

CHAPTER 2

LEGAL RELATIONS: FROM THEORY TO PRACTICE

DEVELOPMENT OF LEGAL TOOLS OF STATE MANAGEMENT IN THE FIELD OF ENSURING BIOLOGICAL SAFETY IN UKRAINE

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Abstract. The paper is dedicated to issues on improving legal tools of state management in the field of providing biological safety in Ukraine. It is emphasized that establishing of measures of relevant legal liability has to be considered as effective means for providing appropriate state of biological safety and stimulation of lawful conduct of all subjects. Issues of lawful conduct in the field of providing biological safety have exclusively applied nature and often stipulate activities of researchers in the field of biological technologies, and entrepreneurs who are involved into the relevant direction of commercial use of biological technologies. It is outlined, that liability is an effective tool for legal influence on social relationship aimed to providing of biological safety. In our opinion, functions of legal liability in the field of providing biological safety have to include the next ones, namely: preventive (protective, of a warning character) which boils down to preventing new offenses, precautions; penalty (punitive) which boils down to punishing the guilty person, the meaning of which is imposing measures of negative consequences of a personal, property or organizational nature (material fines, prohibitions on conducting research or carrying out production) to them; restorative (compensatory) which aims to restore illegally violated property or personal rights, compensation for material or moral damage, losses (in case of socially negative consequences). It is indicated, that improving the mechanism of legal liability for biological safety involves updating the legislation on largely all types of liability known in modern legal theory. These types of liability are as follows: civil (in the case of compensation for material and moral damage); criminal (in the case of application of measures of influence of criminal and legal character; it can be applicable to both legal entities and individuals); administrative (in the case of less social harm of the offense); disciplinary (in case of violations of labour duties).

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Introduction. Establishing adequate legal liability should be seen as an effective means of ensuring the proper state of biological safety and encouraging the lawful conduct of all actors involved. Issues of lawful conduct in the field of biological safety are exclusively of applied nature, they often determine activities of developers and researchers in the field of biological technologies, of entrepreneurs engaged in the relevant field of commercial use of biological technologies.

Determining the grounds for prosecution and imposition of various penalties should be made taking into account a special level of public danger and the likelihood of serious consequences in cases of violation of biological safety requirements. At the same time, it is the preventive impact of the possibility of applying various sanctions to violators that stimulates compliance with the requirements of biological safety in

the process of scientific, experimental and industrial activities.

Literature review. Individual legal aspects of ensuring the biological safety of Ukraine were studied in the national science of public administration by G.I. Balyuk, S.I. Bugera, I.V. Gyrenko, A.D. Dukhnevych, V. Zavgorodnya, V.M. Yermolenko, G.Yu. Gulevska, S.M. Sergeeva. However, the works of these scientists are mainly aimed at describing the legal field, which determines the legal basis for the organization of biological safety and biological protection. At the same time, the problem of strengthening legal liability in the field of biological safety remains underresearched.

Aims. The objective of the study is to substantiate areas of improvement of regulation for legal liability as a tool for public administration in the field of biological safety of Ukraine.

Methods.

Results. The importance of the problem of lawful conduct is explained with the fact that the practical achievement of the ultimate goal of legal regulation, i.e. implementation of legal requirements is exercised through such behaviour. This issue is becoming especially relevant in the period of social transformations, which periodically happen to our society, lead to creation of institutional and legal patterns of behaviour, emergence of new priorities, goals of law enforcement participants, new values, needs, ways and means to achieve these goals recognized that are legally and morally acceptable in the society. This results in creation of new rules of legal interaction, which determine the legitimacy and vice versa the illegality of certain behavioural patterns.

Today a problem arises that is about a necessity to continue research on the impact of lawful behaviour on the sphere of public relations that suffers from marginalism, legal nihilism and outright personal indifference. Thus, it is a question of detailing and concretization of scientific and theoretical understanding of modern realities of lawful behaviour in the field of biological safety and practical application of possible recommendations in everyday human life.

It is well known that human behaviour is of a willed nature. Entering into various social and legal relations, citizens act based on their needs, motives, goals set by them and the ways to reach these goals they have on their mind. Such needs and desires are quite often selfish in nature; they are explained with a significant degree of individual and collective risk.

However, the need to take into account requirements of law by the structure of the personal psyche of conscious human behaviour, in the presence of other social regulators of influence creates a certain advantage over them, more essential prerequisites for their manifestation in socially active behaviour. It is the means of legal liability that traditionally establish motivation to behave properly in the social environment.

Social and legal activity is characterized by a combination of extrinsic and intrinsic features. The intrinsic ones are needs, motives. Value and legal key points, beliefs, legal attitudes of the individual. As a result of influence of the intrinsic social and psychological mechanism of behaviour regulation, such a degree of

understanding, awareness of legal requirements is achieved by a person, which allows defining their behaviour "externally" as active, proactive, positive, appropriate, legal, aimed at achieving objectives of legal regulation.

In other words, human behaviour in the society is a complex anthropological and social phenomenon [8], which is determined by a number of internal and external factors. The most important means of social regulation of human behaviour is social norms, through which the society puts the requirements before an individual that he must be guided with in their behaviour, which guide, regulate, control and evaluate human behaviour. Normal social existence of a person is possible when they are guided by these generally accepted rules, which are based on social values, ideals of society when choosing a pattern of behaviour [7]. In general, lawful behaviour is a socially useful act aimed at satisfying the state and legal, public and personal interests, values and goals [1]. Legitimate behaviour can be discussed only to the extent it meets requirements of the law, which act as a normative regulator of an individual human or collective behaviour. In general, lawful behaviour implies such actions of individuals, officials, state and public organizations that comply with legal requirements; in other words, it is the conduct of legal subjects that is in line with legal rules. Therefore, a criterion against which the legitimacy is determined is the degree real acts, actions of people comply with a behavioural model laid down in norms of law [2].

It should be noted that if an individual does not comply with existing social norms of the society or fulfils them improperly in the way people behave, it will lead to social liability for such individuals. It is a negative reaction of the society to this type of behaviour. In such a situation, the person is obliged to be punished for non-compliance with the requirements of social norms. At the same time, in the context of ensuring biological safety, we can talk about both manifestations of legal liability including positive and retrospective ones.

Positive (perspective) legal liability presupposes a conscientious attitude to one's duties, lawful behaviour both now and in the future in order to create the need for a certain lawful fulfilment of one's duty for the society, state, etc. In other words, in a positive sense legal liability is an obligation to perform the assigned and taken over functions related to work, service, position in the best way possible, to optimally exercise one's competence, using all the opportunities and means allowed by law" [6]. First of all, the embodiment of positive liability in the field of biological safety is the observance of various recommendations and moral rules by medical workers, scientists, employees of research laboratories, employees of enterprises.

In fact, a positive (perspective) legal liability means social liability, which is realized in the lawful behaviour of a person. But such positive liability is nothing else but a characteristic of lawful behaviour. Therefore, attempts to merge such diverse categories as positive liability and negative liability (legal) into one concept of social liability are hardly legitimate and justified from a scientific and practical point of view. After all, with this approach, we have that everyone is responsible, both those who knowingly and conscientiously perform their duties, and those who commit legal offenses and violations. The legislation of Ukraine also stipulates that in exercising

one's subjective rights, a person must adhere to the moral principles of the society. In practical terms, at first glance, it is difficult to determine a list of modern "values" that form the basis of the moral sphere of the society. And so the logical question is where to look for these values?

The answer, in our opinion, can be found in the Christian ethics prevailing in our society. Our modern morality in relation to biological research in terms of positive liability should be fundamentally based on religious Christian teachings. Addressing canonical norms makes it possible to determine moral criteria for evaluating activities of a creative personality. The said moral requirements are common in modern Europe.

The Holy Congregation for Doctrine and Faith (Catholic) has developed the Instruction "Gift of Life" concerning the content of scientific research, especially in the biomedical field. In particular, the second part (science and technology in the service of the human) states: "God created mankind in his own image and likeness: 'male and female he created them' (Gen. 1.27), entrusting the duty to rule over the earth" (Gen. 1.28). Basic scientific and applied research is a clear proof of this dominance of man. Science and technology are useful tools for man when they serve them and promote holistic development for the common good. *But they cannot be the meaning of existence and human progress by themselves.* These means, intended for man, which one creates and develops, acquire the delineation of their purpose and their limits from the person and the person's moral values. On the one hand, it would be misleading to say that research and its applications are morally neutral. On the other hand, one cannot define guiding criteria purely from technical efficiency, from a possible benefit of experiments for some at the expense of others, or, which is worse, from dominant ideologies. Therefore, science and technology need unconditional respect for fundamental criteria of moral law for the sake of their own intrinsic significance. *In other words, they must serve the human, one's inalienable rights, one's true and holistic benefit in accordance with God's plan and will.* The rapid development of technological inventions makes the need to respect the above criteria even more relevant as science "without conscience and due care" can lead to death of the human." And our age, more than previous centuries, requires just such very wisdom that new human inventions become more humane. Because if wiser people do not come, the future of the world will be in danger."

A practical way of ensuring compliance with moral requirements (positive liability) is provided also through acquisition of relevant qualities of responsible attitude to exercising one's duties during training, through mastering requirements of bioethics (Van Ransler Potter, commonly called as "father of bioethics", proposed to understand bioethics as a science of survival, which should be not just a science, but a new wisdom that would combine the most important and essential elements, i.e. biological knowledge and universal values) [3].

At the same time, positive legal liability alone cannot ensure strict compliance with requirements of biological safety. In this sense, the classic (retrospective) liability comes into play, which should include a relevant arsenal of legal means of influencing law-breakers. First of all, it should create confidence about inevitability

of negative consequences for the perpetrators in the event of violations in the field of biological safety.

The legal literature proposes the following definition of the purposes of legal liability: "The purposes of legal liability can be considered as definition, formulation of such social effect or results which the society aspires to and which is legally defined on behalf of the latter by the state (through legislation and by law application and law enforcement activity) in cases if an offense has been committed by the guilty person" [5].

At the same time, from our point of view, functions of legal liability in the field of biological safety should be as follows: preventive (protective, of a warning character) which boils down to preventing new offenses, precautions; penalty (punitive) which boils down to punishing the guilty person, the meaning of which is imposing measures of negative consequences of a personal, property or organizational nature (material fines, prohibitions on conducting research or carrying out production) to them; restorative (compensatory) which aims to restore illegally violated property or personal rights, compensation for material or moral damage, losses (in case of socially negative consequences).

In order to achieve results of these functions of legal liability, it should cover almost all types of liability known in the modern legal theory. In the case of compensation for material and moral damage, it is a question of civil liability; when applying measures of influence of criminal and legal character it is criminal liability (at the same time it can concern both legal entities and physical persons); in the case of less social harm of the offense it is administrative liability, and in the case of violations of labour duties it is disciplinary liability (Table 1).

We suggest taking a closer look at each type of liability stated above. The Civil Code of Ukraine deals with the principles of civil liability of the owner of the source of increased danger (according to part 1 of Article 1187 of the Civil Code of Ukraine such activities include use, storage or maintenance of vehicles, machinery and equipment, use, storage of chemical, radioactive, explosive, flammable and other substances, keeping wild animals, service dogs and dogs of fighting breeds, etc., which creates an increased danger for the person who carries out this activity and other persons). In order to avoid disputes over the interpretation of the meaning of the concept of a source of increased danger, liability for which causes liability without fault, we consider it necessary to propose a supplement to the disposition of this legal norm in the context of biological safety.

We find it necessary to define a source of increased danger using such wording: "1. A source of increased danger is the activity associated with the use, storage or maintenance of vehicles, machinery and equipment, use, storage of chemical, *pathogenic and opportunistic agents (microorganisms), genetically modified*, radioactive, explosive, flammable and other substances, keeping wild animals, service dogs and dogs of fighting breeds, etc., which creates an increased danger for the person who carries out this activity and other persons." It is also desirable to supplement the provisions of Art. 1187 of the Civil Code of Ukraine with the Note of such content.

Table 1. Improving the sphere of regulation of legal liability

Type of liability	Suggestion for improvement
Civil liability	<p>To state the definition of the source of increased danger in the Civil Code of Ukraine in the following form: «1. A source of increased danger is the activity associated with the use, storage or maintenance of vehicles, machinery and equipment, use, storage of chemical, <i>pathogenic and opportunistic agents (microorganisms), genetically modified</i>, radioactive, explosive and flammable and other substances, keeping wild animals, service dogs and dogs of fighting breeds, etc., which creates an increased danger for the person who carries out this activity and other persons." To supplement the provisions of Art. 1187 of the Civil Code of Ukraine with such a Note:</p> <p>"Pathogenic biological agents (pathogens) are microorganisms, viruses, protein-like infectious parts (prions), of biological origin (toxins) and other biological agents, including those created as a result of genetic manipulation, use of synthetic biology and other artificial activities that can cause pathological process in humans, animals or plants, as well as biological materials that may contain processed pathogens"</p>
Criminal liability	<p>To put the wording of part 1 of Art. 130 of the Criminal Code of Ukraine in the way as follows: "Conscious putting another person at risk of virus infection with human immunodeficiency virus or other incurable infectious disease or <i>other particularly dangerous infectious disease</i> that is dangerous to human life." Also, it is necessary to supplement the provisions of Art. 130 of the Criminal Code of Ukraine with part 5 (especially qualified composition) with such wording: "Part. 5 <i>The actions provided for in part 1 of this Article, which have led to the pandemic spread of an incurable infectious disease or other particularly dangerous infectious disease.</i>"</p> <p>To state the disposition of part 1 of Art. 142 of the Criminal Code of Ukraine in the following wording: "1. illegal conduct of medical and biological, <i>research and therapeutic experiments on humans</i>, psychological or other experiments on humans, if it endangered the life or health of the participant of the experiment <i>or other persons.</i>"</p> <p>To make changes and supplements to the structure of part 1 of Art. 362 of the Criminal Code of Ukraine (violation of the rules of handling microbiological or other biological agents or toxins), using the wording as follows: "1. Violation of the rules of storage, use, accounting, transportation of microbiological or other <i>pathogenic and opportunistic agents (microorganisms), genetically modified</i> organisms and substances or toxins, other rules of handling with them, if it has created a threat of death or other serious consequences or harmed the health of the victim."</p> <p>To clarify the body of the crime specified in Art. 258 of the Criminal Code of Ukraine (Terrorist act) in part "... <i>other actions that endangered human life or health...</i>", adding also <i>the spread of infectious diseases</i> to the interpretation of such 'other actions'.</p>
Administrative liability	<p>Changes and supplements to the provisions of Art. 90 of the Code of Administrative Offenses, putting the wording of parts 1 and 2 respectively as follows: "Failure to comply with rules and regulations in the process of creating new strains of microorganisms, biologically active substances, <i>pathogenic and opportunistic agents, genetically modified organisms</i> and other products of biotechnology..." and "Failure to comply with rules and norms of ecological safety in the process of production, storage, transportation, use, neutralization, liquidation, disposal of microorganisms, biologically active substances, <i>pathogenic and opportunistic agents, genetically modified</i> organisms and other products of biotechnology".</p>
Disciplinary liability	<p>Provisions on disciplinary liability should be an integral part of employment contracts, contracts concluded in the course of biohazardous activities (often related to compliance with laboratory safety requirements)</p>

Source: The author's development

When it comes to the Note to Art. 1187 of the Civil Code of Ukraine we can offer the definition as follows: "pathogenic biological agents (pathogens) are microorganisms, viruses, protein-like infectious parts (prions) of biological origin (toxins) and other biological agents, including those created as a result of genetic manipulation, application of synthetic biology and other artificial activities that can cause a pathological process in humans, animals or plants, as well as biological materials that may contain processed pathogens."

When it comes to improvement of the criminal law, first of all, the provisions of Art. 130 of the Criminal Code of Ukraine "Infecting with human immunodeficiency virus or other incurable infectious disease" are worth attention. Disposition of part 1 of Art. 130 of the Criminal Code of Ukraine provides for the imposing liability for "Conscious putting another person at risk of infecting the human with an immunodeficiency virus or other incurable infectious disease that is dangerous to human life." We find it necessary to supplement the provisions of this article with a reference to "another particularly dangerous infectious disease". This is why we suggest stating the title of the article in the following way: "Infecting with a human immunodeficiency virus or other incurable infectious disease or other particularly dangerous infectious disease." Based on the above it makes sense to word part 1 of Art. 130 as follows: "Consciously putting another person at risk of virus infection with a human immunodeficiency virus or another incurable infectious disease or *other particularly dangerous infectious disease* that is life-threatening." Also, it is necessary to supplement the provisions of Art. 130 of the Criminal Code of Ukraine with part 5 (especially qualified composition) with such wording: "part 5 *The actions provided for in part 1 of this Article, which have led to the pandemic spread of an incurable infectious disease or other particularly dangerous infectious disease.*"

We also emphasize that the ideology of counteracting the spread of the negative impact of the results of biologically dangerous activities requires a revision of certain dispositions of norms that provided for incurrance of criminal liability in case of individual harm in the context of the likelihood of collective negative consequences.

In particular, we are talking about the structure of the disposition of Art. 142 "Illegal conduct of experiments on the human", which provided for liability for illegal conduct of medical, biological, psychological or other experiments on the human, if it endangered their life or health (of this particular person). At the same time, certain medical and biological studies may pose a threat not only to a specific participant in such a research but also to other persons (including the personnel conducting it). The Bases of the legislation of Ukraine about health care, Art. 45 is devoted to conducting medical and biological experiments on humans. According to it, medical and biological experiments on humans are allowed for socially useful purposes provided that their scientific validity and prevalence of possible success over the risk of serious consequences for health or life (extreme necessity), publicity of the experiment, full awareness and voluntary consent of the subject of such an experiment. The same article incorporates an important element of the legal regime of medical and biological experiments which is the ban to conduct it on sick people, prisoners or prisoners of war, as well as therapeutic experiments on people whose disease is not directly related to the purpose of the experiment. At the same time, along with the mentioned concept the legislator uses the terms "research experiment on humans" and "therapeutic experiment on humans" in the clauses on carrying out medical and biological experiments. The Bases of the legislation of Ukraine about health care, along with the provisions on the conduct of medical and experimental activities on humans, also incorporates clauses on using new methods of prevention, diagnosis, treatment and drugs (Article 44 of the Fundamentals) in medical practice. According

to the logic of the legislator, such activities are considered within a different legal regime or dimension as compared to medical and biological experimental activities.

Ensuring both individual and collective interests enables us to propose the disposition of part 1 of Art. 142 of the Criminal Code of Ukraine with the following wording: "1. illegal conduct of medical and biological, *research and therapeutic experiments on humans*, psychological or other experiments on the human, if it endangered the experiment participant's life or health or that of other persons."

Discussion. As a result, it is necessary to make changes and supplements to the part 1 of Art. 362 of the Criminal Code of Ukraine (violation of the rules of handling microbiological or other biological agents or toxins), should be revised as follows: "1. Violation of the rules of storage, use, accounting, transportation of microbiological or other *pathogenic and opportunistic agents (microorganisms)*, *genetically modified organisms* and substances or toxins, other rules of dealing with them, if it has created a threat of death or other serious consequences or harmed the health of the victim."

It is also necessary to clarify the body of the crime specified in Art. 258 of the Criminal Code of Ukraine (Terrorist act) in terms of "... *other actions that endangered human life or health...*", adding also *the spread of infectious diseases* to the interpretation of such 'other actions'.

In terms of improving the provisions of administrative tort law the need to change and supplement the provisions of Art. 90 of the Code of Administrative Offenses (failure to comply with rules and regulations in the process of creation, production, storage, transportation, use, disposal, neutralization, disposal of microorganisms, biologically active substances and other products of biotechnology) draws attention. We suggest the wording of parts 1 and 2 respectively be as follows: "Failure to comply with the rules and norms in the process of creating new strains of microorganisms, biologically active substances, *pathogenic and opportunistic agents, genetically modified organisms* and other products of biotechnology..." and "Failure to comply with the rules and norms of ecological safety in the production, storage, transportation, use, disposal, neutralization, disposal of microorganisms, biologically active substances, *pathogenic and opportunistic agents, genetically modified organisms* and other products of biotechnology."

In the context of improving disciplinary liability in the field of work related to biohazardous substances and materials, it is necessary to develop unified safety rules for these types of work and empower the relevant bodies of state control and supervision over labour protection to implement such measures in relation to scientific research, laboratory and production entities whose activities are connected with potentially dangerous biological activities.

Conclusions. Summarizing the issue of improving the regulation of legal liability as a tool for public administration in the field of biological security of Ukraine, we have to draw attention to the following important statements.

1. Legal liability is an important means of ensuring biological safety. Liability is an effective tool for legal influence on public relations to ensure biological safety.

2. From our point of view, the functions of legal liability in the field of ensuring biological safety should be as follows: preventive which boils down to preventing

new offenses, precautions; penalty which boils down to punishing the guilty person through imposing measures of negative consequences of a personal, property or organizational nature (material fines, prohibitions on conducting research or carrying out production) to him; restorative, which aims to restore illegally violated property or personal rights, compensation for material or moral damage, losses (in case of socially negative consequences).

3. Improving the mechanism of legal liability for biological safety involves updating the legislation on largely all types of liability known in modern legal theory: in the case of compensation for material and moral damage, it is a question of civil liability; when applying measures of influence of criminal and legal character it is criminal liability (it can concern both legal entities and physical persons at the same time); in the case of less social harm of the offense it is administrative liability, and in the case of violations of labour duties it is disciplinary liability.

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