Chapter 40

BIOETHICS IN THE HEALTHCARE SYSTEM

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DOI https://doi.org/10.30525/978-9934-26-539-6-40

INTRODUCTION

The obvious fact of the successful establishment and dynamic development of bioethics in our country is a landmark event that clearly reflects commitment to the principles of democratic construction of society, international integration and protection of individual rights. Bioethics has become a logical response to numerous ethical questions and problems that have arisen in recent decades in the process of clinical activity, as well as during biomedical research and experiments. It is designed not only to identify and analyze conflict situations that arise at the junction of medicine, biology, philosophy and jurisprudence, but also to determine specific ways to resolve them. The emergence of bioethics was a direct consequence of the practical implementation of the achievements of the scientific and technological revolution in the conditions of a deep ideological crisis and the accumulation of global environmental problems. Significant successes in the development of medical and biological sciences have led to the emergence of many questions of a moral nature. It has come to the point that man is trying to extend his control over his own evolution and claims not only to maintain his life, but also to improve and change his nature, relying on his own understanding. In such a situation, well-founded discussions arise regarding the ethical basis and moral legitimacy of such actions. Bioethics is not only a modern stage in the development of medical ethics and deontology, but also the basis for creating a scientifically sound balance between the latest medical and biological technologies, on the one hand, and human rights, the principles of humanism, and social progress, on the other. Bioethics is based on respect for life and dignity of a healthy and sick person, whose interests should always be valued above the interests of science or society. The leading postulate of bioethics is the principle of autonomy with the inviolability of the mental and physical status of a person, which is implemented by the rule of informed consent of the patient and society to the conduct of therapeutic and preventive manipulations.

Bioethics combines a wide range of socio-economic, moral-ethical and legal problems that are solved not only within the medical community, but also with the help of state authorities, the public, and the media. Bioethical issues are discussed in authoritative international organizations − the UN, UNICEF, UNESCO, the Council of Europe, WHO. The relevant declarations, conventions, agreements, recommendations, and resolutions of these organizations ensure the development of national legal and ethical regulation of practical healthcare and biomedical research.

1. Biosafety as a science

Today, in Ukraine, when conducting biomedical research, modern requirements of biosafety, biosecurity and bioethics are practically not taken into account, which is a confirmation of the need and relevance of implementing steps aimed at increasing the education and awareness of scientists on biosafety, biosecurity and bioethics in order to predict and prevent possible negative consequences of scientific research. Diagnosis of diseases, analysis of samples obtained in living organisms, epidemiological and scientific research, development of pharmaceuticals – all these activities are carried out in biological laboratories, a structural unit that performs experimental, diagnostic or production processes with pathogenic biological agents. Operations with biological materials are performed in laboratories around the world for many lawful and legitimate purposes. These works are accompanied by replication of small or large volumes of living microorganisms, isolation of cellular components and many other manipulations carried out to implement a wide range of tasks (from educational, scientific, medical and health-related to mass commercial or industrial production). When carrying out work in laboratories, there is a potential risk of infection, so it should be remembered that the biological material concentrated there is a potential source of biological weapons. Biological and medical centers can be suppliers of biological weapons for terrorists. Manipulations to isolate and use genetic material from highly pathogenic pathogens are associated with a high risk of biological danger. The main components of biological risk assessment: specific characteristics of the organisms on which experiments are planned to be conducted; specific characteristics of experimental animals that can be used; equipment and procedures used; isolation equipment and means.

The highest level of biorisks is observed when working with pathogenic microorganisms. An emergency situation in which there is a real or potential possibility of the release of a pathogenic agent into the air of the working area, infection of personnel or the environment is considered an accident. Due to the high concentration of biorisks in biological laboratories and

production facilities, the most important task is to ensure biological safety when working with pathogenic biological agents. The goal of biosafety is to reduce or eliminate the impact on the individual and the environment of potentially pathogenic agents. Issues of biorisk control include management of the production environment, safety technology, occupational hygiene and the health of working personnel, which are components of biosecurity. The latter is interpreted as a set of measures to ensure the storage of infectious pathogens in the laboratory; preventing their unauthorized removal, including scientific and research information; when personnel work with pathogens that are objects of research − protection of the environment and people living near the laboratory; persons in contact with personnel, and the environment. Each component of biosecurity is based on the results of a biorisk assessment. The main components of the biosecurity system are reflected in World Health Organization (WHO) recommendations: physical protection, personal biosecurity of personnel, microbiological equipment, laboratory equipment, transport biosecurity, information security of biomaterials, organization and training of personnel. Potentially dangerous biological objects include not only viruses, bacteria, fungi and parasites, but also agents capable of causing allergic and toxic reactions that cause the development of various diseases. There are more than twenty groups of professions whose employees are exposed to biological hazards. In particular, these are medical workers, laboratory workers working with potentially dangerous biological factors, agricultural workers working with hyperallergenic, toxic substances, and others. Biological factors are risk factors for workers in many other professions; These include, for example, workers in textile factories, sewage treatment plants, restorers, workers working with fertilizers, and others. Therefore, proposals are currently being discussed for the prevention and reduction of occupational risks associated with various biological factors. There are several classifications of sources of biological hazards, different in form but similar in content. The WHO has proposed a classification option that is recommended for use in laboratory premises. Classification of biological objects by degree of biological hazard: Group I − absence or low individual and social danger, risk – micro-organisms that are not potentially causative agents of human or animal diseases; Group II – moderate individual risk, low public risk, limited risk – a pathogenic microorganism that can cause disease, but does not pose a serious risk to personnel, the population, livestock or the environment, i.e. carelessness can cause infection, but there are available treatment and preventive measures; Group III – high individual and low public risk, a pathogenic agent that usually causes serious disease in humans or animals, but, as a rule, does not spread from a sick person to a healthy one, there are

effective treatment and preventive procedures; Group IV – high individual and public risk, when a pathogenic agent that usually causes serious disease in humans or animals and spreads easily from a sick person to a healthy person or indirectly, effective measures in most cases do not exist[1] [2].

At the current stage of development of society, the main sources of biological danger for the population, animals and the environment, and emergencies of a biological and social nature include the following: pathogenic microorganisms, prions, pathogens of parasitic diseases (causing dangerous and especially dangerous infections, including natural-fire, spontaneous, etc.); "new" pathogens that arise from non-pathogenic and pathogenic strains of microorganisms as a result of mutagenesis under the influence of natural and anthropogenic factors; damaging factors – products of the vital activity of microorganisms (toxins, enzymes, protein bioregulators, superantigens, miniantibodies), etc.; genetically modified organisms and genetic constructs (viral vectors, double-stranded RNA, oncogenes, genes encoding protein toxins); pathogens resistant to modern antimicrobial drugs; ecopathogens that damage physical objects of the environment. To ensure healthy and safe working conditions, the following are of great importance: compliance with the system of occupational safety standards, strict maintenance of technological production regimes, implementation of recommendations developed on the basis of the study and operation of existing biotechnological production facilities, safe organization of workplaces and production in general, proper behavior of personnel, compliance with general and personal hygiene. According to the degree of deviation of the quality parameters of the production environment from the current regulatory documents and the impact on the functional state and health of workers, three classes of conditions and nature of work are distinguished: Class I – optimal conditions and nature of work; Class II − permissible conditions under which the level of hazardous and harmful production factors does not exceed the established hygienic standards at workplaces; Class III − harmful and dangerous conditions and nature of work. In Class III, 3 degrees of harmful and dangerous working conditions are distinguished: 1 − conditions and nature of work that cause functional disorders, which, if detected early and the impact is stopped, are reversible; 2 – conditions and nature of work that cause persistent functional disorders, increased morbidity with temporary loss of work capacity; 3 – conditions and nature of work with increased risk of

[1] Ковальова О. М., Лісовий В. М., Амбросова Т. М., Смирнова В. І. Основи біоетеки та біопезпеки. Київ: Медкнига. 2017. 392 с.

[2] Данилова В. В., Дехтяренко Н. В., Горшунов Ю. В., Галкін О. Ю. Біобезпека в контексті охорони праці. Біотехнологічний і нормативно-правовий аспекти // Наукові вісті НТУУ "КПІ". 2016, № 3. С. 20-29.

developing occupational diseases. The purpose of limiting the spread or preventing the leakage of infectious material from the laboratory environment is to reduce or completely eliminate the impact of potentially dangerous pathogens on laboratory personnel, third parties and the external environment. Primary and secondary limitation of the spread of potentially dangerous biological objects are distinguished. Primary limitation of spread – protection of laboratory personnel and the laboratory environment itself from the impact of infectious agents is ensured by the use of microbiological methods and special equipment that guarantees safe work. Secondary limitation of spread – protection of the environment from the impact of infectious material is ensured by a combination of the technological design of the laboratory and work operations. Elements of limiting the spread of potentially dangerous biological objects: work operations and methods; equipment that ensures safe work; engineering and technological design of laboratories. In accordance with WHO recommendations, four biosafety levels (Biosafety level, BSL) have been established, which are a combination of laboratory work instructions and appropriate methods, equipment that ensures safe work, and design features of laboratory premises. Each of these combinations is specifically designed to perform certain procedures, taking into account the established or predicted route of transmission of infectious agents with which work is carried out, and the tasks of the laboratory. Biological safety levels for work with specific microorganisms, subject to compliance with all rules, ensure the safety of manipulations with an infectious agent. Depending on the level of risk, the premises are divided into four categories: BSL-4 – premises in which work is carried out with microorganisms of pathogenicity group I; BSL-3 – laboratory premises where work is carried out with pathogens of pathogenicity group II; BSL-2 – premises where work is carried out with microorganisms of pathogenicity groups III and IV; BSL-1 – premises where work is carried out with microorganisms of pathogenicity group IV.

Biosafety Level 1 is a level of prevention of the spread of infectious agents that requires only careful implementation of standard precautions and does not require the use of any special primary and secondary barriers other than hand hygiene devices and special protective clothing. Biosafety Level 1 is suitable for use in educational laboratories, in laboratories where work is carried out with known, well-characterized strains of viable microorganisms that do not cause disease in healthy people. General requirements for Level 1 laboratories: should not be isolated from the premises of the entire building; work can be carried out without the use of special protective equipment; personnel must undergo routine safety training, work under the guidance of a laboratory manager who has experience working in a standard microbiology laboratory. Biosafety Level 2 is recommended for laboratories

that carry out work with more dangerous biological objects that belong to the moderate risk group and cause diseases of moderate severity in humans. Such work includes: diagnostic, experimental and production work; molecular genetic diagnostics (sample processing and preparation stage); diagnostic studies of cholera and botulism toxin, performed for the purpose of preventing these infections; immunological (serological) studies to detect antigens of microorganisms of pathogenicity groups II, III or antibodies to them in human blood (without accumulation of the pathogen); studies to control the quality of products for the presence of sanitary indicator microorganisms. General requirements for second-level laboratories: for personnel working with agents of moderate danger, the main risk of infection comes from accidental contact of infectious materials with the mucous membrane or skin or from their entry into the digestive tract. All manipulations with a high risk of aerosol formation (centrifugation, drying, preparation of suspensions, etc.) must be carried out using primary barriers. Other primary barriers may also be used: splash shields, safety shields, laboratory coats and gloves. In addition, secondary barriers such as handwashing sinks and waste decontamination equipment should be used to reduce potential environmental contamination. Biosafety Level 3 applies to clinical, diagnostic, teaching, research, or manufacturing facilities where work is performed with indigenous or exotic agents that can cause serious or fatal illness after inhalation. The list includes a variety of bacteria, parasites, and viruses that can cause serious or fatal illness in humans but for which treatments are available. Laboratory personnel should be specially trained to work with pathogenic and potentially fatal agents and supervised by competent scientists experienced in working with such agents. All procedures involving the manipulation of infectious material should be performed in biological safety cabinets, specially designed fume hoods, other physical containment devices, or by personnel wearing appropriate protective clothing and equipment. It should be noted that some existing facilities may not have all the features recommended for biosafety level 3 (e.g., double-door access areas and sealed walkways). In such circumstances, a sufficient level of safety for routine procedures can be achieved in biosafety level 2 facilities that provide the following measures and facilities: exhaust of filtered laboratory air to the outside; ventilation in the laboratory is balanced and provides laminar air flow; access to the laboratory is limited to working hours; standard operating procedures, as well as safety rules for biosafety level 3, are strictly followed. Biosafety level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol transmission of laboratory infections, agents that cause severe and fatal diseases in humans and for which there are no vaccines or other available

treatments. When working with biological hazards at this level, the use of a personal pressure suit with a separate air supply is mandatory. The entrance and exit of such premises should include multiple showers, a vacuum room, an ultraviolet light room and other safety measures designed to destroy all traces of biological objects. Airlocks operate electronically to avoid opening both doors at the same time. Air and water entering and leaving a level 4 laboratory undergo decontamination procedures to eliminate the possibility of accidental release of the pathogen into the environment. Laboratory personnel must have specific and thorough training in working with particularly dangerous infectious agents. Access to the laboratory should be strictly controlled by the laboratory manager. The facility should be located either in a separate building or in a controlled area located inside the building and completely isolated from all other areas of the building. The following methods can be used to prevent contamination in the laboratory: standard and special microbiological techniques; primary and secondary barriers. Personnel working with infectious agents or other material that may be infected should be aware of the potential hazards, have appropriate training, and be able to apply the methods necessary to work safely with such material. Each laboratory working with potentially infectious material should have a biosafety manual that describes in detail all possible hazardous moments that workers may encounter when working with biological objects, all work procedures and safety measures designed to minimize and/or completely eliminate possible contact with the pathogen. All laboratory personnel must be familiar with the potential risk that may arise during work. Laboratory employees are allowed to work with biological objects only after conducting a briefing on compliance with biological safety requirements. All employees working with biological objects of pathogenicity groups III and IV must be under medical supervision. Medical examinations are carried out in accordance with current documents. A research associate who has received permission to work independently is fully responsible for carrying out work with any infectious agents or infected material. Responsibility for implementing biosafety rules lies with the head of the unit and the head of the organization in which various types of work with biological objects are carried out. To minimize the risk when working with dangerous biological objects, the following should be used: personal protective equipment for personnel; biological safety box; sealed devices for centrifuges; sealed devices for transporting infected material. Also, to ensure the proper level of biosafety, boxes are used that are designed to limit the spread of splashes or aerosols containing infectious material that can be formed during operations. Boxes are divided into three main classes. A biological safety box of protection class I is a box

with a front window through which manipulations can be carried out inside the box, designed to protect the operator. This is achieved by removing contamination created in the box using the incoming air flow through the operator's window with its subsequent effective filtration. Such boxes are designed to protect the operator and the environment when working with agents that are hazardous to the operator's health. In this case, the work is carried out in non-sterile conditions, there is no protection of the product from external contamination. A Class II biological safety cabinet is a cabinet with a front window through which the operator can perform manipulations inside the cabinet, designed to provide operator protection, with a low risk of product contamination and cross-contamination, and with the removal of contamination generated inside the cabinet controlled by a filtered internal air flow and high-efficiency filtration of the exhaust air. The usual way to achieve these conditions is to create a unidirectional downdraft inside the laminar flow cabinet and an air curtain in the front window. The purpose of a Class III biological safety cabinet is to provide the maximum initial level of protection for the product, personnel and the environment when working with agents and microorganisms of pathogenicity groups I and II.[3]

2. Biological terrorism and agroterrorism

Biological and ecological hazards are also caused by pollution of natural resources (water, soil, atmosphere), changes in natural diversity, disruption of biological balance (creation and use of genetically modified organisms). The spectrum of biological risks includes natural, unintentional and intentional risks, for example, natural diseases; infectious diseases that return to circulation; unintended consequences of scientific research; laboratory incidents; lack of information; negligence, etc. The concept of biological security is distinguished – the exclusion of intentional or unintentional dangerous effects on people, animals and plants from scientific research and pathogens of especially dangerous infections, as well as the prevention of the use with malicious intent of the achievements of modern biotechnology, primarily genetic engineering and synthetic biology, as well as genetically modified organisms. Biosecurity also refers to the safe storage and movement, processing and use of living modified organisms that have new combinations of genetic material. The main sources of biological threats are: 1) epidemics and outbreaks of human infectious diseases; 2) epizootics (high incidence among animals); 3) epitophytes (spread of infectious plant diseases over large areas); 4) accidents at biologically hazardous facilities; 5) natural reservoirs of pathogenic microorganisms; 6) transboundary transfer of pathogenic

[3] Основи біоетики та біобезпеки / Бобирьов В. М., Дворник В. М., Девяткіна Т. О., Важнича О. М., Девяткіна Н. М. Київ Нова книга. 2020. 248 с.

microorganisms, representatives of flora and fauna, dangerous to ecological systems; 7) sabotage at biologically hazardous facilities; 8) biological terrorism; 9) use of biological weapons by the state. The first six sources of biological threats are unintentional, while those specified in paragraphs 7–9 are intentional. Separately, the problem of biological threat associated with biological terrorism and the use of biological weapons is determined.

Natural risks (infectious epidemic morbidity and mortality)

• According to WHO, the global mortality from infectious diseases in recent years is up to 14 million people annually.

• The first plague pandemic – the "plague of Justinian" (531-580 AD) – killed about 100 million people; it covered all countries known at that time.

• The second plague pandemic – the "black death" (1347-1407) – killed about 25 million people, which was a quarter of the then population of Europe.

• The influenza pandemic ("Spanish flu") in 1918 killed up to 50 million people.

• During the 7th cholera pandemic (from 1961 to 2005), more than 5 million cases were registered worldwide, of which more than 200 thousand were fatal.

• About 50 million people on the planet are infected with HIV/AIDS.

• Up to 300 million people suffer from malaria annually (up to 3 million die)[4].

According to some researchers, humanity has experienced four major epidemic waves caused by pathogens of dangerous infections in its history. The first wave of epidemics was recorded 5–10 thousand years ago (Neolithic, Eneolithic), when humanity made the transition from hunting and gathering plants in the wild to agriculture and cattle breeding, as well as the construction of permanent settlements and the creation of the first state formations. The second wave began approximately 2.5 thousand years ago with the creation of the first empires (the Persian state of Cyrus, the Athenian Union, the state of Alexander the Great, the Roman Empire, etc.): “the plague of Thucydides” (430–425 BC), the first plague pandemic – “the plague of Justinian” (531–589 AD); the second plague pandemic (1344–1354) – “the black death”. The third wave began about 500 years ago during the Age of Discovery: the introduction of the yellow fever pathogen from Africa to America; the introduction of the smallpox pathogen to America (3.5 million Indians died); the syphilis pandemic in Europe (16th century); the third plague pandemic in the late 19th and early 20th centuries; pandemics of smallpox, scarlet fever, typhus, cholera pandemics, etc.

[4] Tucker. J. B. Toxic terror : assessing the terrorist use of chemical and biological weapons // Harvard University Cambridge, 2000. 314 p.

The fourth wave began after World War II and continues to this day: the elimination of smallpox and successes in the fight against other infections controlled by immunoprophylaxis (diphtheria, whooping cough, polio, measles, etc.), the beginning of the 7th cholera pandemic; the emergence of 40 new infections after the elimination of smallpox; pandemics of HIV infection, tuberculosis, and malaria. The problem of biological threat associated with biological terrorism and the use of biological weapons is separately defined. Bioterrorism is the use of dangerous biological agents to harm people's lives and health in order to achieve political or ideological goals. Biological weapons are special ammunition, devices with delivery devices equipped with biological substances. Biological substances include pathogenic microorganisms (bacteria, rickettsia, fungi, viruses); toxins produced by some bacteria; infected insects and insect pests, as well as synthetic chemicals – herbicides and defoliants. Biological weapons are means of mass destruction and are intended to harm people, domestic and service animals, farm animals and plants. The deliberate use of such biological substances to harm or destroy people, as well as farm animals and plants is included in the concept of "biological warfare". The most likely biological agents to be used to harm people are the causative agents of plague, anthrax, tularemia, melioidosis, brucellosis, typhus, yellow fever, smallpox, Venezuelan equine encephalomyelitis, botulism toxin, and some others. Properties of biological weapons: • relatively easily accessible (natural foci of particularly dangerous infections exist everywhere); • easy to manufacture (almost all countries have laboratories for monitoring the sanitary and epidemiological situation with the necessary equipment; • any microbiological production can be converted to produce a large number of pathogenic microorganisms); • relatively easy to store and transport.

The greatest fears are related to the threat of terrorists using the smallpox virus. Smallpox claimed the most lives in human history, killing a total of about half a billion people – more than all wars and other epidemics combined. As one of the oldest examples of the use of the smallpox virus as a tool of terrorism, one can cite the case of infection of the indigenous inhabitants of America – Indians with smallpox, through infected blankets of sick people, which were given to them as a sign of friendship by white colonists in 1763. Later, this method was repeatedly used by British soldiers to exterminate the indigenous population of America. Then, in just a few years, the population of the continent decreased from 75 million to 600 thousand people. The smallpox virus is considered the most dangerous agent due to its clinical and epidemiological properties. Smallpox is characterized by a high percentage of infections when in contact with a patient and a long incubation period, which makes diagnosis difficult. This

virus can be produced in large quantities, persist for a long time, and spread in aerosol form. There is a possibility that such an agent could fall into the hands of terrorists. Officially, this virus is found in only two places in the world: in the scientific center of Atlanta, USA, and in the Russian State Scientific Center for Virology and Biotechnology "Vector", located in the village of Koltsovo, but it cannot be guaranteed that in addition to these two official collections of smallpox strains controlled by WHO, there are no others in the world – underground ones. The availability of official collections for potential terrorists is also not excluded. In addition, quite reasonable hypotheses are now being put forward about the origin in nature of infections similar to human smallpox and equally dangerous from smallpox viruses of monkeys, buffaloes, camels or cows. Thus, in the period from 1996 to 1998, a significant increase in the incidence of monkeypox among people was noted in Zaire. The consequences of the smallpox virus falling into the hands of terrorists and its use as a biological weapon could be catastrophic not only for the country, but also for the entire world community. An example of the development of events in a single country when only one infected person appears is the smallpox outbreak in Yugoslavia in 1972. By the time the first patient was correctly diagnosed, four weeks after the onset of the disease, 150 people had already been infected. The infection spread throughout the country, and other people began to be infected. The measures taken by the government and the health system consisted of mass vaccination and quarantine. 20 million people were vaccinated. 10,000 people who had contact with the infected were isolated for two or more weeks, and borders with neighboring countries were closed. The outbreak was eliminated 9 weeks after the first case of the disease. The result of the smallpox outbreak was: 175 patients, 35 deaths and panic that arose in the country. It should be noted that the outbreak occurred in a country where mass vaccination of the population against smallpox was carried out. At present, according to experts, no more than 10–15% of the population is immune to smallpox. Against this background, a terrorist act using the smallpox virus could have dramatic consequences.

In second place on the list of dangerous agents is Bacillus anthracis, which causes anthrax. For centuries, anthrax has caused epidemics among animals and people around the world. Currently, the incidence is sporadic with individual group outbreaks. Anthrax occurs among people and animals in most countries of Africa and Asia, in some countries of southern Europe, in America and in certain areas of Australia. The study of anthrax as a possible biological agent began more than 80 years ago. Military biologists have always been attracted by such qualities of anthrax as the ability to sporulate (it can be easily stored and create areas of long-term persistent

infection), as well as the fact that the affected person is actually the final link in the infection (there is no danger of a wide epidemic among their own soldiers). An important factor is also the ease of breeding this bacterium in culture. Mortality from the pulmonary form of anthrax reaches 100%. However, since this disease is treatable, the effect of using such weapons is inferior to the effect of using other types of weapons of mass destruction – atomic or chemical. At the same time, the use of Bacillus anthracis by terrorists can, without causing a large number of victims, sow fear and panic among the population and destabilize public life. Next on the list of dangerous biological agents of category A is the plague pathogen Yersinia pestis. Over the past two millennia, plague has claimed a huge number of lives during several pandemics, affecting many countries on most continents. Currently, outbreaks and sporadic cases of plague occur annually in some countries in Asia, Africa and America. In the countries of the former USSR and the CIS from 1959 to 1994, 99 cases of plague were detected. Over the past ten years, isolated cases of plague have been recorded among people in natural foci located in various administrative territories of Kazakhstan and Uzbekistan. Although the availability of effective means of treatment and prevention of plague reduces the danger of this infection for humans, the incidence in the world remains at a fairly high level and the outbreaks that occur can create panic among the population. An example is the outbreak of 1994 in India, when hundreds and thousands of people tried to leave the city of Surat, various countries stopped receiving and sending planes to India, and the import of Indian goods was banned. The last outbreak of the most severe pulmonary form of plague was registered in India on February 4, 2002, in the eastern state of Himachal Pradesh. By February 19, 16 cases of the disease and 4 deaths had been reported. One of the first documented episodes of bioterrorism using plague can be considered the siege of the Genoese fortress of Kaffa (now Feodosia) in the Crimea. The attackers threw rats and the remains of corpses of people who died of the plague into the fortress. As a result, Kaffa surrendered, but from there the plague spread throughout Europe along with refugees from the large trading city, causing a terrible epidemic. Total losses are estimated at 25 million people, or about 10% of the world's population. The list of category A agents is closed by hemorrhagic fevers caused by arenaviruses and filoviruses. New infections attract the most attention: Marburg and Ebola fevers. The Marburg virus was first isolated in the laboratory from materials from a monkey. The Ebola virus was identified in the western province of Sudan and in the adjacent area of Zaire (now the Democratic Republic of the Congo) during large epidemics with a mortality rate of up to 90%. After the outbreaks, thousands of samples from local animals were examined. However, attempts to find the

natural reservoir of the virus and explain the nature of its origin have so far remained unsuccessful. The last outbreaks of the disease were officially recorded in Guinea in March 2014, but recent studies indicate that the first cases appeared earlier – in December 2013, it is just that the disease was not identified at that time. Since the first cases of the disease appeared, the virus has also spread to the territory of Liberia, Sierra Leone and Nigeria, and later isolated cases were recorded in Senegal, the USA, Mali, Spain, the UK, Italy. This epidemic is the largest of all known epidemics of this disease, both in terms of the number of cases and the number of deaths. On August 8, 2014, the World Health Organization (WHO) declared the epidemic an international disaster. As of October 25, 2015 (the 95th week of the epidemic) since the beginning of January 2014. (1st week of the epidemic) WHO registered 28575 cases of the disease, including 11313 deaths in 10 countries (Guinea, Sierra Leone, Liberia, Nigeria, Senegal, Mali, USA, Spain, Great Britain, Italy). In a terrorist attack, biological weapons can be used by spraying aerosols, contaminating animals, water and food. The objects of such an attack can be any places where people gather: metro stations, railway and bus stations, airports, shopping malls, public catering establishments, sports and commercial facilities, holiday homes, areas for concentration of troops, polling stations, etc. Terrorists are particularly attracted to objects with an extensive ventilation system, primarily metro stations. In addition to ventilation, the air in metro stations is actively moved by the movement of trains. Numerous experiments with non-pathogenic bacteria in the London, Paris, Moscow and New York metros have confirmed that under such conditions, even a small amount of pathogens in the form of an aerosol spreads rapidly within the station and around, which is accompanied by the infection of tens of thousands of people. Therefore, special sensors have been installed in the subways of American cities, designed to detect the beginning of a biological attack as early as possible. It should also be taken into account that an attack using biological weapons, in addition to the losses caused by its direct effect, will lead to enormous panic, mass psychosis, demoralization, and possibly even aggression against the current authorities. This will also be accompanied by colossal economic losses for the state. According to experts from the Centers for Disease Control in Atlanta, the total costs associated with the infection of 100 thousand people with the anthrax pathogen (in the case of the pulmonary form of the disease) will amount to $26.2 billion, in the case of tularemia – $5.5 billion, and in the case of brucellosis – $579 million. An attack using biological weapons can be directed not only directly against people, but also at the infection of animals and contamination of crops. In modern conditions, the fight against terrorism is an urgent task of the world community.

A variety of terrorism is agrarian terrorism, which is the use of biological agents, bacteria or toxins for the large-scale destruction of food, agricultural, biological resources of any country in order to establish external total control over them, undermining food independence. Thus, in modern conditions, agriculture is an important component of the country's economic potential, so any targeted external attacks using biological agents by foreign intelligence services, transnational corporations, and industrial and financial groups on the domestic agricultural sector can lead to negative consequences: large-scale crop losses, mass deaths of livestock, epidemics and epizootics, which can potentially provoke an increase in food prices, destabilization of the political and economic situation in the country, import food dependence, the creation of food shortages, chemical, radioactive, or bacteriological contamination of food, including drinking water, and mass food poisoning, which can result in diseases and mass deaths[5] [6].

For the first time, the problem of ensuring biological safety at the state level was considered in the Decision of the National Security and Defense Council of Ukraine "On Biological Safety" only in 2009. It was stated that our country lacks programs on biosafety and prevention of manifestations of bioterrorism, a national system for countering possible biothreats has not been created, in particular, automated and integrated data banks on possible threats of biological and chemical origin have not been created. The issue of state support for genetic engineering research and scientific developments in the field of biological and genetic safety remains unregulated. It has been established that the state of biological safety does not meet national interests and does not provide effective counteraction to biological threats. Thus, one of the priority tasks of the state remains counteraction to manifestations of bioterrorism, protection of the population from uncontrolled and illegal distribution of products containing GMOs, preservation of a healthy and safe natural environment. Unfortunately, the issues of agricultural bioterrorism are not regulated in any way by the above-mentioned act. The currently valid State Target Program for Biosafety and Biological Protection for 2015–2020 is exclusively declarative in nature and is aimed at ensuring an adequate level of protection of the population and the environment from dangerous biological agents (biothreats), and preventing any manifestations of bioterrorism.[7]

[5] Теплоухов Б. П. Зброя масового знищення та захист від неї. Київ: Скіф. 2023. 100 с.

[6] Головацький О. О. Біотероризм: особливості та тактика протидії // Південноукраїнський правничий часопис. 2016. № 1. С. 18–20.

[7] Андрейчин М. А., Копча В. С. Біотероризм. Медична протидія. Тернопіль : Укрмедкнига, 2005. 300 с.

3. Biosafety problems of using genetically modified organisms

Modern biotechnology methods have made it possible to widely use living modified organisms in agricultural, medical, scientific and practical and other spheres of human activity. Thus, the use of living genetically modified organisms (LGM) allows solving a number of the most pressing problems in agriculture, namely, significantly increasing the yield of cultivated plants, improving the nutritional quality of plant products, reducing the environmental load on the environment by significantly reducing the use of herbicides, pesticides and other agrochemicals. Starting from the 70s of the last century, using DNA recombination methods, a number of new, more productive microorganisms were also created – producers of various biotechnological compounds (antibiotics, enzymes, vitamins, microbial pesticides), new breeds of domestic animals, etc. Experience in using genetically modified organisms (GMOs) shows that the release of living modified organisms into the environment can lead to negative consequences and create a potential danger to existing biological diversity due to the independent spread of living modified organisms; uncontrolled formation of new genetic structures through vertical and horizontal transfer of their genes to other organisms that do not belong to the category of living modified organisms, etc. To ensure genetic modification of organisms, scientists have to overcome the molecular stability of their genome by one method or another. GMOs remain insufficiently genetically stable and carry factors that significantly reduce the natural stability of hereditary mechanisms. Food products and medical preparations may contain such components. Experimental studies prove that animals that eat GMOs give birth to offspring with developmental defects or become completely unproductive. The use of products derived from GMOs can lead to a decrease in the stability of the human genome and cause, according to many scientists, an ecological catastrophe. German scientists claim that GM potatoes have a negative effect on soil bacteria. A study conducted by scientists from the Max Planck Institute for Microbiology (Marburg, Germany) showed that growing GM potatoes disrupts the vital activity of soil bacteria. Researchers consider this a reason to start large-scale research in this direction. In their opinion, GM potatoes can threaten biological balance. And huge costs will be required to restore the soil. GMO cultivation can disrupt the biological diversity of regions, displacing familiar species from their habitat, as was the case with transgenic rapeseed. It is not known how the seeds of transgenic plants, carried by birds over long distances, will behave in other biocenoses. The transfer of genes from modified plants to the chromosomes of weeds can lead to the emergence of new organisms with unforeseen, including potentially dangerous, properties. Thus, the transfer of

pollen by pollinating insects from transgenic plants to conventional ones can lead to the emergence of superweeds, as was the case with transgenic oats, the cultivation of which led to the reproduction of wild mustard. The large-scale widespread introduction of GMOs, the danger of which has not been proven at this time, can theoretically lead not only to a sharp reduction in the biodiversity of organisms, but also to the development of infertility, a surge in oncological diseases and genetic defects, and an increase in mortality. The possible danger from GM structures is higher than from chemical compounds, because they are completely "unfamiliar" to the environment, they do not decompose, but, on the contrary, are accepted by the cell, where they can multiply uncontrollably and cause mutations. Artificial genetic material released into the environment can be introduced into the genetic material of cells of all species, including humans. This process, called horizontal gene transfer, has already led to the appearance of new viruses and bacteria that lead to terrible mutations and acute toxicosis, autoimmune reactions, and oncological diseases (Prof. Terry Traavik, Norway). In March 2004. Dr. Terry Traavik discovered the cauliflower mosaic virus, used to modify grain plants, in meat. In June 2004, scientists from the Dairy Control Center at the Munich University of Technology first discovered traces of GM organisms in cow's milk. Gene manipulation can increase the content of natural plant toxins in food or create completely new toxins. There are slow-acting toxins, when the time of manifestation of protein toxicity is 30 or more years. Genetically modified soy differs from conventional soy in protein composition by 74%. These proteins are fundamentally new, since they are hybrids of bacterial and plant proteins and therefore cannot be equated to either one or the other, and the transformation of a useful protein into a pathogenic one can depend on the slightest change in the amino acid composition. In addition to all the above, it is worth remembering that with the widespread introduction of transgenic varieties, there is a risk of so-called monoculture − numerous plant varieties will be squeezed out of the market by one or two improved transgenic ones. In this case, it is necessary to objectively and from different points of view assess the advantages and disadvantages of varieties before replacing one with another[8] [9].

Classification of risks of GM plants and feed, all undesirable phenomena and events that occur during the processing and consumption of GMOs, can be combined into three groups: food, environmental and agrotechnical risks. *Food risks:*

[8] Запорожан В.М., Аряєв В. Л. Біоетика та біобезпека. Київ: Здоров'я. 2013. 456 с.

[9] Півень О. Без ГМО: правда і страшилки про генну інженерію. Київ: Віхола. 2022. 178 с.

• Direct effect of toxic and allergenic transgenic proteins of GMOs; • Risks mediated by the pleiotropic effect of transgenic proteins on plant metabolism; • Risks mediated by the accumulation of herbicides and their metabolites in resistant varieties and species of agricultural plants. • Risks of horizontal transfer of transgenic constructs, primarily into the genome of symbiotic bacteria for humans and animals (E. coli, Lactobacillus (acidophilus, bifidus, bulgaricus, caucasicus), Streptococcus thermophilus, Bifidobacterium, etc.).

Environmental risks:

• Reduction of varietal diversity of agricultural crops due to the mass use of GMOs obtained from a limited set of parental varieties; • Uncontrolled transfer of constructs, especially those that determine different types of resistance to pesticides, pests and plant diseases, due to cross-pollination with wild relatives and ancestral species. In this regard, a decrease in the biodiversity of wild ancestral forms of cultivated plants and the formation of "superweeds" is predicted; • Risks of uncontrolled horizontal transfer of constructs into the rhizosphere microflora; • Negative impact on biodiversity due to the impact of toxic transgenic proteins on non-target insects and soil microflora and disruption of trophic chains; • Risks of rapid emergence of resistance to the used transgenic toxins in phytophagous insects, bacteria, fungi and other pests, under the influence of selection for the trait of resistance, highly effective for these organisms; • Risks of emergence of new, more pathogenic strains of phytoviruses during their interaction with transgenic constructs that exhibit local instability in the host plant genome and thus are the most likely target for recombination with viral DNA.

Agrotechnical risks: • Risks of unforeseen changes in non-target properties and traits of modified varieties associated with the pleiotropic effect of the introduced gene. For example, reduced resistance to pathogens during storage at critical temperatures in varieties resistant to insect pests; • Risks of delayed change in properties over several generations associated with the adaptation of a new gene in the genome and the manifestation of both new pleiotropic properties and changes in already declared ones; • Ineffectiveness of transgenic resistance to pests after several years of mass use of this variety; • Possibility of use by producers of terminal technologies to monopolize the production of seed material. Risks of production of pharmaceuticals from GMOs In 2003 the term "Pharmageddon" arose. The basis is a large number of rice and corn varieties developed and cultivated by various companies that carry biologically active substances, including: vaccines, growth hormones, blood clotting factors, industrial enzymes, human antibodies, contraceptive proteins, etc. [10]

[10] Паренюк О., Шаванова К. Страшне прекрасне та потворне в Чорнобилі. Від катастрофи до лабораторії. Київ: Віхола. 2023. 304 с.

There are the following risks of uncontrolled use of such products: • the threat of cross-pollination and uncontrolled spread of such varieties among food crops; • the risk of uncontrolled consumption by pregnant women; • the spread of vaccines and other substances released in natural conditions from plant residues through soil and surface water. How justified are these risks? In Mexico and Guatemala, wild corn species are already densely saturated with transgenic inserts due to cross-pollination with cultivated crop varieties. At the same time, open field trials are being conducted in California rice fields among food rice varieties of rice varieties carrying human proteins lactoferrin and lysozyme, which are used in pharmacology in enzyme therapy.

The American company Epicyte recently announced the creation and testing of a corn variety that produces human antibodies to sperm surface proteins for the purpose of obtaining contraceptive drugs. Uncontrolled cross-pollination of such a variety with food crops can lead to serious demographic consequences in the territories where such products are produced. Uncontrolled distribution of vaccines in food products carries no less risk. During embryogenesis, the developing immune system "learns" to recognize "its" proteins, without confusing them later with "foreign". Proteins exposed to immune system cells during embryogenesis are recognized as "its". If the vaccine protein enters the bloodstream of the embryo at this time, the child born will not be able to develop immunity to this disease, always recognizing this bacterium or virus as "its". When harvesting any food crop, a huge mass of plant residues − leaves, stems and roots − remains in the fields. The probability of direct spread of proteins that are part of plants in groundwater is low, although much higher than the probability of horizontal transfer of transgenic structures in soil and other bacteria. But, in addition to this, there is another aspect of the risks − this is uncontrolled vaccination of birds and mammals living in a given area. If transgenic vaccines are directed against bacteria and viruses that have local carriers (or bacteria related to human pathogenic bacteria), then such vaccination will provoke a powerful selection among pathogens and the formation of superinfections. Risks of horizontal transfer of transgenic structures Horizontal gene transfer is widely known in the bacterial kingdom. In the course of evolution, gene exchange took place both between them and between bacteria and eukaryotes. Bacteria retain the ability to exchange parts of the genome to this day. And this property of bacteria is directly related to the environmental and nutritional risks of using GMOs. The presence in the gastrointestinal tract of enzymes that use an antibiotic as a substrate in food is practically safe for humans and animals. Enzymes require strictly defined conditions for their activity, so proteins that carry out intracellular metabolism will function only in a living cell. The probability of integrating a transgenic construct from a plant into the genome of mammals

and humans is negligible. It is worth considering that cells of higher eukaryotes have several isolating barriers that effectively prevent horizontal transfer. Even in the case of such transfer, the cell, as a rule, does not multiply, being in the terminal stage of differentiation. The transfer of the construct to germ cells is generally improbable, given the hemato-testicular barrier, which is not permeable to large molecules. But we should not forget that humans have endosymbionts, in particular, intestinal bacterial flora. It is known that bacteria are capable of transformation by both circular and linear forms of DNA with inverted repeats. Fragments of transgenic DNA are found in the intestines, blood and milk of animals fed GMOs. In this case, according to the frequently used method of selection of transgenic constructs under the action of antibiotics, these fragments carry reporter genes of antibiotic resistance as marker sequences. These genes can be either silent or normally expressed. In any case, the transformation of symbiont or pathogenic bacteria by them can "include" them already in the bacterial genome, for example, by recombination and the emergence of so-called chimeric proteins that have enzymatic activity against the antibiotic. This leads to the formation of antibiotic resistance in the symbiont bacteria themselves or in the pathogenic flora[11].

The result of using an antibiotic in case of illness will be the rapid selection of bacteria resistant to it, and the antibiotic will either begin to be processed directly in the intestine, without reaching the target pathogenic bacteria, or will not have an effect on pathogens resistant to it. All this indicates the relevance of the problem of analyzing food and other risks of using GMOs, the need to develop standards for examination and testing of new varieties taking into account already known risks and constant strict control of GMOs in the original varieties. Of course, the assessment of such risks will always be relative − any food products we consume can have various effects on the body, and in the process of producing any food product, human intervention in the surrounding nature occurs. The potential danger of GM crops also lies in their genotype. More than half of the transgenic proteins that provide plants with resistance to pests and diseases are toxic and cause allergies. For example, the use of the Brazil nut albumin gene to create a soybean variety with an improved amino acid composition has led to a significant number of people suffering from allergic diseases. Substances intended for the control of insects can block digestive enzymes not only in insects but also in humans, and affect the pancreas. Most GM crops have additional marker genes that are resistant to antibiotics. There is a danger of transferring them to pathogenic microorganisms, which can make them resistant to antibiotics and then traditional methods of treating inflammatory processes will be ineffective. A number of transgenic varieties of corn, tobacco and tomatoes that are

[11] Кічура Д. Б. Основи біосинтезу. Львів: Сполом. 2023. 192 с.

resistant to pests produce the substance lignin, which can decompose into mutagenic phenols and methanol. Therefore, an increase in the content of lignin in the fruits and leaves of plants is very harmful to humans. The most striking example of GMO toxicity is the case of the Japanese company Showa Denko K.K., which produced the food additive GM-tryptophan. The company believed that it was an analogue of unmodified . However, this additive caused the death of 37 people, another 1,500 remained disabled for life. Until now, the functions of a strategic document on environmental policy are performed by the "Main Directions of the State Policy of Ukraine in the Field of Environmental Protection, Use of Natural Resources and Ensuring Ecological Safety" (approved by the Resolution of the Verkhovna Rada of Ukraine dated March 5, 1998), which provide for the implementation of long-term tasks for a period of up to 10-15-20 years. Today There was a need for a new strategic document that would take into account modern socio-economic and socio-political processes at the global, regional and national levels and respond to new challenges facing Ukrainian society. The Second Review of the Effectiveness of Ukraine's Environmental Protection Activities, prepared by the United Nations Economic Commission for Europe (2007), states that "the country's strategic directions in the field of environmental protection are unclear and are still based on the 1998 document. There is an urgent need for a thorough environmental strategy that would contain updated priorities." Ukraine is at the stage of creating a biosafety system in the state, the main goal of which is to ensure the safe use of genetically modified organisms and genetic engineering activities and prevent their unauthorized and uncontrolled spread on the territory of Ukraine. This goal is achieved through the development and implementation of an effective state instrument capable of preventing potential environmental, economic, social and other risks associated with the introduction of genetically modified organisms and genetic engineering activities, as well as creating a rational counteraction to processes that pose a threat to national interests. At the legislative level, the issues of development, creation, testing, research, transportation, release into the environment and use in Ukraine of genetically modified organisms and genetic engineering activities with ensuring biological and genetic safety are regulated. In the process of joining the World Trade Organization, Ukraine undertook to create a legislative framework in the field of biotechnology in accordance with international norms and principles. It is necessary to carefully study and take into account international experience in this area, in particular, of the EU member states. Proposed tasks: • ensuring and strengthening the human and material and technical potential of institutions involved in the creation and implementation of a biosafety system in the state; • developing a regulatory and institutional framework for state regulation and control in the field

of handling genetically modified organisms and genetic engineering activities and its implementation; • stimulating the implementation of environmental management systems, in particular, on issues of storage, transportation, use, destruction, neutralization and disposal of microorganisms, other biologically active substances and biotechnology products; • improving the permitting system in the field of handling genetically modified organisms, including their cross-border movements, and regulating genetic engineering activities; • creating and supporting the functioning of a certified laboratory accredited to control the import of genetically modified organisms into the territory of Ukraine and prevent their uncontrolled spread and creating regional laboratories in key regions that work with such products; • continuous support for the activities of testing laboratories to determine the content of genetically modified organisms in products[12] [13] [14].

4. Food toxicological and hygienic assessment of products from genetically modified sources

In most countries, a phased assessment of the hazard and quality of GM sources is carried out. This approach is based on the principle of compositional or real equivalence, which consists in comparing GMOs with traditional analogues. According to the results of the comparison, products are divided into safety classes: Class I − if the assessment of compositional equivalence does not reveal any differences between GM food products and traditional analogues. The product is proposed to be considered completely harmless to health; Class II − certain differences are identified; Class III − complete inconsistency with traditional analogues. Products of classes II and III are subject to further safety assessment. The stages of food safety research involve the study of nutritional and toxicological characteristics of products. The assessment of nutritional properties includes the study of: nutritional value of a new product; consumption rates; methods of use in nutrition; bioavailability; intake of individual nutrients (if the expected intake of a nutrient exceeds 15% of its daily intake); impact on intestinal microflora (if the GMO contains living organisms). Toxicological characteristics provide for the determination of the following indicators:

[12] Лушпаєв С. О. Правове регулювання відносин із виробництва рослинницької продукції в аспекті продовольчої безпеки України // Підприємництво, господарство і право. 2013. № 10. С. 69-72.

[13] Ковальова О.М., Ащеулова Т.В., Іванченко С.В., Гончарь О.В Генетично-модифіковані організми: ризики, міфи та реальність / Матеріали конференції «Біоетика та біобезпека: мультидисциплінарні аспекти», Харків. 2017. С. 70-72.

[14] Тригуб А. Ю. До питання міжнародно-правового розуміння поняття продовольчої безпеки // Науковий вісник Національного ун-ту біоресурсів і природокористування України. Серія “Право”. 2010. Вип. 156. С. 269-275.

toxicokinetics; genotoxicity; potential allergenicity; potential colonization in the gastrointestinal tract (in the case of the presence of microorganisms in the genetically modified product); results of a subchronic (90-day) toxicological experiment on laboratory animals and studies on volunteers. However, such a system for assessing the safety and quality of genetically modified food sources, based on the principle of compositional equivalence, can be recommended for products that do not contain proteins and DNA. Such products include flavoring additives, refined oils, modified starch, maltodextrin, glucose syrups, dextrose, isoglucose and other sugars. Among Ukraine's closest neighbors, transgenic crops have been registered in most EU countries, where, taking into account international experience, in particular the American one, a special procedure for assessing the safety and quality, as well as registering food products obtained from GMOs, has been developed and implemented. Expertise of food products is carried out in three areas: medical-genetic, medical-biological and technological.[15]

There are no means of controlling GMO products in food and medical products. Under such circumstances, organizational and legal measures to ensure the biosafety of genetically modified organisms and products obtained from them have begun to be introduced at the international level and in many countries of the world. Thus, the importance of ensuring environmental safety when using biotechnology was emphasized in the Agenda for the 21st Century, adopted at the UN Conference on Environment and Development (Rio de Janeiro, June 3-14, 1992). Laws and other regulatory legal acts on the biosafety of living genetically modified organisms have been adopted in many other countries. In the early 1990s, a number of EU directives on the use of GMOs were adopted, which laid the foundation for the "International Guidelines for Safety in Biotechnology", adopted at the Global Consultation of Experts Appointed by Governments in December 1995. These principles concern human health protection and environmental safety in the use of biotechnology − from scientific developments to the sale of biotechnological products containing organisms with new properties, recommendations for conducting scientifically sound risk assessment. In Ukraine, an important step in ensuring the use of international experience in this area was taken on September 12, 2002, when the Law of Ukraine "On the Accession of Ukraine to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" was adopted. The Cartagena Protocol on Biosafety (adopted on January 29, 2002 at a meeting of the Conference of the Parties to the Convention on Biological Diversity in Montreal) is aimed at ensuring an appropriate level of protection

[15] Paul Knoepfler GMO Sapiens: The Life-Changing Science of Designer Babies. NY: WSPS. 2015. 282 p.

in the field of safe transfer, processing and use of GMOs. The Protocol pays special attention to the transboundary movement of such organisms. This document does not apply to the transboundary movement of GMOs in the form of pharmaceuticals for humans, issues of which are regulated by other relevant international agreements or organizations. This document provides for the mandatory conduct of a risk assessment before the use of genetically modified organisms in new conditions (countries) and the procedure for prior informed consent of the parties (states) that carry out the exchange, use and application of any living genetically modified organisms. The Protocol requires each Party to take measures to process, package and label LMOs during their transboundary movement. The Cartagena Protocol on Biosafety obliges each Party to take appropriate domestic measures regarding violations of national legislation and the requirements of the Protocol during the movement of LMOs, and in appropriate cases, penalties for such violations. It should be noted that the Cartagena Protocol on Biosafety is the first international document on issues of regulating the safe use of living modified organisms for human health and the environment.

Accession to the said Protocol enables Ukraine to apply in its relations with other states the norms of this document, which are agreed upon by almost all UN member states, including the European Union, Canada, Japan, and the states of Central and Eastern Europe, and also, guided by the provisions of the Cartagena Protocol, to improve its own legislation on biosafety. Today, such legislation in Ukraine is only beginning to take shape. Its analysis shows that a significant group of legislative acts only indirectly regulates the issue of biosafety through general legal requirements for the protection of human health and the environment from the impact of hazardous factors of a physical, chemical, and biological nature (it is assumed that these factors are taken into account, criteria for their impact on human health are determined, control over their impact is exercised, etc.). These acts include the Fundamentals of Legislation on Health Care, the Law of Ukraine "On Medicinal Products", the Law of Ukraine "On the Quality and Safety of Food Products", the Law of Ukraine "On Pesticides and Agrochemicals", the Law of Ukraine "On Environmental Expertise" and some others. For example, the Law of Ukraine "On Ensuring Sanitary and Epidemic Well-being" (Article 9) provides for the hygienic regulation of any hazardous factors of a biological nature, the determination of the central executive body responsible for carrying out work on the hygienic regulation of hazardous factors, maintaining the State Register of Hazardous Factors (it must contain the names of hazardous chemical substances and biological factors, data on their purpose, properties, methods of indication, biological effect, degree of danger to human health, nature of behavior in the environment, production, hygienic regulations for use, etc.),

establishes a requirement for the use in the national economy and everyday life of any hazardous factor of a chemical and biological nature only if a certificate is available, etc. Biosafety issues are addressed in more detail in Article 53 of the Law of Ukraine "On Environmental Protection". According to this article, enterprises, institutions and organizations are obliged to ensure environmentally safe production, storage, transportation, use, destruction, neutralization and burial of microorganisms, other biologically active substances and objects of biotechnology, to develop and implement measures to prevent and eliminate the consequences of the harmful effects of biological factors on the environment and human health. The creation of new strains of microorganisms and biologically active substances should be carried out only on the basis of permits from a specially authorized central executive body for health protection and a specially authorized central executive body for ecology and natural resources, provided that there is an assessment of their impact on the environment and human health. When creating the specified organisms and substances, standards for maximum permissible concentrations and methods for determining these organisms and substances in the environment and food should be developed. The production and use of new strains of microorganisms and other biologically active substances may be carried out only after conducting comprehensive studies of their impact on human health and the environment with the permission of the specially authorized central executive body for health protection and the specially authorized central executive body for ecology and natural resources.[16]

The issues of biosafety of living modified organisms are regulated in detail by the Resolution of the Cabinet of Ministers of Ukraine dated August 17, 1998 No. 1394 "On Approval of the Temporary Procedure for the Import, State Testing, Registration and Use of Transgenic Plant Varieties in Ukraine". This Temporary Procedure establishes the mechanisms for the import, state testing, registration and use in Ukraine of genetically modified (transgenic) plant varieties that meet biosafety requirements. Only transgenic plant varieties recognized as biologically safe, officially registered and approved for use in any country that is a member of the International Union for the Protection of New Varieties of Plants are allowed for import, state testing, registration and use in Ukraine. The import of transgenic plant varieties into Ukraine is carried out with the permission of the Ministry of Agriculture. The basis for obtaining a permit for the import of transgenic plant varieties is a positive conclusion of the Interdepartmental Commission on Biosafety, which is being created under the Ministry of Science, on the biosafety of the genetic construct included in the genome of these varieties. It is important to note that

[16] Вадзюк С. Н., Волкова Н. М. Основи біомедичної етики. Тернопіль : Укрмедкнига. 2021. 280 с.

the Temporary Procedure does not apply to the sphere of scientific research and the use of products produced from raw materials of transgenic plant varieties. The Law of Ukraine “On the State Biosafety System in the Creation, Testing, Transportation and Use of Genetically Modified Organisms” regulates the relations between executive authorities, manufacturers, sellers (suppliers), developers, researchers, scientists and consumers of genetically modified organisms and products produced using technologies that provide for their development, creation, testing, research, transportation, import, export, placing on the market, release into the environment and use in Ukraine (hereinafter referred to as the handling of GMOs) with ensuring biological and genetic safety. This Law does not apply to humans, tissues and individual cells in the human body. In this Law, the following terms are used in the following meaning: • biological safety – the state of the human living environment, in which there is no negative impact of its factors (biological, chemical, physical) on the biological structure and function of the human person in the present and future generations, as well as there is no irreversible negative impact on biological objects of the natural environment (biosphere) and agricultural plants and animals; • genetic safety – the state of the human living environment, in which there is no unnatural impact on the human genome, there is no unnatural impact on the genome of biosphere objects, as well as there is no uncontrolled impact on the genome of agricultural plants and animals, industrial microorganisms, which leads to the appearance of negative and/or undesirable properties in them; • organism, living organism – any form of biological existence (including sterile organisms, viruses and viroids) capable of self-reproduction or transmission of hereditary factors; • genetically modified organism, living modified organism (GMO) – any organism in which the genetic material has been altered by artificial gene transfer techniques that do not occur in nature. No publications on clinical trials of GM foods in humans were found. At the same time, a number of animal studies have identified the following main risks of consuming GMOs: suppression of immunity, possible allergic reactions and metabolic disorders as a result of direct exposure to transgenic proteins. Data have been obtained on the disruption of the stability of the plant genome when a foreign gene is inserted into it, which, in turn, may cause a change in the chemical composition of GMOs and the emergence of unexpected, including toxic, properties. The negative impact on health is also associated with the presence of "technological garbage" in the inserted DNA fragment, which includes, among other things, viral promoters, primarily the 35-SH promoter and bacterial terminators. Changes introduced by a foreign genome into an evolutionarily adjusted genome with a high degree of probability also predict the occurrence of carcinogenic and mutagenic effects, therefore independent experts do not

exclude the manifestation of negative consequences associated with such substances in a person consuming GMOs in the future. The results of a number of experiments have demonstrated the emergence of secondary resistance of pathogenic human microflora to antibiotics due to the replication of antibiotic resistance marker genes used in the production of GMOs in the intestinal microflora. One of the positive effects of genetic modification of crops is their resistance to herbicides. However, the data obtained show that sugar beets resistant to the herbicide glyphosate accumulated its toxic metabolites. The basis of modern research on the safety of GMOs is the concept of "substantial equivalence", according to which GM products are as safe as their traditional counterparts. However, until further notice, according to independent experts, it is impossible to accurately determine, for example, whether the composition of conventional soybeans and GM analogues is equivalent or not. Comparing various published scientific data, it was found that some indicators, in particular, the content of phytoestrogens, differed significantly. The most extensive analysis of scientific papers published in the last 30 years on the development, application and results of the use of corn, soybeans and cotton with altered genetic characteristics was carried out by a group of experts of the American scientific organization of the National Academy of Sciences, Engineering and Medicine (NAS). Over 900 scientific papers were analyzed over 2 years, assessments of 80 speakers from 3 open public meetings and 15 webinars and opinions of 700 representatives of the public were taken into account in order to better understand the differences associated with GM crops. Based on the results of this analysis, a report was published in May 2016, the authors of which reached the following conclusions: GM crops are as safe for consumption as their non-modified counterparts. They do not have negative effects on the environment and make it possible to reduce the use of pesticides. No significant correlation was found between the consumption of GM foods and the risk of food allergies, autism, obesity, cancer and kidney disease, as previously noted in a number of other publications. At the same time, according to NAS experts, GM crops do not increase the potential yields of these crops and lead to a significant problem with herbicide resistance of weeds. Animal experiments have also revealed differences in the intestinal microflora when consuming GMO products. The report emphasizes that the solution to the issue of the safety of the use of GM crops should be based on a scientific evidence base with strict state regulation and broad public discussion in order to increase confidence in the conclusions about the safety of GMOs.

CONCLUSIONS

The worldview function of bioethics is to determine the scope of certain “universal” moral norms in different cultural contexts. In most so-called traditional societies, “universal” principles are known, but have specific

features in the scale and areas of their application. For example, in a traditional society, there may be moral equivalents of ideas about the “value of the human person” and corresponding codes of conduct. But such codes have significant limitations and exclusions in relation to different contingents of people based on ethnicity, place of residence, social status, gender and age. Bioethics as a special worldview is open to change. Historically, Potter’s survival ethics gave birth to pragmatically oriented South American principledism. That, in turn, initiated European bioethics, biolaw and global ethics as a combination of medical and environmental directions. In Ukraine, the formation and development of bioethics is additionally influenced by processes related to the tasks of creating a market mechanism of the economy and the formation of a society inclined to the ideals of democracy and humanism. Medicine and healthcare in our country are becoming one of the priority areas of public life. The modification of doctor-patient relations is significantly influenced by the increase in medical awareness of the population, the understanding that the health of a person and his children is primarily the subject of his own concern and responsibility. A scientific worldview helps solve practical problems. The worldview function of bioethics contributes to the protection, preservation and sustainable development of life using ethical mechanisms and principles. In the modern world, GM products are an integral part of the economy of most countries in the world. At the same time, there is no unified scientific, social and legislative framework in this area, which dictates the need for further intensive research aimed at improving technologies for obtaining GMOs and a comprehensive study of the biology of transgenic plants.

SUMMARY

The topic of health, illness, and the rights of the patient has been reflected in important international legal documents, constitutions, and other legislative acts of various states. It is worth noting that on July 22, 1946, the World Health Organization (WHO) was established. The WHO emphasized that "the promotion of one’s own health, to which everyone is capable, is one of the fundamental rights of all people, regardless of their religion, race, or political opinion, and that the health of all people is a fundamental condition for peace in the world." The "Universal Declaration of Human Rights" (UN, 1948) adopted by the UN provides for the right of every person to medical care and the right to social protection. This is “the right to a standard of living adequate for the health and well-being of himself and of his family, including food, housing and medical care and adequate social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or

other lack of livelihood in circumstances beyond his control." The European Social Charter, a Council of Europe convention adopted in 1961 and revised in 1996, enshrines a number of social human rights, including the right to health care, social and medical assistance. It is one of the fundamental international treaties of the Council of Europe and a source of European law. The European Social Charter states that "everyone has the right to the enjoyment of all measures conducive to the enjoyment of a good state of health."

Thanks to the revolutionary development of life sciences, it is becoming increasingly easy and accessible for the vast majority of countries, certain groups and individuals to use materials, technologies and knowledge for dangerous purposes. Biosafety and biosecurity are relatively new areas of scientific knowledge, which are mainly used to protect workers and the environment from the spread of biological material used in scientific and other research. Biosafety is the prevention, reduction and elimination of the impact of dangerous biological factors (agents) on people, animals, plants and the environment, while biosecurity is measures aimed at preventing the loss, theft or use for dangerous purposes (bioterrorism) of microorganisms, biological materials (bioagents) or information. Typically, the principles of biosafety and biosecurity are implemented in those institutions that work with pathogens of both humans and animals.

Ukraine can and should make a significant contribution to the development of bioethics. The geographical position of Ukraine, located between the West and the East, undoubtedly influences the formation of our philosophical views on science in general and medicine with biology in particular. Historically, our country has absorbed elements of the technocratic nature of the West and the spirituality of the East. Such a harmonious unity contributes to the humanization of medicine, the understanding of man as a unity of biological, psychological and social components. The mutual penetration and enrichment of Western and Eastern cultures is facilitated by the cooperation of higher educational institutions of Ukraine with similar institutions of other countries in the administrative, scientific and educational spheres.

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