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STATE CONTROL, MEDICAL-BIOLOGICAL, TECHNOLOGICAL ASSESSMENT OF GMO FOOD PRODUCTS

ДЕРЖАВНИЙ КОНТРОЛЬ, МЕДИКО-БІОЛОГІЧНА, ТЕХНОЛОГІЧНА ОЦІНКА ЗА ГМО ХАРЧОВИХ ПРОДУКТІВ

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Abstract. *For the production of food raw materials it is necessary to ensure state regulation and control in the field of GMO management, ensure measures to state support for genetic engineering, approve the procedure for state testing of GMOs in an open biosafety system and approve safety criteria for GMO handling in a closed system. Central executive bodies maintain state registers of GMOs and products produced with their use, place them on their own official websites and regularly publish them in the media. Examination of products from GM sources includes medical-biological and technological assessment. Medico-genetic assessment includes: assessment of the structure of recombinant DNA; assessment of regulatory sequences; study of the effects of expression of other genes; determination of HMD stability; environmental impact assessment. Medico-biological assessment includes: study of chemical composition (quality and safety indicators); assessment of biological value and digestibility in laboratory animals; toxicological examination on laboratory animals (not less than 5-6 months); assessment of allergenicity and mutagenicity; evaluation of immunomodulatory properties; study of the effect on reproductive function. Technological assessment includes: assessment of organoleptic and consumer properties; assessment of functional and technological parameters.*

Key words: *genetically modified organism (GMO), control, supervision, quality, safety, food, biosafety.*

Actuality of theme.

The twentieth century was characterized by outstanding achievements of scientific and technological progress that radically changed human life. These are, first of all, nuclear technology, electronic and the latest biotechnology. Currently, biotechnology in practice shows great success in agriculture: the introduction of new varieties of plants that are resistant to herbicides, insects, diseases, stress: the creation of new foods with specified properties; production of food and feed protein, veterinary drugs; breeding of highly productive animals and microorganisms with new and enhanced properties and characteristics [1,4].

The use of GMOs began with solving the problems of obtaining cheap and increasing the amount of protein products needed for human treatment. At present, the range of GMO use is too wide: providing humanity with food, preserving biodiversity, treating certain diseases, improving product quality, correcting environmental pollution, and so on. Therefore, state supervision and control over the observance of biological and genetic safety of agricultural plants, animals, food products in the creation, research and practical use of GMOs in open systems at enterprises, institutions and organizations of the agro-industrial complex, regardless of their subordination and ownership is very important. Ukraine [1, 2].

The aim of the work was to substantiate the importance of state control in the food industry of Ukraine with the use of genetically modified organisms.

Research results.

A genetically modified organism, a living modified organism (GMO), is any organism in which the genetic material has been altered by artificial methods of gene transfer that do not occur under natural conditions, namely:

- recombinant methods, which involve the formation of new combinations of genetic material by introducing nucleic acid molecules (produced in any way outside the body) into any virus, bacterial plasmid or other vector system and their inclusion in the host organism in which they are usually do not occur, but are capable of long-term reproduction;
- methods that involve the direct introduction into the body of hereditary material prepared externally, including micro- and macroinjections and microencapsulations;
- cell fusion (including protoplasm fusion) or hybridization methods, when living cells with new combinations of genetic material are formed by fusing two or more cells in a way that is not realized under natural circumstances.

Genetically modified sources are raw materials and food products (components) used by humans in natural or converted form, derived from GMOs or containing them in their composition.

Products obtained using GMOs are products, including food and feed, the production technology of which involves the use of GMOs at any stage.Problems of ensuring adequate safety from the negative effects of GMOs, as well as their transboundary movement, led to the development of the Cartagena Protocol on Biosafety under the Convention on Biological Diversity (1996). In 2002, Ukraine acceded to the Cartagena Protocol, which reaffirmed its position in support of coordinated measures to ensure an adequate level of protection in the safe transfer, handling, processing, transboundary movement and use of GMOs that can affect the conservation and sustainable use of biodiversity, taking into account risk to human health and unpredictable consequences for future generations.

The full implementation of Ukraine’s international obligations under the Cartagena Protocol requires a conceptual definition of the foundations of state policy in the field of GMO biosafety, as well as long-term mechanisms for its implementation.

The State Committee of Veterinary Medicine has developed a Resolution of the Cabinet of Ministers of Ukraine "On approval of the Procedure for state approbation

(testing) and state registration of feed sources, feed additives, premixes and veterinary drugs created on the basis of genetically modified organisms", 2007.

Importation into Ukraine of samples of veterinary drugs, premixes, feeds, feed additives created on the basis of GMOs is allowed provided that the information in the relevant documents and the mark "GMO" on the packaging in Ukrainian. Approbation will be carried out according to the methods of detection and identification of GMOs approved by the State Committee of Veterinary Medicine.

The Law of Ukraine "On the State Biosafety System in the Creation, Testing, Transportation and Use of Genetically Modified Organisms" [3,4] specifies the powers of the Cabinet of Ministers of Ukraine regarding:

- ensuring state regulation and control in the field of GMO management and genetic engineering activities;
- ensuring the implementation of measures for state support of genetic engineering activities;
- directing and coordinating the work of central executive bodies and other executive bodies in the field of GMO management and genetic engineering activities;
- organization of international cooperation in order to ensure the safe handling of GMOs and the development of scientific knowledge in this field;
- approval of the procedure for state registration of GMOs and products obtained with their use;
- approval of the procedure for import of GMO sources of food, feed and food products and feed produced from GMOs;
- approval of the procedure for granting a permit for the transit movement of GMOs through the territory of Ukraine;
- approval of the procedure for licensing genetic engineering activities in closed and open systems;
- approval of the procedure for state testing (testing) of GMOs in the open system and obtaining permission to conduct them;
- approval of safety criteria for GMO handling in a closed system.

Central executive bodies maintain state registers of GMOs and products produced with their use, place them on their own official websites and regularly publish them in the media. Products registered in the State Registers of GMOs: varieties of agricultural plants and animal breeds created on the basis of GMOs; plant protection products obtained using GMOs; GMO food sources, as well as food products, cosmetics, medicines that contain GMOs or obtained with their use; GMO feed sources, as well as feed additives and veterinary drugs that contain GMOs or are obtained using them. State registration takes place for a period of five years free of charge. The term of consideration of registration documents may not exceed 120 days from the date of their submission, including the terms of the relevant examinations. Industrial production and introduction of GMOs, as well as products produced with the use of GMOs, prior to their state registration is prohibited.

In November 2009, a meeting of the profile committee of the Verkhovna Rada of Ukraine on amendments to the Law of Ukraine "On the State Biosafety System in the Creation, Testing, Transportation and Use of Genetically Modified Organisms"

was approved. The purpose of this project is to define the powers of the State Committee of Veterinary Medicine regarding the registration of veterinary drugs, feeds and feed additives obtained using GMOs.

According to the EU Regulation 258/27 and the Directive of the European Parliament and the Council №1829 / 2003 of 22.09.2003 in Ukraine the Resolution of the Cabinet of Ministers of Ukraine № 985 "Issues of circulation of food containing GMOs" [4] was developed, which allows import and sale of food , which contain GMOs in quantities of more than 0.9%, only in the presence of proper labeling indicating the quality of the product. Adaptation of the legislation of Ukraine to the Legislation of the European Union is a priority component of the process of Ukraine's integration into the EU requirements.

According to Greenpeace research, a large number of world-renowned companies use genetically modified ingredients to produce their products: Nestle, Coca-Cola, Damon, Proster and Gamble Kellogg's, Unilever Unilever Heinz Foods Hershey's, McDonalds, Smilas, Cadbury, Mars, Pepsi Cola. On the basis of GM components the following food additives are made: riboflavin E 101, E 101 A; caramel E 150; xanthan E 415; lecithin E 322, E 153, E 160 d, E161 c, E 308 g, E 471, E 472f, E 473, E 475, E 476 b, E 477, E 479 a, E 570, E 572, E 573, E 620 – E 625 and others. [1,5].

Examination of products from GM sources includes medical-biological medical-biological and technological assessment. Medico-genetic assessment includes: assessment of the structure of recombinant DNA; assessment of regulatory sequences; study of the effects of expression of other genes; determination of HMD stability; environmental impact assessment. Medico-biological assessment includes: study of chemical composition (quality and safety indicators); assessment of biological value and digestibility in laboratory animals; toxicological examination on laboratory animals (not less than 5-6 months); assessment of allergenicity and mutagenicity; evaluation of immunomodulatory properties; study of the effect on reproductive function. Technological assessment includes: assessment of organoleptic and consumer properties; assessment of functional and technological parameters.

According to the materials of the international conference in Brussels "Methods of detection of new food derived from GMOs" (1998), there are currently two main methods that can identify the presence of even traces of GMOs: immunological method (ELISA method) and polymerase chain reaction (PCR). The first method detects specific proteins, but one of the disadvantages of the method is the low efficiency of evaluation of foods that have been subjected to heat treatment. The PCR method is more accurate, characterized by high sensitivity, which allows for qualitative and quantitative assessment of genetic material.

Ukraine has approved national standards for products containing GMOs: GSTU GEN / TS 15568: 2008, GSTU ISO 21569: 2008, GSTU ISO 21570: 2008 [5, 6, 7]. These standards define methods for detecting GMOs and their derivatives in food. After the establishment of the control system, Ukraine introduced labeling for food products containing GMOs.

Conclusion.

The biological safety of genetically modified organisms among other environmental safety is very specific and still little studied. Therefore, biosafety systems are currently being developed in many countries around the world. There is a UNEP-GEF project in more than 100 countries (an environmental program in conjunction with the Global Environment Facility), which aims to involve more professionals in the study of a full-fledged legal framework and administrative framework to address issues related to using GMOs. Ukraine concludes international agreements, participates in the international exchange of information in order to further develop and strengthen international cooperation in the field of biological and genetic safety in the implementation of genetic engineering and GMO management in accordance with applicable law.

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Анотація. *За виробництва харчової сировини необхідно забезпечити державне регулювання і контроль у сфері поводження з ГМО, забезпечити здійснення заходів щодо державної підтримки генетично-інженерної діяльності, затвердити порядок проведення державної апробації ГМО у відкритій системі біобезпеки та затвердити критерії безпеки поводження з ГМО у замкненій системі. Центральні органи виконавчої влади ведуть державні реєстри ГМО та продукції, виробленої з їх застосуванням, розміщують їх на власних офіційних веб-сайтах та регулярно публікують у засобах масової інформації. Експертиза продукції із ГМ-джерел включає медико-біологічну та технологічну оцінку. Медико-генетична оцінка включає: оцінку структури рекомбінантної ДНК; оцінку регуляторних послідовностей; вивчення ефектів експресії інших генів; визначення*

стабільності ГМД; оцінка впливу навколишнього середовища. Медико-біологічна оцінка включає: вивчення хімічного складу (показники якості та безпеки); оцінка біологічної цінності і засвоюваності на лабораторних тваринах; токсикологічне дослідження на лабораторних тваринах (не менше 5–6 місяців); оцінка алергенності та мутагенності; оцінка імуномодулюючих властивостей; вивчення впливу на репродуктивну функцію. Технологічна оцінка включає: оцінка органолеетичних та споживчих властивостей; оцінка функціонально-технологічних параметрів.

Ключові слова: *генетично-модифікований організм (ГМО), контроль, нагляд, якість, безпечність, харчові продукти, біобезпека.*