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CONCERNING THE FOOD SAFETY MANAGEMENT IN UKRAINE IN ACCORDANCE WITH THE REQUIREMENTS OF BIOLOGICAL SAFETY IN EU

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РЕЗЮМЕ. *The main ways and tendencies of formation and development of the regulatory and legal base of Ukraine in the sphere of ensuring biological safety in the creation, storage and delivery of food products to the consumer are investigated in the period of intensification of the European integration processes that are successfully developing nowadays.*
Key words: biological safety, food, the threat of biological safety (bio-threat), a dangerous biological factor, biological terrorism.

Formulation of the research problem. Threatening trends of declining average life span in Ukraine, increased morbidity caused by using water and food of poor quality, remain urgent and require substantial research of social relations in the field of biological security of Ukraine, as well as developing on this basis effective means of legal regulation.

In addition, the rapid development of biotechnology, the introduction of its achievements in the industry, notably food, pharmaceutical and cosmetic caused humanity to face with new, previously unprecedented opportunities and global threats. Thus, creating organisms with new combinations of genetic material and, therefore, new qualitative properties (such as high productivity, increased content of nutrients, resistance to adverse environmental influences) offers the potential to solve the global food problem, price reduction and efficiency of drugs produced from biological raw materials, and so on. However, issues on the safety of genetically modified organisms (GMOs) and products derived from them remains unresolved. Some experts point to the risks of uncontrolled transfer of alien genes in natural organisms, unpredictable formation of toxic, allergenic or other harmful to human health substances, the lack of reliable methods to currently control the safety of GMOs, as well as low awareness about their impact on the environment [1]. In addition to above-mentioned, in the present context of globalization, even terrorism has the ability to influence the international community in a new way, through agriculture using deliberately-created products by trans-genesis. As Josling et al., [2003] points out: "... after the terrorist attacks of September 11, 2001, aimed at the World Trade Center and the Pentagon ... biological safety moved into a new dimension and the products transported across the border are subject to more careful review" [2]. This possibility lies in the danger of the food derived from genetically modified organisms which have been provided with unusual opportunities that are enclosed in the ability to synthesize certain drugs, vaccines, growth hormones, clotting factors, human antibodies, contraceptive proteins that cause abortion and substances that suppress a person's immune system. The activity of developed countries in carrying out biotechnological military-aimed research draws attention too. For example, each year, for medical defense against chemical and biological weapons the U.S. government spends 90-140 million dollars, of which about a third of the funds are spent on the development of vaccines against infectious diseases. However, American experts note that there is no significant difference between the research in creating genetically engineered vaccines and new potential agents of biological weapons [3]. Thus, there is a danger of using modern biotechnology achievements in armed conflicts, hostilities or terrorist acts.

One of the main known methods of combat employment of biological weapons is direct contamination by pathogens or their toxins food or water by sabotage.

Given the above, the study of issues related to the legal regulation of the creation, storage and delivery of food to the consumer in order to develop a reliable system of protection against biological threats is extremely important.

Analysis of the recent research and publications. Yu. Bobylov, A.Vorobiev, A. Golovko, S. Komisarenko, M. Liapin, M. Paltsev, V. Sergiev dedicated their scientific works to particular aspects of theoretical and practical handling a problem of bio-safety and bio-threats [4].

V. Andreytsev, H. Baliuk, N. Barbashova, L. Bondar, P. Vahanov, H. Vinter, M. Kopylov, L. Kremer, L. Strutynska-Struk, M. Frolov studied issues of environmental protection regulation and the protection of human beings in biotech activities [5].

I. Bakai, T. Kovalchuk, T. Lozynska, O. Piddubnyi considered some aspects of legal regulation related to ensuring the quality and safety of food. However, the issue of food safety standardization as a component of bio-safety has not been comprehensively investigated in Ukraine [6].

The aim of the article is to determine on the basis of foreign experience basic ways and tendencies of formation and development of the legal framework of Ukraine in the field of biological safety in the creation, storage and delivery of food to the consumer.

The body. The object of jural relations in biosafety is the full-fledged functioning of the human body as a whole and all its organs and systems, as well as saving the human genome — the integrity of genetic information. Thus it comes about preventing genetic mutations, diseases, functional disorders, premature death. The implementation of this essential requirement is achieved by neutralizing existing hazardous biological factors. These factors include natural (viruses, bacteria, rickettsia, protozoa, fungi, worms, macro-organisms and other pathogenic organisms, their metabolic products — toxins, pathogenic proteins — prions) and artificial (genetically modified organisms, biotechnology and biochemistry products etc.).

From the environment through foodstuff the human body can get up to 70 % of toxins of different nature. These substances are accumulated in the food both in the biological chain providing exchange between living organisms and air, water and soil and the food chain, including all stages of foodstuffs and food production as well as their preservation, packaging and labeling. In this regard the safety and quality of foodstuffs and food products is one of the main problems that determines the health of human society and the preservation of its gene pool.

Thus, food safety is one of the important components of bio-security.

The Law of Ukraine "On the Safety and Quality of Food Products" in Article first determines that an item of food (food) — is any substance or product (raw, including agricultural products, raw, semi-finished or finished) is intended for human consumption. This food safety is defined as a state of food as a result of the production and circulation, which shall be subject to the requirements established by sanitary measures and / or technical regulations , and provides assurance that an item of food does not harm people (consumers), if consumed on purpose [7].

Thus, biological safety is ensured, including through the establishment of effective control over the quality of food that rules out any threat to life and health for consumers of such products [6].

According to Taras Kovalchuk, food safety is such a state of social relations in which a set of state-legal, organizational, scientific and technical as well as other resources is aimed at protecting human life and health from hazardous foodstuff through compliance by legal and physical persons with standards of admissible content of harmful substances in these products at the stages of their production, processing, storage, transportation and sale [8].

Implementation of food safety management in connection with the dynamic growth of varieties of biological threats requires constant harmonization of the laws of the world leading countries.

The HACCP concept (Hazard Analysis and Critical Control Points) forms the basis of the standards of food safety management — a system for the identification, evaluation, analysis and control of risks that are important for food safety. HACCP is part of enterprise management system, based on existing programs of compulsory previous measures — GHP (Good Hygiene Practice), GMP (Good Manufacturing Practice) and sanitation standard operating procedures SSOP (Sanitation Standard Operating Procedures), which ensure compliance with sanitary requirements for food business of the appropri-

ate profile, equipment, buildings and structures. GHP and GMP are called HACCP accompanying programs or prerequisite programs, since they are carried out long before the main production process. The purpose of GMP/GHP is to minimize the microbiological, physical and chemical risks in the production of food.

The concept of HACCP is applied internationally as a reliable means of consumer protection from the dangers accompanying foodstuff. HACCP system and guidelines to its application are set in the standard of Codex Alimentarius Commission CAC/RCP 1-1969 (Rev. 4-2003) "Recommended International Code of Practice Food Hygiene".

Trends in global economic policy forced Ukraine to make fundamental decisions on the harmonization of legislation in the area of food production and adaptation of national food safety standards with international requirements. Application of HACCP system in accordance with the national legislation is mandatory for all the enterprises involved in the manufacture or trade turnover of the food.

Compared with other systems HACCP has the following advantages:

— enables enterprises to change the approach to quality assurance and food safety from retrospective on preventative;
— enables responsibility for ensuring food safety;
— provides consumers with documented food safety;
— provides a systematic approach that encompasses all the characteristics of food safety from raw material to finished product;
— enables economical use of resources for food safety management;
— provides additional opportunities when integrating with ISO 9000;
— places responsibility for the conditions that guarantee the quality of products directly on the manufacturer;
— reduces barriers to international trade.

Development of technology, cultivation into open systems (which, unlike the closed ones admit GMOs contacts with the environment) as well as appearance on the market of foodstuff produced using GM ingredients, caused an urgent need for the introduction of such activities in the legal framework in order to control and minimize the potential hazards.

The concept of cautious attitude towards GMOs and, consequently, a clear control over their creation and implementation into production and circulation prevails in the European law.

The biosafety policy is an important component of EU policy in the field of environmental, health and consumer protection. Today we can say that the European standards in this area are the highest in the world.

The following EU regulations are important for GMOs management: № 258/97 on novel food ingredients and new products [9], № 1829/2003 on genetically modified food and feed [10], № 1830/ 2003 on monitoring and labeling genetically modified organisms and foodstuff produced from genetically modified organisms and amendments to Directive 2001/18/EU [11], № 1946/ 2003 on trans-boundary movements of genetically modified organisms [12], № 641 /2004 on the admission of new genetically modified food and feed, notification on existing products and technologically provided or accidental use of genetically modified material , found at the positive risk assessment [13], № 1981/ 2006 on detailed rules for the application of Art. 32 EU Regulation № 1829/ 2003 on Community laboratories for testing genetically modified organisms [14], as well as other acts taken for their development.

Procedure on admission of GMOs use in the EU is unified, regardless of GM products type (food or feed). Scientific safety assessment is carried out by the European Food Safety Authority (EFSA) and its independent expert bodies on the basis of manufacturer's applications and analyses, as well as necessary examination, the nature of which depends on each individual case. The decision to grant permission for the release of GMOs into the environment and placing them on the market is made by the European Commission and the Standing Committee of Foodstuffs, which is represented by all member-states. A permit is limited to up to ten years with possibility of extension. Directive 2001/18/EU, amended by EU Regulation № 1830/2003 also sets out further GMOs tracing after obtaining permission for their production and use in the EU, thus provides monitoring of GMOs impacts on human health and the environment, control over the accuracy of labeling and in case of products adverse effects it permits their removal from circulation. Content of more than 0,9% GM ingredients is the basis for mandatory instructions on the label concerning the presence of GM ingredients in the product. Indication of the GMO should con-

tain both packaged goods and on unpackaged products directly next to the place of sale (showcases, counters, etc.). Before 2004 GM products had always been marked only if GMOs could be detected in the final product as in the result of recycling it often becomes impossible. The current European regulation foresees that the information on the use of GMOs should be passed through all stages of production of the product. It should also be noted that the procedure for granting permission is transparent. All documents relevant to the access are available to the general public, except those which may be regarded as a producer's trade secret. Allowed GM foodstuffs are entered in the register, information from which is also open to review.

Lack of scientific knowledge on the possible effects of GMOs on human health and the environment leads to the need for a strict legislative framework on the handling of GMOs and, above all, control over their use. Therefore, we believe that the only acceptable way for Ukraine is to take into account the EU progress in creating national legislation on biosafety.

In 1998, by the resolution of Cabinet of Ministers of Ukraine, the National Commission of Ukraine on Food of the Codex Alimentarius was created, which was renamed in 2006 as the National Commission of Ukraine for the Codex Alimentarius. It operates on the basis of Article 8 of the Law of Ukraine "On the safety and quality of food" and the Cabinet of Ministers of Ukraine resolution dated July 3, 2006 № 903 "Issues of the National Commission of Ukraine for the Codex Alimentarius". The main objectives of the National Commission is to analyze the international and national legislation on safety and quality of food and elaborate their improvement, harmonize domestic legislation with international, promote the introduction of new technologies and international standards, national technical regulations and international sanitary measures in the sphere of food production as well as new methods of research.

With the advent of new technologies, global environmental deterioration on the planet, the current system of food security requires constant upgrading.

In order to implement the relevant international and European rules on food safety in Ukraine, the following regulations that govern the factors affecting the quality and safety of food products are developed: industrial, administrative and ancillary buildings (ventilation, heating, lighting, water, sewage, waste water, sanitation etc.) staff (personal hygiene, clothing, etc.), equipment, utensils, containers, equipment (construction, placement, start-up and operation, sanitary processing and disinfection), organization and management of the process, documentation, monitoring the production processes, quality control of finished products, transportation of finished goods.

Thus, in our country the national standard DSTU 4161-2003 "Systems of food safety management. Requirements" has been valid since July 1, 2003 and since August 1, 2007 the national standard DSTU ISO 22000:2007 (identical to the international standard ISO 22000:2005) has come into force. Due to certain difficulties in meeting requirements of the standard DSTU ISO 22000 by Ukrainian enterprises (e.g. leased rather than own production facilities) the two standards will operate collaterally for some period of time. The process of implementation of DSTU ISO 22000 for enterprises, which operate a system of food safety management according to DSTU ISO 4161-2003, will be easier than for companies that just begin this work, because both of these standards are based on HACCP principles and on the basis of system control.

Ukraine has a very serious export potential and it is not limited to crops, but also includes a complete set of all products produced in Ukraine. In this regard, the issue of quality and biosafety of food is a priority in the work of all state security structures.

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ДО ПИТАННЯ РЕГУЛЯЦІЇ ТА ВІДПОВІДНОСТІ БІОЛОГІЧНОЇ БЕЗПЕКИ ХАРЧОВИХ ПРОДУКТІВ В УКРАЇНІ ЗАСАДАМ ЄС

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***РЕЗЮМЕ**. У статті досліджено основні шляхи та тенденції формування і розвитку нормативно-правової бази України у сфері забезпечення біологічної безпеки при створенні, зберіганні та доставці до споживача харчових продуктів у період інтенсифікації європейських інтеграційних процесів, які в наш час стрімко розвиваються.*
Ключові слова: біологічна безпека, харчові продукти, загроза біологічній безпеці (біозагроза), небезпечний біологічний чинник, біологічний тероризм.

К ВОПРОСУ РЕГУЛЯЦИИ И СООТВЕТСТВИЯ БИОЛОГИЧЕСКОЙ БЕЗОПАСНОСТИ ПРОДУКТОВ ПИТАНИЯ В УКРАИНЕ ТРЕБОВАНИЯМ ЕС

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***РЕЗЮМЕ**. В статье исследованы основные пути и тенденции формирования и развития нормативно-правовой базы Украины в сфере обеспечения биологической безопасности при создании, хранении и доставке к потребителю пищевых продуктов в период интенсификации европейских интеграционных процессов, которые в наше время успешно развиваются.*
Ключевые слова: биологическая безопасность, пищевые продукты, угроза биологической безопасности (биоугроза), опасный биологический фактор, биологический терроризм.

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