23–39.

[70] *Implementation of the International Health Regulations (2005): Report by the Director-General*, World Health Organization 2024, https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_8-en.pdf [accessed: 8 III 2025].

have the potential to cause significant harm to human populations, as well as outbreaks of naturally occurring diseases, accidental events involving biological agents and toxins due to work-related accidents or negligence, acts of vandalism or sabotage, and deliberate criminal use[71]. Thus, the IHRs also indirectly refer to the BTWC.

In the IHRs, biosafety and biosecurity issues are concerned on national public health security capacities. Each country should have its own diagnostic capacity and, and in the absence of this, should establish cooperation with another country's facility to ensure an optimal level of health security for all countries[72]. It is also obliged to develop, strengthen and maintain preparedness to respond quickly and effectively to health threats and emergencies of international concern[73]. The Member State should also provide occupational safety and health measures to minimise risks associated with biological agents in laboratories[74], procedures for responding to the natural, accidental and intentional use of biological agents and toxins that may have adverse effects on the health of the public[75], and ways to prevent and control the transboundary spread of communicable diseases and other health threats[76]. Similarly, the BTWC, in its Article IV, calls on States Parties to nationally implement all possible biosecurity and biosafety measures, including improved detection methods and means of surveillance for infectious diseases. This was emphasised during the 2011 and 2016 review conferences. Also during the intersessional period between 2007 and 2010, issues related to the protection of workers in laboratories, secure of pathogens, toxins and equipment, applicable to the provisions of the Convention (2008), and issues related to improving response capacity for detection, identification, diagnosis and control of infectious diseases (2009) were addressed.

The health threats that have emerged over the past two decades, including the COVID-19 pandemic, have prompted the revision and

[71] *The International Health Regulations...*, Appendix II, 2005.

[72] Ibid., art. 5.1, 14, Annex 1, paragraph 6(b), 2005.

[73] Ibid., art. 13.1, 2005.

[74] The World Health Assembly Resolution 58.29, *Enhancement of laboratory biosafety*, 2005.

[75] The World Health Assembly Resolution 55.16, *Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health*, 2002.

[76] The World Health Assembly Resolution 58.3, *Revision of the International Health Regulations*, 2005.

updating of IHRs in some areas (e.g. data protection, use of digital documents). In May 2024, amendments were adopted to adapt the IHRs to current and future health security challenges.

It is also worth mentioning the currently drafted Pandemic Treaty, which aims to better prepare countries for future health threats. Similar to the BTWC, here as well, during the negotiation process the dichotomy of statements between developing and developed countries was observed. Mostly related to the access to genetic material of biological agents with pandemic potential, biomedical technology, scientific results and intellectual property protection of medical devices used during a pandemic[77].

Safe transport of biological substances

Infectious substances are classified as dangerous goods, the uncontrolled acquisition or release of which may cause biological contamination of the environment and create health risks. The main framework regulations for the classification, packaging and transport of hazardous materials have been defined by the UN Committee of Experts on the Transport of Dangerous Goods (UNCETDG). On the basis of these, and with the support of international organisations playing a leading role in relation to specific types of hazards and modes of transport (road, rail, air and sea), specific regulations were developed. The WHO has advised the UN in the development of regulations for the transport of toxic and infectious substances.

The main piece of legislation concerning the international carriage of dangerous goods by road, including infectious materials, is the *Agreement concerning the International Carriage of Dangerous Goods by Road* – ADR[78]. Among other things, it introduces the obligation to ensure the safe transport of infectious materials and sets out the responsibilities of the shipper, carrier and driver.

The WHO Guidance on regulations for the transport of infectious substances[79], which compiles the applicable regulations and provides a lot

[77] *Intergovernmental Negotiating Body*, World Health Organization, https://apps.who.int/gb/inb/index.html [accessed: 17 XI 2024].

[78] *ADR 2023 – Agreement concerning the International Carriage of Dangerous Goods by Road*, United Nations 2022.

[79] *Guidance on regulations for the transport of infectious substances, 2023–2024*, World Health Organization 2024.

of practical advice on how to classify a consignment, how to pack it safely, how to label it and how to handle it during loading and carriage, is also helpful in addressing transport issues. All biohazardous substances are classified into Class 6 – toxic and infectious substances and Subclass 6.2 – infectious substances. Individual Class 6.2 materials have been assigned classification code numbers: I1 – hazardous materials for humans, I2 – hazardous materials for animals only, I3 – clinical waste, I4 – diagnostic samples. They should be additionally marked with one of the following UN codes for the time of transport: UN 2814 – infectious substances affecting humans, UN 2900 – infectious substances having an animal effect, UN 3373 – diagnostic speciments from human and animal materials, UN 3291 – infectious clinical waste. The individual codes determine the method of packaging. For example, UN 2814 and UN 2900 should be packed in accordance with Instruction P620, UN 3291, in accordance with Instruction P621, and in case of UN3373 the packaging instruction P650 applies. On the other hand, genetically modified biological agents that do not meet the definition of 'toxic substance' or 'infectious substance' are included in Class 9 – miscellaneous dangerous substances and articles, including substances hazardous to the environment, which must be labelled UN 3245 and packed according to instruction P904.

In addition to this, the transport of infectious biological materials is divided into Category A and Category B. Category A is infectious material known or suspected to be capable of causing a fatal disease, a life-threatening disease or capable of causing permanent damage to health in man or animals. Category B is infectious material that does not meet the criteria of Category A, such as clinical specimens transported to the laboratory for diagnostic purposes.

According to WHO recommendations, it is the responsibility of the sender to properly classify the biological material, to pack and label the package so that it reaches its destination and does not pose a risk to humans, animals and the environment during transportation. It is the responsibility of the sender to attach transport documentation, select the appropriate mode of transport and inform the consignee of the date of shipment to ensure that the package is protected at every stage of the journey.

The carriage of infectious materials is further detailed in the regulations applicable to the type of means of transport. Poland is also obliged to comply with them.

International recommendations on biosecurity

The BTWC, in its Article IV, obliges States Parties to take all possible measures and actions to prevent the development and production of biological agents, toxins and biotechnologies that could be used as weapons or as means of bioterror. This provision obliges not only to enact criminal law, but also to implement preventive measures that would allow peaceful work with micro-organisms to be carried out safely and protect them from hostile use. The wide range of places and activities where harmful biological agents and toxins are used (medical activities, including therapeutic entities, medical diagnostic laboratories, genetic engineering facilities, laboratories of sanitary and epidemiological stations, veterinary activities, including vivaria, veterinary clinics, scientific research activities, the pharmaceutical, biotechnology, agri-food sectors) required the use of supporting tools in addition to legally binding regulations. Handbooks, manuals, guidelines and other measures that discussed how to properly handle biological agents in order to protect health and facilities for their use were effective. International organisations, centres, institutions and associations specialising in narrow areas of safety and biosecurity in different spheres of activity have also played an important role.

Moreover, non-binding legal instruments proved to be clearer than prescriptive acts and easier to use in practice. It was much shorter and simpler, compared to amending existing legal acts, to amend them in order to adapt them to changing conditions, including current biological risks and advances in science.

Biosafety and biosecurity in the laboratory

Beside the health protection of workers exposed to harmful biological agents, no less important is the prevention of criminal acts in which these agents are used (bioterrorism, sabotage, etc.).

One of the most important recommendations is the WHO manual on laboratory biosafety[80], the first edition of which was published in 1983[81]. It accepts that biological agents are a major cause of risk and identifies the conditions for safe laboratory work and the principles for classifying biological agents, defines containment levels to delimit exposure and discusses equipment and apparatus as well as good practices for

[80] *Laboratory biosafety manual. Fourth edition*, World Health Organization 2020.

[81] *Laboratory biosafety manual. First edition*, World Health Organization 1983.

the different groups of hazardous agents and toxins. Standard operating procedures are described taking into account contingencies, personal protective equipment, rules for handling biological waste and infectious material, disinfection measures and sterilisation techniques. Subsequent editions of the manual have developed topics related to the individual responsibility of persons for safety and security, addressed bioethical aspects, issues of new developments in life sciences and biotechnology, issues of safe transport of consignments. A chapter on the physical protection of the facility and the premises of use of biological agents has been added, and the need for inventories of microorganisms and equipment, the protection of information and knowledge resources and the control of personnel with access to them has been developed.

Upon examination of the WHO's approach to laboratory biosafety, starting in 1983 and ending with the latest version of the manual, which was published in 2020, it can be seen that it was decided to move away from the original premise and accept that agents belonging to a given risk group need not be strictly subject to the rules assigned to a given biosafety level. The rationale for this was that the actual risk is not so much influenced by the biological agent as by the surrounding circumstances (staff competence, discipline in following internal laboratory procedures). Consequently, after taking into account the assumptions of the three previous editions of the handbook and in order to meet the needs of developing countries, it was assumed that the risk assessment of a hazard should take into account the individual, site- and situation-specific circumstances (e.g. the epidemic situation in the region or country, the level of containment of the laboratory, its equipment, the qualifications of the staff, the availability and type of personal protective equipment, as well as the geopolitical situation, including the likelihood of robbery, the presence of extremist groups).

In 2024, the WHO published guidelines in a publication entitled *Laboratory biosecurity guidance*[82]. This is a continuation of the above-mentioned handbook and supplements it with issues related to biosecurity in the laboratory. It provides an overview of practices and principles to help prevent serious biological incidents and discusses potential causes of these incidents and actionable steps at institutional, national and international levels. It covers topics such as:

[82] *Laboratory biosecurity guidance*, World Health Organization 2024.

a) biosecurity risk assessment using risk management methodologies, including storage conditions for biological agents, transport and possible use of micro-organisms and technologies in experimental research by type of activity (diagnostic, research, repository, biobank),
b) emerging and new technologies as well as potential risks associated with them (genetic engineering, including genome-editing technology[83], gene drive[84], epigenetic modification[85], synthetic biology, artificial intelligence, information protection and cyber-security, do-it-yourself (DIY) techniques, publication of research results that may provide information on how to produce biological and toxin weapons),
c) existing regulations in this area and guidelines for the development of national regulations (international and national law),
d) strengthening the role and responsibility of institutional biosafety committees,
e) critical situations – war, civil unrest, natural disasters.

When analysing these guidelines, it is also worth noting the background, namely the affiliation of the authors of the publications and the subject matter experts who supplemented their knowledge. It is then not difficult to interpret the intention of this endeavour, especially when one looks through the prism of variables such as the epidemic situation of the region, endemic diseases, the risk of serious public health threats with a cross-border impact, the current geopolitical situation, national positions presented at meetings on international disarmament and non-proliferation agreements, as well as taking into account the country of origin and profile of the financial backer. This gives hope that the guidelines developed,

[83] Genome editing technology – involves cutting out one or more genes and replacing them with another or others, or deactivating a gene. This technology is used in many areas of biological science and as an innovative therapeutic method for some previously incurable genetic diseases.

[84] Gene drive – a technique involving the genetic design of individuals so that they deliberately introduce new genes into the entire population of a species, which are then passed on in subsequent generations. It is mainly used to alter an entire free-living population or destroy it, e.g. crop pests, but also to regulate certain mosquito species that are vectors of infectious diseases, e.g. malaria or endemic haemorrhagic fevers.

[85] Epigenetic modifications – chemical changes affecting hereditary mechanisms of gene activity regulation, among others, pathogenicity, host immune response, pathogenesis and/or clinical picture of the disease.

by building on the experience of developed countries, will more effectively reach the right addressees in developing countries and thus, by promoting biosecurity at the source of the potential threat, strengthen the security and protection of biological resources and technologies globally.

The promotion of the principles of biosafety and biosecurity is also being addressed by other centres worldwide. An interesting reference is the textbook *Biosafety in Microbiological and Biomedical Laboratories*[86] published by the US National Institutes of Health, which extends the discussion of these issues to biomedical laboratories, veterinary facilities and vivaria used for research purposes.

In contrast, another handbook, authored by Peter Clevestig, titled *Handbook of Applied Biosecurity for Life Science Laboratories*[87], is a source of knowledge on how to secure facilities using particularly hazardous biological agents. It provides many useful instructions on laboratory biosecurity. Among other things, it describes in an easy-to-understand manner how to carry out a risk assessment for biosecurity and how to put the results into practice; what an employee's responsibility is for the agents he or she works with; how to exercise qualitative and quantitative control over laboratory resources; how to protect sensitive information relating to lists of infectious agents in possession, apparatus and equipment on the premises, personal data of patients from whom pathogens have been isolated and personal data of employees; how to secure the transfer and transport of particularly dangerous pathogens to minimise the risk of their illegal acquisition.

In contrast, the guidelines for the protection of biological resources developed by the Organisation for Economic Co-operation and Development (OECD) address the protection of microbial culture collections, their gene pools, biotechnology and the safety of laboratory workers and scientists potentially exposed to harmful biological agents. This is all the more so because the definitions of biosafety and biosecurity developed by the delegates of the States Parties participating in the BTWC meetings are the same as those used in the OECD publications[88]. The guidelines

[86] P.J. Meechan, J. Potts, *Biosafety in Microbiological and Biomedical Laboratories. 6th edition*, Centers for Disease Control and Prevention, National Institutes of Health 2020.

[87] P. Clevestig, *Handbook of Applied Biosecurity for Life Science Laboratories*, Stockholm International Peace Research Institute 2009.

[88] OECD, *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*, Paris 2001. https://doi.org/10.1787/9789264193550-en; OECD, *OECD Best Practice Guidelines for Biological Resource Centres*, Paris 2007. https://doi.org/10.1787/9789264128767-en.

of specialised organisations and federations (World Federation for Culture Collections (WFCC)[89]; World Data Centre for Microorganisms (WDCM)[90]; European Culture Collections' Organisation (ECCO))[91] provide additional substantive and practical support in safeguarding the world's microbial cultures and enhancing biosecurity.

Medical and veterinary activities are some of the most important areas for the use of biological agents, so biosecurity at these sites is of particular importance. Unauthorised acquisition of biological agents and technology can also occur in other sensitive sites. Dissemination of dual use research of concern (DURC) is another area that needs to be monitored and protected, which is why it is important to educate and raise the awareness of those dealing with harmful biological agents about the risks, as well as to develop attitudes of responsibility[92]. Biosecurity is also an important element in countering intentional threats and acts of bioterrorism[93], safeguarding food resources from deliberate contamination (food terrorism) and deliberately causing damage to crops and livestock (agroterrorism)[94].

Summary

The aim of biosecurity is to prevent biological threats, including intentional ones. Given the wide range of potential threats (microorganisms, biological toxins, biological equipment, technology and specialised knowledge),

[89] *Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms. 3rd edition*, World Federation for Culture Collections 2010.

[90] World Data Centre for Microorganisms, https://www.wdcm.org/ [accessed: 24 XI 2024].

[91] The European Culture Collections' Organisation (ECCO), https://www.eccosite.org/ [accessed: 24 XI 2024].

[92] *Biosecurity – Freedom and Responsibility of Research*, Deutscher Ethikrat 2014; *Responsible Conduct in the Global Research Enterprise*, The InterAcademy Partnership (IAP) 2012; *Research and methods*, Robert Koch Institut, https://www.rki.de/EN/Content/infections/Dual_Use/code_of_conduct.html [accessed: 29 XI 2024]; *Dual-use research*, RIVM / Bureau Biosecurity, https://www.bureaubiosecurity.nl/en/dual-use [accessed: 29 XI 2024].

[93] *Preparedness for the deliberate use of biological agents : a rational approach to the unthinkable*, World Health Organization 2001; *Mental health of populations exposed to biological and chemical weapons*, World Health Organization 2005; *Public health response to biological and chemical weapons: WHO guidance*, World Health Organization 2004.

[94] *Terrorist threats to food: Guidance for establishing and strengthening prevention and response systems*, World Health Organization 2002.

their sources (natural, accidental, intentional) and the potential for the use of biological agents and biological technology (type of activity), biosecurity must be approached in a multifaceted manner. Disarmament and non-proliferation agreements and WMD control regimes (BTWC, Resolution 1540, CWC, AG) clearly indicate what should be the common denominator for effective protection of biological agents with dual-use potential and how to establish these measures at the national level[95]. Regulations referring to them indirectly (CBD and its protocols, IHRs, transport agreements) can strengthen biosecurity, even though they pursue completely different objectives. In turn, the recommendations and guidelines of the leading centres in the field provide valuable knowledge and guidance for their practical implementation at not only institutional and departmental level, but also at national level. They thus contribute to strengthening biosafety and security on a global scale.

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[95] Namely: a) ensure the physical protection of laboratories and storage and collection sites for biological agents referred to in Article I of the BTWC against unauthorised access and illegal seizure; b) take appropriate measures to ensure the protection of biological agents, toxins and technologies relevant to the BTWC, including through access control measures, the proper handling of such agents and specialised equipment during their use and transport; c) adopt, in accordance with the constitutional arrangements of States Parties, legislative, administrative, judicial and other measures, including penal legislation, to ensure the safety and security of biological agents, toxins and technologies in laboratories, facilities for their use and during their transportation; d) establish comprehensive and specific national measures to control the use of biological agents, toxins and technologies for peaceful purposes; e) periodically review these agents, toxins and technologies and, where necessary, enact or update national legislation, including regulatory and penal measures, to ensure the effective implementation of the prohibition in Article I of the BTWC, and update the lists of biological agents and facilities relevant to ensure the safety, security and maintenance of regimes during the transfer of these agents.

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