

VIOLATION OF THE HANDLING RULES OF PATHOGENS: DISCOURSE ON THE DEFINITION OF THE SUBJECT OF THE CRIMINAL OFFENSE

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Annotation. The relevance of the study is determined by the growing importance of ensuring the biological security of the state, in particular, by criminal legal means in the context of strengthening control over the activities of research, diagnostic and production microbiological laboratories that work with pathogenic material, as well as by the uncertainty of the criminal legal doctrine regarding the mandatory signs of the composition of the criminal offense under Art. 326 of the Criminal Code of Ukraine. The purpose of the article is to develop a scientifically grounded approach to the understanding of the subject of violation of the handling rules of microbiological objects that are pathogens of dangerous diseases, and the responsibility for which is provided for by Article 326 of the current Criminal Code of Ukraine, as well as by Articles 5.1.12, 5.1.13 and 5.1.19 of the draft of the new Criminal Code of Ukraine. To achieve this goal, the following scientific methods were used: hermeneutical, normative-dogmatic, formal-logical, system-structural. The provisions of international and national legislation of Ukraine, which determine the content of the subject of the relevant criminal offense, were analyzed. It was found out that, despite the dual interpretation, the term “biological agents” is used both in the current and in the prospective legislative acts of Ukraine, and the lists of dangerous biological agents are approved by the Government and the Ministry of Health of Ukraine. In the absence of the legal definition of the term “infectious agents” and the absence of any normative defined lists of such agents, the use of this term in the construction of the relevant criminal law norms is considered to be questionable. The meaning of the concept of “biotechnology products,” which was used by the authors of the draft of the new Criminal Code of Ukraine to criminalize the violation of the handling rules of pathogens, has been determined. It was found out that there is no legally defined list of biotechnology products, which significantly expands the meaning of this concept. It was argued that the application of the definition of “biotechnology products” in a prospective codified criminal legal act will create unjustified competition of norms and will negatively affect the qualification of relevant criminal offenses. The optimal version of the disposition of the criminal legal norm on the violation of the mentioned rules of biological safety in terms of determining the subject of this criminal offense has been given.

Key words: subject of the criminal offense; blanket disposition; prospective criminal legislation; biological agents; infectious agents; biotechnology products; toxins.

1. Introduction.

The problem of ensuring the biological security of the state, particularly by the criminal legal means, has recently become of great importance: the COVID-19 pandemic and Russia's military aggression against Ukraine left no doubt among scientists and practitioners that the prevention and neutralization of biological threats are important components of ensuring the security of individuals, society and the state. «In the 21st century, humanity faced the problem of controlling laboratories where bacteriological, virological or other types of research as well as accumulation and storage of biological material are carried out, since they can be small and declare officially another direction

of research, as in the case of the laboratory in Wuhan in China» [1]. It is also necessary to take into account the fact that since the beginning of the Russian-Ukrainian war in particular 17% of Ukrainian laboratories of microbiological profile, that had been working with pathogens of infectious diseases, remained in the temporarily occupied territory.

The current Criminal Code of Ukraine (2001) provides for liability for violation of the handling rules of microbiological or other biological agents or toxins in Article 326 of Chapter XIII "Criminal offenses in the sphere of circulation of narcotic drugs, psychotropic substances, their analogues or precursors and other criminal offenses against the health of the population" of the Special Part. However, due to the lack of judicial practice of applying this criminal legal norm, legal scholars did not show proper interest in a comprehensive study of the constitutive signs of the composition of this criminal offense, and existing scientific and practical views to the mentioned article of the Criminal Code of Ukraine are contradictory, ambiguous, and sometimes insufficiently reasonable.

Recently, when the interest of researchers in the criminalization of certain encroachments on the biological safety of Ukraine has increased significantly, and the Working Group on the development of criminal law as a part of the Commission on legal reform under the President of Ukraine is developing a draft of the new Criminal Code of Ukraine, which establishes a criminal legal prohibition of violation of the handling rules of infectious agents, toxins and biotechnology products (Chapter 5.1 "Criminal offenses against the procedure for protecting human health"), the uncertainty of the criminal legal doctrine regarding the mandatory elements of the composition of a criminal offense under Art. 326 of the Criminal Code of Ukraine has resulted in a discussion about the form and content of its subject, formulated in dispositions of both current and prospective criminal legal norms.

2. Analysis of scientific publications.

The composition of the criminal offense provided for in Article 326 of the Criminal Code of Ukraine was not studied at the monographic level. In the works of Yu. Baulin, O. Horokh, O. Dudorov, O. Lytvyn, A. Muzyka, E. Fesenko, M. Khavronyuk, Yu. Yaschurinsky and some other scientists, this criminal offense was considered among other crimes against public health. However, scientists did not provide a detailed description of the mentioned criminal offense, and their conclusions and proposals regarding the relevant criminal legal norm lost a bit their relevance due to the significant changes that the current legislation in other branches has undergone to which the disposition of the relevant criminal legal norm refers.

The exceptions are the publications of I. Salahor, dedicated to its individual components (an object, a subject, an offender, socially dangerous consequences), as well as some works of N. Hutorova, Yu. Zabuha, T. Mykhailichenko, that were carried out as a part of the study of legal support for epidemiological safety [2]. However, despite the significant contribution made by these scientists to the study of criminal liability for the violation of the handling rules for pathogens and toxins, a single doctrinal approach to the characteristic of the mandatory signs of this criminal offense, in particular of its subject, has not been developed.

3. The aim of the work.

The purpose of the article is to develop a scientifically grounded approach to the understanding of the subject of violation of the handling rules for microbiological objects that are pathogens of dangerous diseases, the responsibility for which is provided for by Article 326 of the current Criminal Code of Ukraine, as well as by Articles 5.1.12, 5.1.13 and 5.1.19 of the draft of the new Criminal Code of Ukraine. To achieve this purpose, the following objectives have been set: to examine the viewpoints of researchers on a controversial issue; to analyze the provisions of international and national legislation that determine the content of the subject of the relevant criminal offense; to formulate an optimal version of the disposition of the criminal legal norm on violation of certain rules for biological safety in terms of determining the subject of this criminal offense.

4. Review and discussion.

The criminal offense provided for in Art. 326 of the Criminal Code of Ukraine refers to the substantive one because its subject is an obligatory objective feature that plays a fundamental role in the qualification of relevant socially dangerous encroachments on the biological safety of Ukraine. However, the definition of the content of the subject of this criminal offense and its legislative wording, which is proposed for implementation in the draft of the new Criminal Code of Ukraine, have turned into discussion, to which the author decided to join.

In particular, I. Salahor suggested replacing the “statutory” wording of “microbiological, other biological agents or toxins” used in the disposition of the Ukrainian criminal law with the universal and at the same time known to the current legislation of Ukraine concept of “biological pathogenic agents”, i.e. natural or genetically modified pathogens of people, animals, plants, which include pathogenic microorganisms (bacteria, viruses, rickettsia, chlamydia, mycoplasmas, protozoa, fungi), helminths, prions, toxins [3, p. 21].

Criticizing this approach, Yu. Zabuha notes that there is no single understanding of the term of “biological agents” in the world and in Ukraine its legal definition doesn’t exist, as well as there are no approved lists of biological agents. The scientist proposes instead to use a narrower meaning of the term “infectious agents”, which is used both in microbiology and in current legislation, and its content is established. Under infectious agents, she understands any microorganisms, helminths and prions, which are the pathogens of infectious diseases of people, animals and plants. In other words, the meaning of the concept of infectious agents does not cover toxins. This is how Yu. Zabuha explains the need to distinguish toxins as a separate subject of a crime under Art. 326 of the Criminal Code of Ukraine: “these substances are products of microorganisms or animals, and therefore exist in the environment separately and have a completely different effect on a living organism than an infectious agent does: they cause a non-infectious disease” [4, p. 53].

In this context, we immediately note that such a sharp separation of toxins from infectious agents is exaggerated. After all, the science of microbiology also includes intoxications caused by the products of vital activity of microorganisms to infectious diseases [5, p. 69]. Such products are toxins, i.e. microbial poisons. Strong toxins are produced by some gram-positive microorganisms: by pathogens of diphtheria, tetanus, gas gangrene, botulism [6, p. 168]. Some of the fungi secrete mycotoxins. Mycotoxicosis is a kind of food poisoning that occurs after eating grain products on which fungi are developing (for example, alimentary toxic aleukia) [5, p. 32]. So intoxications caused by accumulated in food toxins are also considered infectious diseases.

It should be noted that the mentioned above term of “infectious agents”, which was hitherto unknown to criminal law, has been accepted by the authors of the draft of the new Criminal Code of Ukraine, in particular it has been used in dispositions of norms provided for by Articles 5.1.12, 5.1.13 and 5.1.19 (Chapter “Criminal offenses against the procedure for protecting human health”), which establish responsibility for violation of the relevant rules for biological safety [7].

Let’s consider the validity of the views expressed.

Should agree with the conclusions of Yu. Zabuha that the term of “biological agents” is interpreted ambiguously in various international documents. For instance, in the World Health Organization Laboratory biosafety manual (2020) the term of “biological agent” means a microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants [8, p. 10]. And International Biorisk Management Standard (CWA 15793:2008), developed by the European Committee for Standardization (CEN), gives the definition of “biological agent” as any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants. Prions are also regarded as “biological agents” [9]. Meanwhile toxins are not covered by the concept of biological agents in this Standard and are defined separately as a substance, produced by a biological system, which in small or moderate amounts produces an adverse effect in humans, animals or plants.

However, international legal acts also do not contain a clear definition of the term of “infectious agents.” Thus, in the International health regulations (2005), the terms of “infectious agent” and “toxic agent” are simultaneously used in defining such concepts as contamination, decontamination, disinfection, etc. However, the meaning of the definition of “infectious agent” is not disclosed. For instance, “infection” is regarded as an entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk [10, p. 7].

In the current legislative acts of Ukraine, there are no definitions of both biological and infectious agents. However, in the Draft Law of Ukraine “On Biological Safety and Biological Security” (2023), drafted by the Ministry of Health of Ukraine pursuant to the decision of the NSDC of Ukraine “On challenges and threats to the national security of Ukraine in the environmental sphere and the priority measures for their neutralization” [11], there are definitions of the following terms: “biological agents” (corresponds to the terminology of the WHO Laboratory biosafety manual), “collection of biological agents”, “circulation of biological agents” etc. [12]. The draft law does not handle the definition of “infectious agents.”

The Law of Ukraine “On the Public Health System” (2022), which regulates public relations in the field of public health and sanitary-epidemic well-being of the population, the term of “infectious agents” is not used. Instead, there is “biological agents”, in particular, in interpreting the terms of “quarantine,” “mass non-infectious diseases,” “dangerous factor” [13]. Furthermore, there are definitions of the terms of “biological agents” and “biological pathogenic agents” in several existing by-laws. For instance, Guidelines for the organization of work and functioning of the system of biological pathogenic agent indication (2003) [14], State sanitary norms and rules for “Organization of work of laboratories in the study of material containing biological pathogenic agents of pathogenicity groups I-IV by molecular genetic methods” (2008) [15], State sanitary norms and rules for “Disinfection, pre-sterilization cleaning and sterilization of medical devices at healthcare facilities” (2014) [16], Single list of dual-use goods (2018) [17], Procedure for record keeping, registration and epidemiological surveillance of infectious diseases (2020) [18], Procedure for assessment of the hazard level of biological agents impact on employees (2023) [19] etc. It is noteworthy that the mentioned regulations put different meaning in the term of “biological (pathogenic) agents”: some of them take as a basis the definition of the WHO Laboratory biosafety manual, others – International Biorisk Management Standard.

Perhaps the only regulatory definition of “infectious agents” is the one given in the Measures and Means for the prevention of infection when nursing patients (2020), but this notion relates only to humans and does not relate to animals and plants [20]. There are no lists of infectious agents in Ukraine.

Instead, several lists of biological agents that are pathogens of dangerous and especially dangerous human diseases have been developed and approved so far. Thus, the Ministry of Health of Ukraine approved the List of biological pathogenic agents which are subjects to epidemiological surveillance (observation) (2020) [18]. By the way, paragraph 4 of this List states that the nomenclature of classified biological pathogenic agents, included in it, corresponds to the latest international agreements on the taxonomy and the nomenclature of biological agents. This List includes bacteria, viruses, parasites and fungi that can infect humans. In addition, the Ministry of Health of Ukraine approved the Unified list of biological agents that pose or may pose a danger to human health (2023) [19], and the Cabinet of Ministers of Ukraine approved the List of prior biological pathogenic agents that cause dangerous diseases (2023) [21]. These Lists actually correspond by categories to the previously mentioned List (2020), i.e. they include bacteria and similar organisms, viruses, parasites (helminths) and fungi. As you can see, the existing lists do not contain toxins, i.e. the legislator is inclined to the provisions of the International Biorisk Management Standard in the understanding of biological agents.

Turning to the dispositions of the criminal legal norms that establish liability for violation of the handling rules for pathogens and toxins (Article 326 of the current Criminal Code of Ukraine and Articles 5.1.12, 5.1.13 and 5.1.19 of the draft of the new Criminal Code of Ukraine), it is necessary to pay attention to the obvious fact that they are blanket. That is why, to clarify the bounds of criminal illegal behavior, the enforcer is obliged to refer to the provisions of regulatory legislation. In particular, it is necessary to establish a specific norm of another branch of law that has been violated by the subject. Under such conditions, the following question arises: what kind of legislative acts should

be addressed if infectious agents are identified as the subject of a criminal offense? International Health Regulations (2005) and the Measures and Means for the prevention of infection when nursing patients (2020), that use this term, contain norms aimed at preventing the international spread of diseases and combating them, preventing infection when nursing patients. However, the liability for violation of such health regulations is established by other criminal legal norms, in particular Articles 131, 140 and 325 of the Criminal Code of Ukraine, as well as Articles 5.1.9, 5.1.10 and 5.1.18 of the draft of the new Criminal Code of Ukraine.

As V. Navrotsky notes, the application of blanket dispositions due to the lack of the regulations of other branches of law, to which the criminal legal norm refers, is a serious drawback of criminal law and an obstacle to the correct qualification of crimes [22, p. 76-77]. Therefore, the use of the term of "infectious agents" *de lege ferenda* is too questionable.

In view of the above, biological pathogenic agents are obviously a more acceptable definition for identifying the subject of a crime under Article 326 of the Criminal Code of Ukraine. However, as explained above, this term is also not perfect.

Turning to the provisions of those legislative acts that establish certain rules for the treatment of pathogens and toxins, including genetically modified (for instance, the Laws of Ukraine "On Environmental Protection" (1991), "On Veterinary Medicine" (1992), "On the Quarantine of Plants" (1993), "On Fauna" (2001), "On the State Biosafety System for the Creation, Testing, Transportation and Use of Genetically Modified Organisms" (2007) and some others), one will make sure that they operate with terms such as "microorganisms," "pathogenic microorganisms," "pathogens," "harmful organisms," "genetically modified organisms," "biotechnology products" etc.

One should not overlook the fact that the provisions of the disposition of the criminal legal norm provided for in Art. 326 of the Criminal Code of Ukraine, which determine the subject of this crime, are implemented in the current criminal law legislation from the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1972) and according to its Art. 1 "each member state is obliged never in any circumstances to develop, produce, stockpile or otherwise acquire or retain microbiological or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes" [23].

In addition, we fully agree with the statement of H. Yaremko, who studied blanket dispositions comprehensively: "Where possible, the disposition should be expressed descriptively, which does not deprive the need to appeal subsidiarily to the norms of other branches of law" [24, p. 105].

Therefore, in our opinion, the most compromise (conventionally acceptable, sufficiently descriptive, harmonized with the Ukrainian legislation of other branches of law) will be the following wording of the subject of the crime under Art. 326 of the Criminal Code of Ukraine: "pathogenic microorganisms, toxins or other dangerous biological agents, both natural and genetically modified."

Meanwhile, the authors of the draft of the new Criminal Code of Ukraine in Articles 5.1.12, 5.1.13 and 5.1.19 apply a different formulation, in particular: "infectious agent, toxin or biotechnology product." The question of the feasibility of including "biotechnology products" into the subject of this criminal offense requires a separate study.

Thus, there is a definition of the term of "biotechnology" in Art. 2 of the Convention on Biological Diversity (1992) [25], ratified by the Law of Ukraine on November 29, 1994 under No. 257/94-VR, and in Art. 2 of 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 (2010) [26], ratified by the Law of Ukraine on December 12, 2021 under № 1926-IX. In particular, biotechnology refers to any type of technology that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

National Standard of Ukraine DSTU 3803-98 "Biotechnology. Terms and definitions" defines "biotechnology product" as "a substance formed as a result of a targeted biotechnological process" [27]. According to this regulatory document biotechnology products include interferon (a substance

of protein origin synthesized by human and animal cells), biogas (a mixture of gases formed by biological agents), bacterial fertilizer (a product created on the basis of cultures of microorganisms), diagnosticum (a drug that contains inactivated viruses or cells of microorganisms, etc., and is used to diagnose an infectious disease), monoclonal antibodies (antibodies synthesized by cloned hybrids), vaccine (a drug for the prevention and treatment of infectious diseases of humans and animals), probiotic (concentrate of human intestinal microflora for restoring normal biocoenosis), etc. In other words, it is about synthesized biological substances and microbial products (i.e. which contain viable microorganisms as an active ingredient).

As noted in the guidelines "Medical and biological studies of product strains of microorganisms and toxicological and hygienic assessment of microbial preparations, determination of their safety and reasoning of hygienic standards and regulations" (2004), strains of microorganisms, used in the production of a biotechnology product (production strains), are either active factors of microbial preparations themselves, or are producers of biologically active substances (antibiotics, enzymes, vitamins, etc.). Meanwhile, strains of microorganisms that are pathogens of infectious diseases in humans and animals are not allowed to be used as production [28].

The Law of Ukraine "On Fauna" (2001) refers to biotechnology products new strains of microorganisms, biologically active substances, genetically modified organisms, etc. (Art. 51) [29]. A genetically modified organism (or living modified organism) is any organism in which genetic material has been modified by artificial techniques of gene transfer that do not occur in natural conditions [30].

Under such circumstances, genetically modified microorganisms and macroorganisms, i.e. plants and animals, are also considered to be biotechnology products. Thus, making transgenic animals, which are characterized by modified or fundamentally new properties, is one of the key directions of biotechnology development in livestock. In particular, the followings are created: animal-producers of biologically active recombinant proteins for medicine, veterinary medicine and food industry; animal-models of human and animal diseases; transgenic animal-donors of organs for transplantation; transgenic animals with modified livestock product quality [31, p. 43-44; 32, p. 138-142].

So with no clear legally defined list of biotechnology products and guided by the analysis of the relevant provisions of the mentioned regulations, we summarize that such products are microbial preparations; genetically modified microorganisms, animals and plants; biologically active and other synthesized biological substances. Public relations in the field of handling such products are regulated by the laws of Ukraine "On Medicines" (1996), "On Veterinary Medicine" (1992), "On the Basic Principles and Requirements for the Safety and Quality of Food Products" (1997), "On the Safety and Hygiene of Feed" (2017), "On By-products of Animal Origin not Intended for Human Consumption" (2015), "On Pesticides and Agrochemicals" (1995), "On the State Biosafety System in the Creation, Testing, Transportation and Use of Genetically Modified Organisms" (2007), etc.

Meanwhile, along with the criminalization of violation of the handling rules for biotechnology products, which caused harm (to human health, objects of flora, fauna or material harm) or created the danger of its causing (Art. 5.1.12, 5.1.13 and 5.1.19), the draft of the new Criminal Code of Ukraine also provides for liability for violation of phytosanitary rules or rules for plant pest control, veterinary rules, if this caused material harm (Art. 6.5.6 – 6.5.9, 6.5.18); illegal trafficking of dangerous items (in particular, biotechnological preparations - paragraph 30 of part 2 of Art. 1.4.1), which caused material harm (Art. 7.3.7); non-compliance with the requirements for the storage of dangerous objects, which created a risk of harm (paragraph 12 of part 1 of Art. 7.3.10). In other words, the application of the rather broad in meaning term of "biotechnology product" by the authors of the draft of the new Criminal Code of Ukraine creates unjustified competition of criminal legal norms, which may have a negative impact on the qualification of relevant criminal offenses.

Therefore, it is proposed to abandon the use of this and other concepts that do not have clear substantive boundaries, and focus on terminology that meets the goal of establishing a criminal legal prohibition of violation of the handling rules for pathogens and toxins and namely to protect people, as well as of objects of fauna and flora from mass infection with dangerous diseases, with the pathogens of which the subject works (explores, grows, modifies, stores, disposes, etc.) while performing their professional/official duties.

5. Conclusions.

The term of “biological agents,” which is used by the legislator in the disposition of Art. 326 of the Criminal Code of Ukraine to indicate the subject of this criminal offense, has a twofold interpretation in by-laws: some of them take as a basis the definition of the WHO Laboratory biosafety manual (such agents include various infectious material including toxins), others – International Biorisk Management Standard (toxins are not included). However, this term is used in both current and prospective legislative acts of Ukraine, and the lists of dangerous biological agents are approved by the Cabinet of Ministers and the Ministry of Health of Ukraine.

The term of “infectious agents”, as an alternative to biological agents, has no legal interpretation and is applied only to humans. There are also no normatively defined lists of infectious agents. Due to the fact that the disposition of the criminal legal norms under study is blanket, we suggest not to use this term.

The draft of the new Criminal Code of Ukraine, developed by the Commission on legal reform under the President of Ukraine provides for the criminal legal norms that establish responsibility for the violation of the handling rules for infectious agents, toxins and biotechnology products. Based on the results of the analysis of the current legislation, it was established that the biotechnology products should include: microbial preparations; genetically modified microorganisms, animals and plants; biologically active and other synthesized biological substances. However, there is no legally defined list of biotechnology products, which significantly expands the meaning of this concept. Given that certain medicines, feed and supplements, pesticides, cloned and transgenic animals and plants, etc. can be considered the biotechnology products, the application of this term in the aforementioned norms will create problems in the qualification of the relevant criminal offenses.

According to the study, we offer the following wording of the subject of violation of the handling rules for microbiological objects that are pathogens of dangerous diseases: “pathogenic microorganisms, toxins or other dangerous biological agents, either naturally occurring or genetically modified.”

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