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ANALYSIS OF LEGAL REGULATION OF BIOLOGICAL SAFETY AND BIOLOGICAL DEFENSE: THE EXPERIENCE OF GERMANY AND FRANCE

The article conducts a comprehensive study of the legal regulation of biological safety and biological defence in Germany and France in order to identify effective mechanisms that can be adapted to Ukrainian conditions. The main legislative and institutional approaches to biological risk management are analysed, including the state control system, regulation of genetic engineering, the work of a network of specialised laboratories, as well as measures to train personnel and respond to biological threats.

Particular attention is paid to French practices in integrating military structures into the biodefense system, which allows for an effective response to biological incidents in wartime or under terrorist threats. Germany, in turn, has demonstrated a high level of legal regulation of biotechnology and a multi-level system for monitoring and containing biological threats.

In the context of full-scale armed aggression against Ukraine and the actualization of the risks of the use of biological weapons, the adaptation of these standards and practices is of key importance for strengthening national security. The proposed approaches to harmonizing Ukrainian legislation with international norms will contribute to increasing the stability of the state biosecurity system, improving interdepartmental coordination mechanisms and developing rapid response capacity. The implementation of these approaches will minimize the consequences of potential biological incidents, protect the population, military personnel and critical infrastructure in martial law.

In conclusion, it is emphasized that the transformation of the Ukrainian biological security system, taking into account European experience, is not only a matter of legislative adaptation, but also a strategic condition for ensuring the sustainable development of the state and its defense capability in the face of hybrid threats.

Keywords: *biological safety; biological protection; biological weapons; biological risks; health protection; national security; implementation of legal standards; civilian population; military formations; military personnel; war; genetic engineering technologies; control system.*

Statement of the problem. Issues of biological security (hereinafter – biosecurity) and biological protection (hereinafter – biosafety) are of paramount importance in the context of contemporary global challenges, which arise in light of scientific and technological advancement, as well as emerging risks associated with the use of biological agents. These concerns pertain to both civilian and military purposes, including the potential development of biological weapons or the production of harmful biological substances. In this context, the protection of military formations becomes particularly relevant, as they may serve both as potential targets and as active agents in responding to biological threats during armed conflict.

The increasing international exchange of goods and ideas, globalization, and pandemics such as COVID-19 underscore the critical importance of preparedness for biological threats and the implementation of effective measures for their prevention and control. Particular attention should be paid to the biosecurity of medical personnel, who stand on the front lines in the fight against biological threats and are at heightened risk of infection (see Fig. 1). This is especially pertinent in combat zones, where they are responsible not only for treating the wounded but also for monitoring the bio-epidemiological situation within military units.

In addition, the advancement of biological technologies increases the potential threat of the malicious use of biological agents, necessitating the continuous improvement of biosafety strategies. In the military context, biosecurity is critically important for the protection of personnel, mobilization resources, medical and logistical units, as well as for ensuring the continuity of combat operations in the event of biological attacks or sabotage involving biological agents. Given that modern warfare encompasses elements of both hybrid and biological threats, a reliable biosafety system within military formations is one of the key factors in maintaining combat readiness and ensuring the safety of the civilian population in conflict zones.

An analysis of the legal regulation of biosecurity and biosafety, particularly in the context of the experiences of Germany and France, reveals effective models that may be adapted for implementation in Ukraine to enhance national security and resilience in addressing contemporary biological threats. Given the rapid advancement of biological technologies, it is imperative for states to develop and implement comprehensive legal and organizational measures for the effective control of biological risks. These measures should include individual protective strategies, preventive programs, and vaccination campaigns, forming an integrated framework for mitigating both intentional and naturally occurring biological hazards.

Figure 1. The image was taken from source [1]

An analysis of recent studies and publications reveals considerable scholarly interest in the legal regulation of biological security and biosafety. This attention is driven by the increasing risks associated with the advancement of biotechnology, globalization, and emerging challenges in the sphere of international security. In both foreign and domestic academic works, biosecurity is highlighted as a key component of national and global security systems. Existing research addresses international legal instruments in the field of biosecurity, such as the Cartagena Protocol on Biosafety, as well as European Union documents that set forth requirements for the control of biological agents and the regulation of innovations in this domain. Issues of biological security and biosafety have also been explored in the context of the National Security of Ukraine. Scholars such as A. Halushka, R. Hrevtsova, O. Ivanko, V. Pashkov, I. Seniuta and others have contributed to this area of research. However, the specific approaches of Germany and France to biological security and biosafety, particularly their legislative regulation of genetically modified organisms, genetic engineering, and mechanisms for the prevention of and response to biological threats, remain underexplored within Ukrainian legal scholarship.

The purpose of the article is to examine the experience of Germany and France in the field of biosafety and biosecurity with a view to adapting these standards and practices into Ukrainian legislation.

Presentation of the Main Material. It is worth noting that the EU Member States do not have a separate legislative act dedicated specifically to biosafety and biosecurity. Nevertheless, the acts of the European Parliament establish general requirements for biosafety and biosecurity, which each Member State is obliged to transpose into its national legislation.

In the context of comparative approaches to the implementation of EU biosafety and biosecurity requirements by Member States, it is appropriate to refer to the examples of Germany and France, whose legislation, in our view, is among the most developed in this field in Europe.

Germany. Biosafety and biosecurity in Germany are of great importance both at the national and international levels. Germany possesses a high level of technological expertise and considerable experience in this field, and it actively cooperates with other countries to ensure safety and protection against biological threats.

In Germany, the regulation of biosafety and biosecurity issues is carried out in accordance with a range of laws and regulatory acts. In particular, the Infection Protection Act *(*Infektions schutz gesetz) [2] sets out the fundamental rules and procedures for the prevention and control of infectious diseases. This legislative act also contains provisions on biosecurity and establishes guidelines for responding to biological threats. In turn, the Genetic Engineering Act *(*Genetic Engineering Act – GenTG) [3] takes into account ethical values and the importance of protecting human life and health, as well as preserving the environment from the harmful effects of genetic engineering processes and products, and provides for measures to prevent such risks. The National Strategy on Biological Diversity (Nationale Strategie zur biologischen Vielfalt) [4] encompasses a wide range of measures aimed at preventing and responding to threats related to biological agents; the development and implementation of advanced technologies for the detection, monitoring, and elimination of biological threats; and the provision of appropriate training and preparation of personnel for effective response. The Ordinance on Safety and Health Protection at Workplaces Involving Biological Agents (BioStoffV) [5] sets out requirements for safeguarding the safety and health of workers against hazards arising from such activities, as well as for protecting other individuals who may be at risk due to the use of biological agents by employees or self-employed business operators. The guiding module for the Radiation Protection Ordinance (StrlSchV) [6] defines the necessary specialized knowledge in the field of radiation protection for medical purposes and other related contexts.

A variety of legislative acts and regulatory mechanisms are in place to govern biosafety and biosecurity issues in specific sectors such as agriculture, medicine, science, and others. The relevant norms and standards establish requirements for the safe use of GMOs, measures for monitoring their distribution and impact on the environment, as well as define liability for violations of these regulations. This approach enables effective regulation of areas that require special attention from the perspective of biosafety and biosecurity, ensuring a high level of protection for both the population and the environment.

In Germany, the responsibilities for ensuring biosafety and biosecurity are assigned to several

governmental institutions and organizations. The Federal Ministry of Health (Bundesministerium für Gesundheit) is responsible for developing and implementing policies related to the safety and control of food products, particularly those that may be associated with biological threats. The Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft) is tasked with regulating agricultural activities and overseeing the quality and safety of products that may be linked to biological factors; The Federal Ministry of Defence (Bundesministerium der Verteidigung) is responsible for protecting national security, including measures against potential biological threats and conducting research in this area. The Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR) is tasked with scientific evaluation and risk assessment to ensure food safety, particularly in relation to potential biological threats. The Federal Office of Civil Protection and Disaster Assistance (Bundesamt für Bevölkerungsschutz und Katastrophenhilfe – BBK) is responsible for planning and coordinating emergency response measures, including those related to possible biological threats and epidemics.

These governmental institutions jointly carry out oversight, develop strategies, and implement measures to ensure biosafety and biosecurity in Germany.

The main features of biosafety and biosecurity measures in Germany include: the development and implementation of laws, regulations, standards, and rules governing the use of biological materials, assessing risks to human health and the environment, and establishing safety and control procedures; conducting scientific research, expert assessments, and risk evaluations related to the use of biological technologies and materials; the establishment of monitoring and control systems for the use of biological agents, including systems for the detection of and response to potential threats; conducting educational activities on safety rules, procedures, and protection measures to train personnel working with biological materials; and Germany international cooperation with other countries and international organisations in the areas of information exchange, experience sharing, and technology transfer to ensure biosafety and biosecurity at the global level.

These measures contribute to ensuring safety and protection against potential biological threats across various sectors, including healthcare, agriculture, the military, and others.

At the same time, it should be noted that in the context of military formations in Germany, a special role in the field of biosecurity is played by the Central Medical Service of the Bundeswehr (Zentraler Sanitätsdienst der Bundeswehr) and the Bundeswehr Institute of Microbiology (Institut für Mikrobiologie der Bundeswehr), which specialize in the identification, assessment, and neutralization of biological threats in military settings. Their activities are governed by internal guidelines of the Ministry of Defence, as well as by documents such as the Framework Concept for CBRN Protection (Rahmenkonzeption CBRN-Schutz – chemical, biological, radiological, and nuclear protection), published by the Federal Office of Civil Protection and Disaster Assistance (BBK). This document outlines interagency and interregional principles for organizing CBRN protection in Germany. It defines the necessary capacities and standards for effective response to CBRN threats. In addition, the book CBRN-Schutz in der Gefahrenabwehr by Andreas Kühar and Klaus Ehrmann [7] provides a detailed account of potential threats and protective measures related to chemical, biological, radiological, and nuclear hazards. The book also examines the organizational and technical aspects of CBRN protection, including the training and preparation of personnel.

It is also worth noting that Germany actively participates in NATO initiatives related to CBRN protection. In particular, it leads the CBRN cluster within the Framework Nations Concept (FNC), which aims to enhance the capabilities of European allies in this domain. In 2014, Germany initiated the establishment of the CBRN Defence Cluster, which brings together NATO member states to strengthen cooperation and improve readiness for CBRN threats. This cluster serves as a platform for sharing experience, coordinating exercises, and developing joint standards in the field of CBRN protection.

In addition, Germany supports the project to establish a CBRN Defence Facilities Network, which aims to integrate various CBRN protection facilities, such as training centers and laboratories, into a unified network. This enables participating entities to share resources and enhance overall preparedness for CBRN threats.

Thus, Germany is actively conducting research in the field of biological protection, aimed at developing

new methods and technologies for the prevention and elimination of biological threats. Particular attention is given to cooperation with international organisations and other countries to facilitate the exchange of experience and the coordination of efforts in this area. The experience of Germany in the context of military formations demonstrates a high level of preparedness to respond to biological threats, the integration of civilian and military security mechanisms, as well as a well-defined legal and regulatory framework for relevant actions in emergency situations.

France. In France, legislation on biosafety and biosecurity encompasses a range of laws, regulations, and standards aimed at protecting public health and safety from biological threats. Key aspects of this legal framework include: The Public Health Code [8], which establishes provisions for combating epidemics and specific infectious diseases (Articles L3111-1 to L3116-6), tuberculosis and leprosy (Articles L3112-1 to L3112-2), the international spread of diseases, vaccination requirements, and related matters; National Environmental Health Plans*:* "One Environment, One Health" (Plan National Santé Environnement, PNSE) [9] illustrate the evolving understanding of biosafety and biosecurity. While the first plan addressed primarily environmental risks, by the fourth plan these aspects have been integrated systematically. With each new iteration, the focus has shifted from purely chemical risks to biological ones, reflecting current challenges such as climate change and infectious disease threats; PNSE 4 demonstrates a strategic approach by integrating biosecurity issues with the management of infectious disease risks, climate change, and even potential acts of bioterrorism. It encompasses measures for prevention, emergency response, and coordination among various agencies and organizations; the Order of 29 September 2021 on biosecurity measures applied by operators and professionals working with animals on premises where domestic poultry or captive birds are kept, as part of the prevention of animal diseases transmissible to animals or humans [10] establishes regulations for the prevention of zoonotic and epizootic diseases; it defines biosecurity measures applicable to the operational functioning and physical protection of facilities and the personnel working therein; the Order of 16 October 2018 on biosecurity measures implemented on farms where pigs are kept, in the context of preventing African swine fever and other regulated health hazards [11] establishes provisions for the prevention of African swine fever and other health risks as regulated by the Ministerial Order of 29 July 2013, which defines first- and second-category animal health hazards; it defines biosecurity measures concerning physical protection as well as the operational conditions of farms; the Order of 8 October 2021 on the establishment of technical and administrative measures related to the prevention, surveillance, and medical monitoring of infections in cattle, goats, and pigs, as well as in camelid and cervid farms, by the Mycobacterium tuberculosis complex [12], sets forth technical and administrative measures concerning prevention, collective prophylaxis, and medical control of infections caused by the Mycobacterium tuberculosis complex.

In addition, this order establishes national requirements in accordance with European legislation and repeals the amended decree of 15 September 2003, which set forth technical and administrative measures for collective prophylaxis and health control of cattle and goats; the Order of 11 July 1990 establishes technical measures related to the detection of bovine tuberculosis for the purpose of halting operations, the Order of 13 March 1995 concerns the sanitary conditions required for the trade of certain ruminant animals within the Community, the Order of 11 February 1998 sets sanitary conditions regarding the keeping, movement, and sale of certain ruminants; the Decree of 29 September 2011 establishes specific measures for combating bovine tuberculosis in the departments of Bouches-du-Rhône, Gard, Hérault, and Landes, and the Decree of 18 November 2009 lays down special measures for combating bovine tuberculosis in the departments of Bouches-du-Rhône, Gard, and Hérault.

In France, the responsibilities for ensuring biosafety and biosecurity are entrusted to several organizations and institutions. The Ministry of the Armed Forces of France (Ministère des Armées) is engaged in the development and implementation of strategies and procedures aimed at preventing the emergence of biological threats at both military and civilian facilities; it conducts training activities, exercises, and simulations to prepare military personnel and civilian services for effective response to biological incidents; military research institutions under the authority of the Ministry of the Armed Forces are actively engaged in the development and

refinement of technologies for the detection, analysis, and neutralization of biological threats. The Ministry collaborates with other governmental bodies, agencies, and international
partners to facilitate information exchange, coordinate actions, and enable joint responses to biological threats. The Ministry of the Interior and Foreign Affairs of France (Ministère de l'Intérieur) is responsible for coordinating actions in emergency situations, including responses to biological threats and acts of terrorism; it ensures the coordination and provision of assistance in crisis situations involving biological hazards, such as epidemics or biological terrorist attacks; the police and other law enforcement agencies under the jurisdiction of the Ministry of the Interior are involved in ensuring public safety in the event of biological threats; the Ministry closely cooperates with other national and international institutions to facilitate information exchange and coordinate measures in the field of biosecurity; the National Agency for Food, Environmental and Occupational Health Safety (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail – ANSES) conducts research and risk analysis related to diseases that can be transmitted from animals to humans (zoonoses), such as viruses, bacteria, or parasites; it performs risk assessments concerning microbiological contamination in food products, such as bacteria, viruses, or fungi that including analysis of potential health impacts on consumers and the development of strategies to ensure food safety; the agency also studies the effects of biological agents, such as microorganisms, on the health of workers across various industrial sectors; it investigates the impact of various environmental factors, such as air, water, and soil pollution, with the aim of assessing their effects on human health and ecosystems; the agency contributes to ensuring biosafety by conducting scientific research, performing risk assessments, and developing recommendations for the protection of public health and the environment; the Pasteur Institute (Institut Pasteur) conducts research on microorganisms, including viruses, bacteria, and parasites, that may pose a threat to human and animal health; it is actively involved in the development of vaccines and immunotherapies for the prevention and treatment of zoonotic diseases (those transmitted from animals to humans), as well as other illnesses with significant public health implications; the Institute maintains a network of laboratories and diagnostic centers that facilitate the rapid detection and diagnosis of diseases, as well as the monitoring of epidemics and viral outbreaks; it conducts research and develops methods of biosecurity, including the
detection and control of pathogens, the creation of safe handling protocols, and the formulation of strategies to prevent accidental or unintended release of hazardous microorganisms; the Institute operates at both national and international levels to prevent and control diseases that may pose a threat to public health and safety; t*he* General Directorate for Civil Security and Crisis Management (Direction Générale de la Sécurité Civile et de la Gestion des Crises – DGSCGC) is responsible for the development and implementation of strategies and measures aimed at protecting the population and property from various hazards, including the prevention of natural disasters, fires, and technological accidents etc.; it plays a crucial role in coordinating biosecurity measures and responding to biological threats, such as disease outbreaks or terrorist acts involving biological weapons.

These authorities cooperate with one another and with international organisations to ensure biosafety and biosecurity in France.

France has a range of instruments and measures in place to ensure biosafety and biosecurity. These include laws, regulatory acts, and international agreements governing biological safety, particularly the control over the dissemination and use of hazardous biological agents, as well as preventive and responsive measures to address biological threats. National and regional action plans are developed and implemented to detect, prevent, and respond to biological threats, including disease outbreaks and bioterrorist acts; a network of specialized laboratories and diagnostic centers performs functions related to the detection, identification, and diagnosis of biological agents, as well as the analysis of their properties and potential consequences; investments are made in the development and enhancement of technological tools and equipment for the detection, analysis, and neutralization of biological threats; training activities, exercises, and simulations are conducted for personnel working in the field of biosecurity to ensure preparedness for effective response to biological hazards. These measures also

have practical implementation within the defense sector. The experience of France in the context of military formations illustrates the integration of biological security into national security strategies. The French Armed Forces are actively engaged in interagency coordination during biological crises and participate in simulations and training exercises that model biological attacks and epidemics.

Through collaboration with civilian structures, particularly the Ministry of Health and specialized agencies, effective response to threats is ensured. Military research institutions, such as the Directorate General of Armaments (DGA), are engaged in the development of innovative detection and protection technologies, while military medical units provide prompt medical assistance and mobile laboratory diagnostics.

Particular attention is devoted to the training of personnel for operations in biologically hazardous conditions, which is fully aligned with the overarching national policy in the field of biosecurity.

Thus, the experience of France illustrates the close interconnection between the legal-regulatory, scientific-technical, and practical dimensions of biological security in both the civilian and military domains.

Conclusions and Prospects for Further Research. An analysis of the legal regulation of biosafety and biosecurity in Germany and France reveals that both countries possess a well-developed and comprehensive legal framework addressing both current and emerging biological threats. Particular emphasis is placed on the regulation of genetic engineering, the control of genetically modified organisms, and the assurance of environmental and food security. At the same time, effective interagency coordination, the availability of specialised laboratories, early warning systems, personnel training, and strategic planning within the defence sector together form an integrated response system to biological incidents.

Against the backdrop of the armed aggression by the russian federation against Ukraine, biological security has acquired particular importance as an element of national security. The full-scale war presents additional challenges, including the risks of bioterrorist attacks, the potential release of hazardous pathogens from combat zones, threats to both the civilian population and military personnel, as well as an increased need to protect critical infrastructure.

In comparison with the experiences of Germany and France, the national legal framework for biological security in Ukraine is still in the process of development and requires further advancement. Existing legal acts possess the potential for improvement in terms of alignment with international standards, strengthening institutional oversight, and expanding technical capacities. A comprehensive modernization of this sector would contribute to enhancing the state's resilience to biological threats amid contemporary challenges.

The scientific findings of this study may serve as a foundation for drafting proposals to implement best practices from Germany and France into national legislation. In particular, this includes: the establishment of a unified interagency response system to biological threats involving the security and defense sectors; the creation of a national biosafety center capable of coordinating actions during emergencies; the enhancement of genetic engineering and biotechnology regulations with consideration for environmental and ethical aspects; the improvement of legal acts concerning the use and storage of hazardous biological agents; the introduction of safety standards for medical and research institutions working with pathogens; and the systematic training of professionals in the field of biosecurity.

The adaptation of these standards and approaches will not only enhance the capacity of Ukraine to counter biological threats in peacetime but also ensure its national security during wartime. This will contribute to better protection of military personnel and the civilian population, reduce the risk of infectious disease spread, maintain the continuity of medical services and infrastructure, and strengthen public trust in state institutions during times of crisis.

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