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LAW ENFORCEMENT PRACTICE OF REGULATING FREEDOM OF SCIENTIFIC BIOMEDICAL RESEARCH IN THE EUROPEAN UNION ON THE EXAMPLE OF GERMANY

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ABSTRACT. Aim. *Using the example of Germany, which has an advanced economy and an effective system for ensuring biological safety and biological protection, to study the practice of legal regulation of freedom of scientific research in the EU, in particular in the medical and biological field.*
Materials and Methods. *Based on the analysis of the legislation of this country, the EU approaches to the creation of a system of regulatory support for this area at the level of development and improvement of the general strategy on biosafety and bioprotection, which is mandatory for implementation in the national programs of the member states, have been analysed. The creation and entry into force of specific regulatory legal acts which in detail administer the procedure for conducting biomedical research work is carried out individually in each participating state, considering national characteristics.*
Conclusions. *It is proposed for Ukraine when creating an appropriate domestic system to counter bioterrorism, biological sabotage, and other biological threats to use both the positive experience of the EU member states in the development of national programs of biological safety and biological protection as well as regulatory support for their implementation.*
Key Words: *bioterrorism, bio-threats, bio-risks, biological safety, biological protection.*

Introduction. Human life is closely related to activities (work) aimed at transforming the environment for the existence and realization of various needs of both an individual and whole society. At the end of the twentieth century, there was a population outbreak. Currently, the world's population exceeds 7 billion people who need to be provided with vital resources, primarily with food, medicine, drinking water and a place to live. As a result of "overpopulation" of the planet, an active anthropogenic load on the environment occurs. It leads to the destruction or disruption of ecological ties in nature which are caused by human economic activity without considering the laws of nature development. Due to the excessive use of resources, plants and animals are killed, their habitats are destroyed under the influence of environmental pollution caused by harmful and toxic substances or because of biological invasions through accidental colonization of new species, which propagate in the absence of natural enemies and displace native species.

Aim. Searching solutions to these problems, humans are increasingly using the scientific sphere. The medical and biological sphere is not an exception. So, in recent years, scientists have decoded the human genome and created its genomic passport, obtained a synthetic living organism and technology for changing a person, learned to create genetic constructs and transform them into a genome of the organism's with new characteristics, and even have already created and are improving a biocomputer based on DNA. That is, we have reached a new level of biotechnology, and at the same time, of opportunities. But along with certain preferences, people also received new threats of a biological nature, and this, in turn, requires the need to comply with the requirements of biosafety and bioprotection when conducting biomedical research by establishing appropriate legal relations. An example is the contemporary global problem of overcoming a pandemic of Wuhan SARS, caused by the MERS-CoV2 coronavirus, which causes the Covid-19 disease. This problem is also urgent for Ukraine, which is currently at the stage of developing its own biosafety and bioprotection system as a component of Ukraine's national security.

As Ukraine is oriented towards integration with the EU, international experience, primarily European, in the legal regulation of the freedoms of scientific research in the biomedical sphere is important.

Analysis of recent research and publications. Over the past decade, more and more attention among scientists in the biomedical field has been paid to the study of topical problems of ensuring biological safety and biological protection as a component of national security. This is due to a scientific breakthrough in the field of genetic engineering at the beginning of the XXI century, carried out under the international program "Genome". Biology scientists immediately understood the potential of this area of scientific research. The first artificial genetic constructs appeared, later they were transformed into the genome of a living organism and a genetically modified organism was obtained. In 2005, the human genome was sequenced, and its first genetic passport was obtained. The use of modern information technologies has significantly accelerated the development of biotechnology.

According to forecasts, in a few years, centres for storing and processing information from individual human genomes will be created on the planet. Obviously, they will be in California, Washington, New Delhi, Beijing, Moscow, Munich, Paris, London. Having the necessary scientific resources and highly qualified specialists, Ukraine could also take its rightful place in this list. Receiving, storing, and transferring individual genetic information of the population, as well as sharing it, is a strategy of state security in the future, which Ukraine, unfortunately, has not yet started.

But along with the obvious progress in the development of new genetic technologies, new problems arise that also need to be decided in parallel.

Despite the indisputable economic positive from the use of transgenic organisms, scientists are increasingly paying attention to the importance of solving the problems of predicting, and, if necessary, eliminating possible negative consequences of their use for public health and the environment. Uncontrolled release of transgenic organisms into the environment can lead to disruption of the ecological balance and cause some harm to biological diversity. Today, such potential risks are appearing as the transfer of artificial genetic constructs into the genotype of existing organisms and the emergence of more viable harmful organisms that can displace other organisms from their ecological niches (antibiotic-resistant pathogenic microorganisms, weeds resistant to herbicides, etc.), the emergence of new proteins and biologically active substances harmful to humans and animals, etc. (A. Spirin, 2004) [1]. Therefore, now in technology of genetically modified organisms, humanity is faced not with a scientific and technical problem of their creation, but with safety problems as well as with ethical and legal problems that require fundamental scientific research and solutions. One of these problems is the issue of freedom of scientific research in general and particularly of biomedical research.

That is, a problem triangle has appeared, i.e. scientific freedom, expediency, and safety.

Despite the fact that the works of many well-known researchers are devoted to the issues of biological safety and biological protection. For example, among foreign scientists, M. Meselson in his work "Averting the Hostile Exploitation of Biotechnology" (2000) examines the possibility of illegal use of the results of scientific advances in biomedical research for bioterrorism or for the development of new types of biological weapons. He proposes strengthening control by international institutions and the community to counter possible biological threats. S. Rose in work "The Coming Explosion of Silent Weapons" (1989) notes that twenty years ago the United States unilaterally abandoned its biological warfare program. At that time, germs and toxins were imperfect and unguided weapons that posed threats even to those who developed them. But with the beginning of the rapid development of genetic engineering, the new developments of biological weapons, which were carried out by the USSR and by other countries, became, perhaps, "even more dangerous" than nuclear weapons. Therefore, the question arose about strengthening international control over such developments. T. Novoselova in her work "Textbook on Biological Dйfense: Opportunities for Team-Oriented Learning" (Bradford Centre for Disarmament Research, University of Bradford, 2016; unofficial Ukrainian version) explores the issue of improving biosafety and bioprotection in biomedical research. She suggests a more effective use of the method of team-oriented learning in working with scientists. Jennifer A. Doundna and Emmanuelle Carpentier in work

"The New Frontier of Genome Engineering with CRISPR-Cas9" note that the biological industry is currently undergoing a transformational phase with the emergence of genome engineering in animals and plants using the RNA-programmed CRISPR-Cas9 system. CRISPR-Cas9 technology comes from II CRISPR-Cas systems, which provide bacteria with adaptive immunity to viruses and plasmids. Peter Katona, John P. Sullivan, Michael D. Intriligator in monograph "Global Biosecurity: Threats and Responses (Contemporary Security Studies)" (Routledge, Taylor & Francis, NY, 2010) show several threats to biological health and biosecurity. In particular, concerning bioterrorism, emerging infectious diseases, pandemic disease preparedness and recovery, agro-terrorism, food safety and environmental issues, researchers argue that a global, networked, and multidisciplinary approach is essential to combat any terrorism.

Among Ukrainian scientists V. Gorbulin and A. Kachinsky in their work "Fundamentals of National Security of Ukraine" consider the essence of biological safety as an ecological subsystem in the balance between natural and anthropogenic factors that is optimal for humans. V. Zavgorodnyaya defines biosafety as a state of protection of a person and the environment from any negative biological factors. At the same time, a scientist includes biotechnological safety (biosafety in the field of using biotechnological products) and genetic safety (biosafety in the field of using genetic engineering methods and genetically modified organisms) in this concept. Also V. Zavgorodnya joins the opinion of previous authors that biosafety is a part of environmental safety. T. Kovalenko in her work "Legal aspects of biological safety", in turn, considers biosafety and bioprotection as one concept, i.e. biosafety in a broad sense, and proposes to define it as a special state of human and environmental protection, in which the risk of harm to human life or health and / or environmental components in the process of biotechnology or as a result of the application of their results is minimized using a system of economic, technical, organizational, managerial, legal and other means based on the precautionary principle of biotechnological activities. V. Kurzova in her work "Priority directions of ensuring biosafety in the sphere of national interests" also axiomatically considers biological safety to be a component of environmental safety and determines its content, proceeding from the characteristics of "a kind of environmental threat, namely bio-threat". However, the researcher admits that ensuring biosafety is not limited to the environmental sphere and is associated with the military, economic, social, scientific and technological, as well as information spheres. In turn, L. Strutinska-Struk in her study "Legal support of biological safety in the implementation of genetic engineering activities" (Institute of State and Law named after V. Koretsky of the National Academy of Sciences of Ukraine, 2005) considers biosafety as an integral component of environmental safety, limits it to the sphere of implementation of genetic engineering activity and defines as "a condition in which the occurrence of consequences, dangerous for human health and the environment, of using genetically modified organisms is prevented, and it is due to the absence of unacceptable risk."

These and other researchers in their works focus mainly on the theoretical aspects of the definition of the concept of "biological safety, biological protection", on the organization of monitoring and the problems of reducing the unacceptable risk associated with harm or threat to the life of the population. In some cases, the question was raised about the relevance of studying the scientific freedom of biomedical research. Therefore, this issue requires further study by scientists. Based on Ukraine's aspirations concerning European integration, the study of European experience in search of an optimal balance between scientific freedom of biomedical research and their expediency and safety with the aim to transform them into Ukrainian biotechnology is now especially important, considering the challenges facing all mankind today.

The general legislation of the European Union (EU) on biosafety has been developed and is aimed at preventing risks arising both directly during the work of employees of an enterprise or institution with hazardous biological material, and during its storage in places of anthropogenic consolidation and transportation. And what is also important restrictions on unauthorized access to the results of these biomedical studies [2].

EU member states have already developed their own systems based on common EU biosafety and bioprotection legislation, considering national circumstances, which, in particular, reflect the rules and other measures regarding the storage, transportation, export and

import of biological materials, as well as the specifics of compliance with biosafety requirements and bioprotection [3].

Aim of the Research. So, the purpose of the article is to analyse the modern European legal regulation of freedom of scientific biomedical research on the example of Germany with its advanced achievements in the field of biological safety and biological protection.

Materials and Methods. The guarantee of scientific freedom is important not only as a protection against government interference, but it also obliges the state to create an auxiliary legislative framework and take protective measures for this freedom [4]. That is, the state is obliged to ensure the independent development of science, including biological, within its functional framework. Scientific freedom of biomedical research is always considered in the context of categories such as biological safety and biological protection, as well as the expediency of planning scientific research with potential bio-risk (freedom, safety, expediency).

Modern scientific activity is a joint activity between the state, scientific organizations and society, its regulation accordingly had a complex nature. The state has to fulfil a double function as a "mediator" entrusted with the establishment of certain rules, as well as a coordinator who should facilitate this process [5]. Performing a regulatory function concerning sciences, the state can resort to various forms of self-government, applying the knowledge of special experts in practice. Establishment of internal scientific standards in this way, for example, through a code of conduct, helps, on the one hand, to ensure openness to innovation and flexibility, and on the other, to promote consensus through participation in scientific projects where there is a state interest, as well as to mediate in them. This is a multifaceted process, so there may be a danger of controversial reporting, selective articulation of interests and control tools [6]. Scientific commentaries and other regulatory documents on this issue regarding the provisions of scientific freedom, including biomedical research, contained in the Basic Law of Europe, deeply interpret the process of scientific freedom itself. However, is it possible for the state to withdraw itself from control over biomedical research? It is also about how the state should limit scientific freedom (for example, through regulations to restrict research itself or to limit the publication of its results). A legitimate question arises, what is the purpose of this restriction? Firstly, it is preventive, that is, the prevention of harm to humanity. Secondly, the assessment of bio-risks that may arise, especially of those which are dangerous from the point of view of bioprotection. The issues to be assessed in this case, when conducting biomedical research, are the sufficient reasoning for biosafety and bioprotection of the planned results, for irreversible consequences of the utilization of biomaterials, potential bio-risks, and the likelihood of damage, and finally the amount of possible benefits from the results of biomedical research [7]. Since such research is dangerous from the point of view of biosafety and bioprotection, it can jeopardize and harm both the individual and the material and cultural values of society (especially it concerns public health, threatens the environment). And as it is known, the state has the only fundamental constitutional duty to the people of Ukraine, namely, to protect their legitimate interests. The Constitution of Ukraine guarantees the fundamental rights of citizens, in particular the law protects its citizens. [8].

In the context of biosafety and bioprotection legislation, EU Basic Law provides for the protection of life and physical integrity, which refers to the protection of human health and society in general. On the other hand, there are other constitutional provisions that demand protection from the state. Thus, Article 20 of the EU Basic Law obliges the state to protect the natural foundations of life and makes it responsible to future generations [9]. This is a very important article. Let us consider other postulates of this law.

Consequently, the provision of the Basic Law also provides for the adoption of measures to limit the risk as much as possible, in particular, an obligatory condition is set for the experimenter. According to this condition the results of the relevant biomedical research should be used only for peaceful purposes. Thus, the requirement to ensure peace, fixed in article 26, paragraph I of the Basic Law, is largely structurally comparable [10]. Initially, the implementation of these constitutional provisions as well as their harmonization with respect to national characteristics at the levels of the EU member states is entrusted to the EU legislature. Thus, the Federal Constitutional Court of Germany, guided by the relevant experience on the example of previous cases on the implementation of the abovemen-

tioned obligations to protect freedom of scientific research, if necessary, provided the legislature with a wide field for freedom of opinion and with a wide scope for assessing and taking the necessary adequate security measures. So, the state has taken upon itself the responsibility to create a certain minimum of effective protection against possible threats (including biological ones) of the results of innovative research [11]. At the same time, the state must consider violations by security structures that can provoke unjustified interference with the fundamental rights of those who are a source of danger. In the EU, this "protection by intervention" complex has resulted in a complex structure of fair balance. The challenge for European legislators is to harmonize, assess and enforce laws. It is based on more specifically defined structural elements, namely:

1. The EU's duty as for protection (bioprotection) is activated when individual or collective values may be directly harmed or at the level of threat. According to European legal scholars, in order to justify restrictions on the unconditional freedom of science, such values must also be protected constitutionally. This provision is enshrined both at the level of the constitutional values of the EU and member states, for example in the first sentence of Article 2, paragraph 2 of the Basic Law of Germany, as well as at the level of national laws on the protection of the environment, biodiversity, and peace.

2. The EU's duty to protect is activated in the event of any action in the field of scientific research, when the threshold of their predicted safety is crossed, regardless of the significance of the expected results for humanity. This means activating action not only in the event of actual violations of biosafety and bioprotection as well as the presence of real bio-threats (in the sense of police law), but also under certain circumstances and risks. To decide whether a level of biohazard or bio-risk has been reached, at which the responsibility of institutional structures (management, law enforcement, and in some cases, special services) is activated to apply administrative and legal regimes regarding preventive adequate countermeasures to threats or risks of a biological nature. But for this, it is necessary, with the involvement of permanent commissions on biosafety and bioprotection, to conduct a relational assessment (among other mandatory measures in this case) of the probability of an event and the degree of possible harm.

3. The EU grants member states broad powers in the choice of biosafety and bioprotection instruments. As noted, the theoretical applicability of the tools ranges from recourse to professional standards (guidelines) such as codes of conduct, mandate and authorization obligations, to prohibition of open publication and of conducting research in generally. There is also a dissenting opinion of some international experts that the restriction of publication does not fall under the prohibition of preliminary censorship set out in the third sentence of Article 5, paragraph I of the Basic Law [12].

4. The decision on the use of special interventions or on the application of a specific biosafety and bioprotection program for a biomedical research which has a particular importance for humankind is taken by the permanent commission on biosafety and bioprotection based on the relevant evaluation criteria, namely the intensity and degree of infringement, that are predicted, the possibility or impossibility of auxiliary bio-risk management etc. But in its actions the commission is limited by the degree of infringement on scientific freedom. At the same time, it is imperative to take appropriate measures when there are reliable grounds for a real danger of using biological weapons. In contrast, sometimes the overall risk of possible malicious use of research results, when the danger to human life or health is not well understood, may also be limited, but this depends on the circumstances. In this case, simple procedural and organizational measures are applied. As noted by European experts in the field of state and law, the complexity of this conflict of interest increases in cases where state intervention in order to protect life and health contradicts the scientific freedom to conduct biomedical research, which is also aimed at ensuring the life and health of the population.

However, the parliamentary prerogative of the EU, which follows from the constitutional principles of democracy and the rule of law and which, among other things, is guided by one of the founders of the European Union, Germany (Rechtsstaatsprinzip), is also decisive in making decisions in this area of legal relations. This means that where key legal norms are expected to be applied on all life safety issues that are significant for public health in general (since they are in any case subject to state regulation), the final decision should be made by the parliament, i.e. the legislature. [13]. According to the EU

Constitution, European legislators in the field of regulation of scientific research freedoms are obliged not only to raise the issue of monitoring the results of relevant research (including biomedical) as for the safety for humanity before the scientific community, but also to develop appropriate volumes and levels of regulatory documents for all cases [14]. According to the constitutional requirements, the legal regulation of scientific freedoms should be flexible and provide sufficient opportunity to ensure political freedom to the governments of EU member states in the event of potential threats from planned or ongoing scientific research, including of biological nature, and act quickly and effectively, having the legal field of such activities for this [15]. Despite this, the very possibility, and various forms of restrictions on the scientific freedom of a scientist, assessment criteria, if applicable, and the need for such measures will remain a subject of discussion among defenders of both international and national institutions of human rights and freedoms, not only in the field of scientific activity, but also in other normative areas of law. At the same time, European legislators to implement the necessary requirements for biosafety and bioprotection of biomedical research give the supervisory administrations the right to attract specialists for external expertise. This is especially true for new areas of biomedical research (synthetic and space biology, etc.) where the experimenter himself and the facility commission on biosafety and bioprotection can absolutely guarantee the exclusion of the uncontrolled release of the results of such new research into the environment [16].

The German legal framework for biosecurity and protection has been developed and adopted within the framework of EU legislation, in which Germany played a key role. The fundamental legal document, which also consider the own national characteristics of the German legal framework on biosafety and bioprotection, is the Federal Law on Biological Substances of January 27, 1999 [Biostoffverordnung further (BioStoffV)], which approved the Ordinance on Biological Substances, which came into force April 1, 1999 [17]. The importance of legal innovations in the field of biosafety and bioprotection is evidenced by the fact that the regulatory law was signed not only by the Chancellor, but also by three relevant federal ministers, in particular of the Federal Ministry of Labour and Social Affairs, of the Federal Ministry of Health and of the Federal Ministry of the Interior, Building and Community.

The adopted law contains provisions on the requirements for the protection of workers in the field of biomedical research from the risks arising from working with hazardous biological substances. These regulations were intended to implement Directive 90/679/EEC of November 26, 1990 on the protection of workers against risks associated with exposure to biologically active substances (BAS) (the seventh separate directive within the meaning of Article 16 (1) of Directive 89/391/EEC).

BioStoffV on BAR has since been repeatedly changed and supplemented until 2013 in accordance with changes in EU legislation in this area. Thus, in 2004, Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers against hazards arising from the influence of biological agents at work (the seventh separate directive, in the sense of part 1 of Article 16 of Directive 89/391/EEC) was put into effect [18]. In 2008 and 2013, further amendments to this Directive took place. The revision of the existing German legislation on biosafety and bioprotection in 2013 was based on the implementation of Directive 2010/32/EU of May 10, 2010, which implements the Framework agreement on the prevention of potential infection of personnel working with BAS because of acute injuries both in the hospital and in the health sector where biomedical research is conducted. This agreement is concluded in accordance with the requirements of HOSPEEM and EPSU (social services partners of employers in the EU countries involved in protection of working people) [19].

In addition to the Biological substances act of January 27, 1999 [Biostoffverordnung], the regulation of biosafety and bioprotection in the field of biomedical activities is also enforced by the following German laws, namely On labour protection, On civil protection, and On security measures in private households.

Conclusions. European legislation regulating the levels of scientific freedom, including biomedical research, is flexible enough, where, on the one hand, unreasonable restrictions, and interventions in the field of biomedical research are prohibited, and on the other hand, a legal framework is provided for control and restrictions in the absence of sufficiently guaranteed evidence of the safety of their results for public

health and environment. This legislation recommends parliamentarians of EU member states to consider the impossibility or inappropriateness of formulating a well-defined program of legislation on biosafety and bioprotection while shaping national legislation in the relevant regulatory areas which govern freedom of biomedical research. However, legislators should at least create procedural rules within parliamentary prerogatives, which, if necessary, will determine the need to draw on individual rules from international experience. Based on the recommendations of European legislation, a formal law should outline the order and organization as well as ensure the adoption of targeted decisions by other state bodies both to prevent restrictions on the scientific freedoms of researchers, and to ensure a reasonable exclusion of biological threats from the experiments themselves and the results obtained.

Considering the European integration processes in Ukraine, such approaches to ensure scientific freedom in conducting research and at the same time to establish restrictions in the absence of reliable data on their safety should be introduced into Ukrainian legislation.

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ПРАВОЗАСТОСОВЧА ПРАКТИКА РЕГУЛЮВАННЯ СВОБОДИ НАУКОВИХ МЕДИКО-БІОЛОГІЧНИХ ДОСЛІДЖЕНЬ В ЄВРОПЕЙСЬКОМУ СОЮЗІ НА ПРИКЛАДІ НІМЕЧЧИНИ

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РЕЗЮМЕ. Мета. *На прикладі Німеччини, яка має передову економіку і дієву систему із забезпечення біологічної безпеки та біологічного захисту, дослідити практику правового регулювання в ЄС свобод наукових досліджень, зокрема в медико-біологічній царині.*
Матеріали та методи. *На підставі аналізу законодавства цієї країни проаналізовано підходи ЄС до створення системи нормативно-правового забезпечення даного напрямку на рівні розробки та вдосконалення загальної стратегії з біобезпеки та біозахисту, яка обов'язкова для реалізації в національних програмах держав-учасниць. Створення і набуття чинності конкретних нормативно-правових актів, які детально регламентують порядок проведення медико-біологічних науково-дослідних робіт. У кожній державі-учасниці вонии здійснюються індивідуально із урахуванням національних особливостей.*
Висновки. *Запропоновано використання в Україні позитивного досвіду країн-учасниць ЄС із розробки національних програм біологічної безпеки і біологічного захисту та нормативно-правового забезпечення їхньої реалізації при створенні відповідної вітчизняної системи з протидії біотероризму, біологічним диверсіям та іншим загрозам біологічного характеру*
Ключові слова: *біотероризм, біозагрози, біоризики, біологічна безпека, біологічний захист.*

ПРАВОПРИМЕНИТЕЛЬНАЯ ПРАКТИКА РЕГУЛИРОВАНИЯ СВОБОДЫ НАУЧНЫХ МЕДИКО-БИОЛОГИЧЕСКИХ ИССЛЕДОВАНИЙ В ЕВРОПЕЙСКОМ СОЮЗЕ НА ПРИМЕРЕ ГЕРМАНИИ

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РЕЗЮМЕ. Цель. *Изучить на примере Германии с ее развитой экономикой и действенной системой по обеспечению биологической безопасности и биологической защиты практику правового регулирования в ЕС свобод научных исследований, включая и медико-биологическую сферу.*
Материалы и методы. *На основании анализа законодательства Германии показаны подходы ЕС к созданию системы нормативно-правового обеспечения этой программы на уровне разработки и совершенствования общей стратегии по биобезопасности и биозащиты, которая обязательна для реализации в национальных программах государств-участников. Создание и вступление в силу конкретных нормативно-правовых актов, детально регламентирующих порядок проведения медико-биологических научно-исследовательских работ, в каждом государстве-участнике осуществляется индивидуально с учетом национальных особенностей.*
Выводы. *Предложено использовать в Украине положительный опыт стран-участниц ЕС по созданию национальных программ биологической безопасности и биологической защиты, а также нормативно-правового обеспечения их реализации, для создания соответствующей отечественной системы по противодействию биотерроризму, биологическим диверсиям и другим угрозам биологического характера для национальной безопасности.*
Ключевые слова: *биотерроризм, биоугрозы, биориск, биологическая безопасность, биологическая защита.*

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