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LEGAL REGULATION OF BIOSAFETY IN UKRAINE

At the present stage of development of the Ukrainian society, there is a growing negative influence of biological factors on the population and potential for biological threats related to such factors as:

- the development of modern biotechnologies, the emergence of synthetic biology, manifestations of bioterrorism;
- the absence of clear rules of conduct necessary for activities related to genetic engineering and hazardous biological agents.

This topic is relevant due to the fact that one of the main directions of the state policy at the present stage of development of the Ukrainian society is the realization of citizens' rights as set forth in the Constitution of Ukraine and other statutory instruments¹.

The scientific and theoretical background of the legislation issues concerning administrative and legal regulation includes general theoretical papers of such scholars as V. Averianov, Yu. Bytiak and L. Koval, who focus on the administrative law and other areas of law; yet their academic papers, are dedicated to the issue of administrative and legal regulation in general. Certain aspects of the issue of administrative and legal regulation in the research area are addressed in the academic papers of A. Berlach, N. Bondarchuk, L. Vasylenko, V. Kurylo and N. Frolova. Certain issues are the subject of the academic research conducted by such scholars as Yu. Kosenko, V. Lukianchuk and I. Lukianchuk.

Thus, the said issue is important and relevant as it has not been examined properly.

The term "biosafety" is defined in the Law of Ukraine "On State System of Biosafety in the Process of Production, Testing, Transportation and Management of Genetically Modified Organisms" as "the state of the human environment where there is no negative impact of its factors (biological, chemical, physical) on the biological structure and function of the human person in the present or future generations as well as no irreversible negative impact on biological objects of the natural environment (biosphere) and agricultural plants and animals"².

The existence of a significant number of high-risk objects with exhausted technical and technological resources as well as the existence of biological centers with high concentrations of pathogenic organisms (that may cause severely hazardous infectious diseases) increase a risk of emergencies, creates a real threat to the living conditions of the population, the future social and economic development and national security of Ukraine.

The main objectives of the legislation in the sphere of biosafety in Ukraine are as follows:

- regulation of social relations which occur during any activities in the research area;
- development of legal principles of the system of administrative and legal regulation of countermeasures against negative biological factors and biological hazards;
- establishment of laws, obligations and principles of the legal liability of bodies of state power and bodies of local self-government, institutions, enterprises and organizations, corporate officers and public officials, citizens of Ukraine, foreigners and persons without citizenship as regards their activities related to the compliance with the rules of conduct when performing genetic engineering activities and working with hazardous biological agents;
- involvement of citizens and associations in the formation of state policy in the research area;
- determination of fundamental principles for protection of the population during manifestations of biological threats;
- future development of the international cooperation³.

Negative aspects of the current legislation are the reason why actions of the executive authorities are not regulated properly and they enact a number of controversial and non-constitutional statutory instruments which make the imperfect legal regulation of different spheres of life even more complicated⁴.

The mechanism of legal regulation in the sphere of biosafety consists of the following elements:

- norms of law – compulsory rules of conduct established to regulate social relations;
- legal relationship – voluntary social relations that occur by virtue of the norms of law in the research area;
- realization of the norms of law – the process of actual realization of certain instructions set in the norms of law in relation to particular subjects⁵.

In Ukraine, the state regulation in the sphere of biosafety is carried out by the authorities of general competence as well as by the authorities of special competence.

The legislative, executive and judicial authorities exercise their powers within limits specified in the Constitution and the laws of Ukraine (Part 2, Article 6 of the Constitution of Ukraine)⁶.

Article 19 of the Constitution of Ukraine reads that bodies of state power and bodies of local self-government are obliged to act only on the grounds, within the limits of authority, and in the manner envisaged by the Constitution and the laws of Ukraine⁷.

The issues that concern dealing with genetically modified organisms, state support of research projects in the sphere of genetic engineering alongside with scientific and practical research in the sphere of biological and genetic safety, and mechanisms of safe practical application of genetically modified organisms are not sufficiently regulated. In fact, the government does not coordinate the activities of central executive bodies in dealing with genetically modified organisms and genetic engineering.

It is necessary to improve the program for biosafety and prevention of biological terrorism as well as the national system of countermeasures against biohazards, particularly in terms of creation of automated and integrated databases of potential biological and chemical hazards.

The laboratories that work with extremely hazardous pathogens of infectious diseases and store collections of such pathogens require better funding and maintenance support. The staff's professional skills deteriorate, and there occur violations of anti-epidemic regime and sanitary standards during the production, processing, circulation and utilization of biological agents.

Such factors as the reduced state control and supervision in the sphere of biological safety, particularly in the process of changing ownership of high-risk objects, the imperfect organization of protection of pathogenic microorganisms and strains of hazardous and extremely hazardous infectious diseases, that are kept in microbiological laboratories, increase risks of an unauthorized access or release of pathogenic microorganisms into the environment, which can lead to large-scale outbreaks of infectious diseases⁸.

According to Article 7 of the Law of Ukraine "On the Fundamentals of National Security of Ukraine", the following factors constitute a menace to the national interests and security of Ukraine:

- the uncontrolled import into Ukraine of ecologically dangerous technologies, substances, materials, transgenic plants and pathogenic agents, dangerous to humans, animals, plants and organisms;
- growing risks of emergency situations of anthropogenic and natural character;
- the threat of biological terrorism;
- the intensification of the impact of harmful genetic effects in populations of living organisms, particularly in terms of genetically modified organisms and biotechnologies;
- ecologically unreasonable application of genetically modified plants, organisms, substances and related products.

One of the most important means of realization of the state biosafety policy is the development of efficient laws and regulations that can ensure the rule of biosafety law. The rule of biosafety law cannot exist without a well-functioning system of legal liability⁹.

The liability for violation of the biosafety laws can be classified in several different ways. For instance, there are positive and retrospective liabilities¹⁰.

The legal liability for violation of the biosafety laws performs the following functions:

1. Enforcement function provides security and maintenance of the proper biosafety conditions.
2. Preventive function lies in the prevention of new violations and precautionary measures.
3. Compensatory function is aimed at the reparation and compensation of damages.
4. Promotional function helps to promote the implementation of and compliance with the statutory requirements by all citizens and legal entities, regardless of their form of ownership.
5. Educational function is a means to educate people, to enhance personal culture and to create confidence in the stability of current public order as well as in the protection of their rights and interests.
6. Punitive function lies in the restriction of rights and freedoms of the offender or in the imposition of additional obligations on him; it leads to negative consequences¹¹.

Furthermore, Article 22 of the Law of Ukraine "On Removal from Circulation, Processing, Utilization, Destruction or Further Use of Products of Poor Quality or Unsafe Products" states that persons who are guilty of violations of laws concerning the removal from circulation, processing, utilization, destruction or further use of products of poor quality or unsafe products shall bear disciplinary, administrative, civil or criminal liability in accordance with the law.

Article 64 of the Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products" establishes liability of market operators for legislation violations and noncompliance with certain quality standards of food products, namely for:

- 1) noncompliance with legal requirements for safety and certain quality standards of food products regarding hygienic requirements for foodstuffs at all stages of production and circulation, including admission of persons, who have contraindications for work with foodstuffs and whose presence may lead to the production and/or circulation of dangerous foodstuffs, to the process of production and/or circulation of foodstuffs;
- 2) producing or storing foodstuffs in facilities that are not registered in accordance with the law;
- 3) producing or storing foodstuffs without an operation permit, if it is statutory required to obtain one;
- 4) noncompliance with an obligation to implement permanent procedures based on the principles of the hazard analysis and critical control point system at production facilities;
- 5) realization of mislabeled foodstuffs;
- 6) violation of traceability requirements;
- 7) noncompliance with an obligation to recall dangerous foodstuffs or remove them from circulation;
- 8) use of unregistered auxiliary processing materials and unregistered materials which contact with foodstuffs;
- 9) realization of unregistered objects of sanitary measures;

- 10) circulation of foodstuffs unsuitable for consumption;
- 11) violations of parameters' values for safety of objects of sanitary measures set forth in the laws on safety and certain quality standards of food products;
- 12) non-fulfillment of legal requirements (decisions) made by officials of the competent authority to remedy violations of laws about safety and certain quality standards of food products within the terms coordinated with the competent authority;
- 13) non-fulfillment of legal requirements (decisions) made by officials of the competent authority to destroy food products and auxiliary processing materials that are dangerous for human consumption or other use;
- 14) concealment (failure to provide) or refusal to provide information, and provision of inaccurate information in response to a request of officials of the competent authority;
- 15) refusal to allow officials of the competent authority to conduct the state control.

Article 166-22 of the Code of Ukraine on Administrative Offenses envisages administrative liability for legislation violations and noncompliance with certain quality standards of food products.

Officials of the executive bodies bear liability in accordance with the law as regards removal of low-quality and dangerous products from circulation and their further use.

The main statutory instruments in the sphere of circulation of animal source foods are the Constitution of Ukraine, the Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products", the Law of Ukraine "On State Regulation of Import of Agricultural Products", the Law of Ukraine "On State System of Biosafety in the Process of Production, Testing, Transportation and Management of Genetically Modified Organisms", the Law of Ukraine "On Protection of Consumer Rights", the Law of Ukraine "On Veterinary Medicine", the Law of Ukraine "On Sanitary and Epidemiological Provision of Population", the Law of Ukraine "On Protection of Population against Infectious Diseases" and the Law of Ukraine "On Removal from Circulation, Processing, Utilization, Destruction or Further Use of Products of Poor Quality or Unsafe Products".

The provisions of Article 35 of the Law of Ukraine "On Safety and Quality of Food Products" which were put off in 2010 and which prohibited to sell raw milk, homemade cheese, whole carcasses and parts of even-toed ungulates and other ungulates of home slaughter at agro food markets, came into force on 01 January 2015.

Thus, from 01 January 2015 up to the date when the Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products" came into force, that is, during almost 10 months, it was prohibited to sell livestock of home slaughter, milk and homemade cheese at agro food markets.

Meanwhile, the Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products", that came into force on 20 September 2015, regulates issues concerning the sale of raw milk, homemade cheese, whole carcasses and parts of even-toed ungulates and other ungulates of home slaughter at agro food markets, taking into account the provisions of the European law.

Article 36 of the Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products" (as amended) reads that "Whole carcasses and parts of even-toed ungulates and other ungulates, poultry, rabbits and small wild animals, fish, honey, eggs, raw milk, homemade cheese and plant products can be sold at agro food markets if their suitability for consumption is verified due to results of the examination carried out by a certified laboratory of the agro food market and a state inspector who works at the same market. Non-domestic food products accompanied by documents that provide their traceability are not subject to the said examination".

The requirement to verify the suitability of foodstuffs intended for sale at agro food markets by obtaining results of the examination carried out by a certified laboratory will make it possible to secure consumers against products of poor quality and to comply with the Ukraine-EU Association Agreement.

Article 35 of the Law of Ukraine "On Safety and Quality of Food Products" that came into force on 01 January 2015 is presented in the amended Article 36 of the new Law of Ukraine "On Basic Principles and Requirements for Safety and Quality of Food Products".

That means of solving the problem managed to adapt provisions of the Ukrainian statutory instruments to the requirements of the European Union law, which made it possible to avoid social tension and protest moods among private households.

All the above leads to the conclusion that the current condition of biosafety does not meet the national interests and requirements of the national security of Ukraine; it does not provide effective countermeasures against biohazards that may endanger the population, agriculture, environment, etc.

The high-priority objectives of the executive authorities include taking systemic measures for effective organization of the state biosafety system, countering manifestations of bioterrorism, protecting the population against uncontrolled and illegal dissemination of genetically modified organisms and preserving the healthy and safe environment.

Countering negative impact of biological factors and hazards is complicated by the imperfection of corresponding statutory instruments in Ukraine and absence of a system of standards or certified research methods in this sphere, etc.

¹ Німко О. Б. Державне регулювання забезпечення соціальним житлом: правові та організаційні засади / О. Б. Німко // Техніка и технология. Современные тенденции в науке и образовании / Inżynieria i technologia. Współczesne tendencje w nauce i edukacji (29.01.2013 – 31.01.2013) – Kraków, 2013. – С. 5–8.

² Supreme Council of Ukraine (2015) “*On State System of Biosafety in the Process of Production, Testing, Transportation and Management of Genetically Modified Organisms*” [“Pro derzhavnu systemu biobezpeky pry stvorenni, vyprovuvanni, transportuvanni ta vykorystanni henetychno modyfikovanykh orhanizmiv”], available at: <http://zakon0.rada.gov.ua/laws/show/ru/1103-16>

³ Німко О. Б. Міжнародне співробітництво та адміністративно-правове регулювання атомної енергетики в Україні та світі / О. Б. Німко // Часопис Київського університету права : український науково-теоретичний часопис. – 2016. – № 2. – С. 276–281.

⁴ Василенко Л. П. Правові проблеми діяльності органів виконавчої влади з питань екології: монографія / Л. П. Василенко. – Житомир: Житомирський національний агроєкологічний університет, 2014. – 167 с.

⁵ Німко О. Б. Механізм правового регулювання організації та проведення земельних аукціонів в Україні / О. Б. Німко // Підприємництво, господарство і право. – 2009. – № 10. – С. 130–132.

⁶ Німко О. Б. Проблемні питання законодавства, що регулює встановлення внесків загальнообов’язкового державного соціального пенсійного страхування фізичними особами – суб’єктами підприємницької діяльності, які обрали особливий спосіб оподаткування / О. Б. Німко // Наукові праці Національного авіаційного університету. Серія : Юридичний вісник «Повітряне і космічне право». – № 4 (17). – 2010. – С. 97–101.

⁷ Німко О. Б. Правові засади державного регулювання здійснення оціночної діяльності для цілей оподаткування / О. Б. Німко // Ученые записки Таврического национального университета им. В. И. Вернадского. Научный журнал. Серия: Юридические науки. – № 4. – Симферополь, 2012. – С. 292–295.

⁸ National Security and Defense Council of Ukraine (2009) “*On Biological Safety of Ukraine*”, available at: <http://zakon0.rada.gov.ua/laws/show/ru/n0003525-09>

⁹ Німко О. Б. Адміністративна відповідальність у сфері охорони навколишнього природного середовища / О. Б. Німко // Наукові читання – 2013 : наук.-теорет. зб. / ЖНАЕУ. – Житомир : ЖНАЕУ, 2013. – Т. 1. – С. 185–187.

¹⁰ Бондарчук Н. В. Поняття, ознаки та види юридичної відповідальності за порушення природоресурсного законодавства // Сучасні тенденції розбудови правової держави в Україні та світі : Зб. наук. статей за матеріалами II Міжнар. наук.-практ. конф. (Житомир, 10 квітня 2014 р.) / Мін-во аграрної політики та прод-ва України; Жит. нац. агроєкологічний ун-т. – Ж.: ЖНАЕУ, 2014 – 356 с. – С. 255–257. – С. 256.

¹¹ Юридична відповідальність за порушення природоресурсного законодавства України : монографія / О. Б. Німко, Н. В. Бондарчук, Р. Д. Ляшенко [та ін.] ; за заг. ред. О. Б. Німко. – Житомир : ЖНАЕУ, 2016. – 208 с.

Резюме

Німко О. Правове регулювання біологічної безпеки в Україні.

В статті досліджено правове регулювання біологічної безпеки в Україні. Наведено фактори, які впливають на виникнення загроз біологічного походження, окреслено основні завдання законодавства у сфері біологічної безпеки в Україні, механізм правового регулювання у сфері біобезпеки, його недоліки. Досліджено види юридичної відповідальності у сфері біобезпеки.

Ключові слова: правове регулювання біологічної безпеки, біологічна безпека, загрози біологічного походження, юридична відповідальності у сфері біобезпеки.

Резюме

Німко О. Правовое регулирование биологической безопасности в Украине.

В статье исследовано правовое регулирование биологической безопасности в Украине. Приведены факторы, влияющие на возникновение угроз биологического происхождения, определены основные задачи законодательства в сфере биологической безопасности в Украине, механизм правового регулирования в сфере биобезопасности, его недостатки. Исследованы виды юридической ответственности в сфере биобезопасности.

Ключевые слова: правовое регулирование биологической безопасности, биологическая безопасность, угрозы биологического происхождения, юридическая ответственность в сфере биобезопасности.

Summary

Nimko O. Legal regulation of biosafety in Ukraine.

The article deals with the legal regulation of biosafety in Ukraine. It covers the factors that influence the emergence of biological hazards and presents the main objectives of the legislation in the sphere of biosafety in Ukraine, the mechanism of legal regulation in the sphere of biosafety and its shortcomings. It examines the types of legal liability in the sphere of biosafety.

Key words: legal regulation of biosafety in Ukraine, biological safety, biological hazards, legal liability in the sphere of biosafety.