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COMPLIANCE OF THE PATENTABILITY OF GENETICALLY MODIFIED ORGANISMS IN UKRIANE WITH EUROPEAN UNION PATENT LAW

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Abstract

The following work is focusing on the problem of patenting genetically modified organisms and in particular, the problem of procedural requirements in acquiring the patent rights for genetically modified organisms in Ukraine compared to European Union and United States of America. The aim of the research is to define the legal gaps in Ukrainian legislation and analyze what components are not in compliance with European legislation in regards to genetically modified organisms and their patentability under Directive 98/44 EC, as for Ukraine it is a subject of the high importance to join the European Union and harmonize the legal procedures accordingly to EU standards. In particular, author were interested in analyzing what are the problems in the process of acquiring patent rights on GMO in Ukraine compared to EU and what are the concerning areas in legislation regarding public order and morality.

In the presented work, by using the special legal method, author defined the term genetically modified organism, presented the current situation in Ukraine regarding patenting GMO and author defined the requirements and procedural steps in acquiring patent rights for genetically modified organisms (from now and onwards - GMO) in Ukraine, European Union and United States, which are the strategic country partners and legal role models for Ukraine while using the formally-logical method of research. Additionally, author analyzed what are the main cornerstones and differences in process of acquiring patent right in EU versus US and what should be the Ukraine's choice when it comes to adopting the model of legislation on GMO. Whilst using analytical method, the author came to conclusion that there are major issues concerning the public order and morality when patenting the biotechnology inventions under EU legislation, in particular, Directive 98/44 EC and author provided corresponding conclusions on what should be adopted by Ukrainian legislation in order to avoid similar obstacles in the national legislation. By using the legal analytical method, author came to conclusion that strategically and procedurally it is more beneficial for Ukraine to adopt European model of acquiring and legalizing the GMO and specifically author analyzed what are the gaps in law of Ukraine and what must be in compliance to European Union legislation to harmonize the national law of Ukraine on patenting GMO.

Key words: patent, genetically modified organisms, legislation, patentability

List of abbreviations

APHIS - The Animal and Plant Health Inspection Service

EDRPOU - Ukrainian "Unified Register of Businesses and Organizations"

EFSA - European Food Safety Authority

EPA - United States Environmental Protection Agency

EPU - Experimental Use Permit

EU – European Union

FDA - US Food and Drug Administration

FFDCA - Federal Food, Drug and Cosmetic Act

FIFRA - Federal Law on Insecticides, Fungicides and Rodenticides

GM – genetically modified

GMOs - Genetically modified organisms

GRAS – "Generally recognized as safe"

JRC - Joint Research Center

LMOs - Living modified organisms

SCFC- Standing Committee on Food and Veterinary Affairs

TRIPS -Trade-Related Aspects of Intellectual Property Rights

USDA - Department of Agriculture, USA

VPSS - Veterinary and Phytosanitary Supervision Service under the Ministry of Agrarian Policy

WTO - The World Trade Organization

Introduction

Nowadays, the market of Ukraine is saturated with new little-known goods, legal regulation and circulation of which is not always adequately ensured by domestic law. One of these products is the genetically modified organisms that are the result of the introduction of scientific research in the field of transfer of heredity units (genes) from one organism to another to provide them with predetermined one's qualitative characteristics (the so-called "genetic engineering", which is an integral part biotechnology). Genetically modified foods serve as a basis for creation of food products, medicines, fuel and lubricants materials, recycling products, etc.

Genetically modified products are new and specific objects civil legal relations, which stipulates a special legal regulation relation with it, first of all, within the framework of patent law. World experience indicates the lack of a unified approach to patent protection genetically modified products, which determines the global nature of the legal problem of protection of these objects. In the developed world, the biotechnology field refers to priority directions of activity in both scientific and industrial spheres. In all the strategic documents recently adopted by the UN, the EU, the WTO, the governments of individual countries, provided provisions concerning problems the study of genetically modified organisms (GMOs) and their practical application. According to forecasts of specialists of the Earth's population will grow drastically and it will require extra resources to provide the adequate feed. Part of this problem can be solved by biotechnology, an important component of which is the development and application of genetically modified organisms (hereinafter referred to as GMOs). The use of GMOs in the cultivation of agricultural products of plant origin has its advantages (increasing the yield of agricultural crops, the possibility of growing crop production with regulated quality indicators, etc.), and has potential food, environmental, socio-economic and many other threats. That is why one cannot underestimate the role of legal means in regulating relations with regard to the use of GMOs in the process of growing agricultural products of plant origin. At the level of the European Union (hereafter the EU), the use of GMOs in agriculture and its legal provision are quite elaborate, which is still lacking in the legislation of Ukraine.

The use of GMOs (including in the cultivation of agricultural products) is regulated by the norms of the Law of Ukraine "On the State Biosafety System for the Creation, Testing, Transport and Use of Genetically Modified Organisms" of May 31, 2007, No. 1103-V, which is of a general nature, but in many respects does not comply with EU law and law. The problem of adaptation of the national agricultural legislation (including the use of GMOs in agriculture) to EU legislation

and law is of considerable relevance, taking into account the necessity to implement the provisions of the Association Agreement between Ukraine and the EU signed in 2014.

The relevance of the research topic is also influenced by Ukraine's accession to The World Trade Organization (WTO) and the implementation of European integration processes, as well as the determining economy barrel for Ukraine is agricultural sector which is a field where GMO are most used. The work is of a peculiar interest of the author due to the national interest and actuality of the research since there were minor number of scientific works done on the topic.

As well as within the framework of the WTO accession, Ukraine has brought its national legislation to the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides for patent protection in any field of technologies, including genetic engineering. Within the framework of the European integration procedures Ukraine has undertaken to bring the national patent legislation in line with the European one. This is a necessity bringing the norms of national patent law into conformity with Directive 98/44 / EC on the legal protection of biotechnological inventions.

The following work consists of introduction, three chapters and summary. First chapter provides the background on what is genetically modified organisms and how this subject is regulated under the Ukraine legislation as well as the current situation in the legal field. Second chapter introduces legal regulatory systems of United States and European Union in regards of patenting specifics on genetically modified organisms. Third and main chapter provides the analyzes of European and American regulatory systems, as well as a comparative analysis for Europe and Ukraine to determine which model of regulation of patenting GMOs is more suitable and strategically more beneficial for Ukraine, revealing what parts of Ukraine legislation are not complied to the European standards. The work is supplied with summary and list of references.

The aim of the research is to reveal the essence of the legal provision of the use of GMOs in the cultivation of agricultural products of plant origin in Ukraine in comparison with the legal provision of this activity in the EU, as well as to analyze what exact points of Ukrainian legislation need to be compiled to the requirements of European Union as one of the main tasks for Ukraine is European integration.

In accordance with this goal, the **following main tasks** were set as follows:

- to characterize the existing regulatory systems on GMO in USA, Ukraine and EU;
- to analyze which legal model regarding GMO regulation is more beneficial to adopt for Ukraine;
- to characterize the legal regulation of tracking and labeling of agricultural products of plant genetic material containing GMOs in USA, Ukraine and the EU;

- to analyze Ukrainian legislation on GMO in comparison to EU legislation regarding GMO and determine what needs to be complied in Ukrainian law on GMO towards the EU integration;
- to determine the conditions for exclusion of the patentability the biotechnological invention based on Directive 98/44 within the scope of public order and morality;
- to analyze the European Directive 98/44 EC through the prism of the questions regarding public order and morality while patenting biotechnological inventions.

Methods of the research

In the following work, the complex of general scientific and special methods of scientific knowledge are used. Special legal method gave the ability to examine the content and nature of the genetically modified product as the object of civil-law relations. Logical method has resulted in a sequence of exposition of existing doctrinal provisions regarding the location of genetically modified products among other results of biotechnological activities. Formally-logical method contributed to the discovery of contradictions in the conceptual series patent law. By method of analysis and the current state of legislation, judicial practice and proposals for improving the regulatory framework have been developed. The comparative legal analysis method enabled to provide the current gaps in legislation of Ukraine that are still needing to be complied to the EU requirements.

The thesis hypothesis and/or research question(s)

- What are the problems in the process of acquiring patent rights on GMO in Ukraine compared to EU?
- What is not in compliance in Ukrainian legislation on GMO compared to EU?

1. CURRENT SITUATION IN UKRAINE REAGARDING GENETICALLY MODIFIED ORGANISMS

1.1Basic information on genetically modified organisms

A genetically modified organism is a plant, an animal or a microorganism, the genetic code of which has been changed, withdrawn or added (from the same species or others) in order to provide characteristics that are not laid down naturally.[1]

EU Directive 2001/18 / EC, dated March 12, 2001, legally defines the term „Genetically Modified Organism" regarding the preparation prepared for its release. According to Art. 2 (2) of this directive, the body is genetically modified if its genetic material has been altered unnaturally, due to mating and / or natural recombination. The directive lists several technologies for use, which is given by genetically modified organisms. This is the transfer of the recombinant DNA, created outside the body with the help of laboratory technology and certain procedures used to merge cells. Sometimes different terms are used to distinguish living GMOs, that is, living modified organisms (LMOs)[2], and inanimate GMOs. LMO is, for example, genetically modified (from now and later in the work GM) plants and their seeds, which can be propagated in the environment, as well also GM fish and GM microorganisms for bioremediation. The oil from the kernels of GM plants is an example of inanimate GMOs. The most commonly used genetically modified organisms are agricultural ones and the first generation of these crops is grown on a commercial basis since 1996. Currently, the most common genetically modified feature is resistance to herbicides.[3] It is characteristic of all major GM crops[4].

Researchers develop GM crops resistant to environmental stress, namely:

- resistant to drought - the first commercial variety of maize may appear on the market soon after 2012[5]. As it was reported, Australian researchers are developing a drought-tolerant wheat and

[1] Nationamaster vocabulary, Accessible: www.nationmaster.com/encyclopedia/Genetically-modified-organisms, 12, February 2018

[2] The Cartagena Protocol on Biosafety proposes the following definition of LMOs: "LMOs are any living organisms that have a new combination of genetic material obtained through the use of modern biotechnology"(Article 3g).

[3] Herbicide-resistant cultures contain genes that enable them to reduce the active ingredients in, making them harmless. Herbicides are used to control weeds and do not harm these crops.

[4] Dobbs Mary (2017). Genetically modified crops, agricultural sustainability and national opt-outs: enclosure as the loophole?, C.M.L. Rev. 2017, 54(4), 1093-1122.

[5] BASF and Monsanto Corn, Accessible: www.transgen.de/aktuell/974.doku.html 19 February 2018

achieve significant success in field trials. It is expected that this kind of GM wheat[6] will be available in 5-10 years[7];

- resistance to salts - the technology is developed for cotton, rice, canola and tomatoes;

- canola (for which nitrogen fertilizers are required) that will require significantly less nitrogen fertilizer than conventional varieties (field trials). The first generation of GM crops has advantages primarily for agricultural producers. Also, it turns out that it is less threatening to the environment. GM technology:

- allows farmers to reduce the use of pesticides for their plants, which is beneficial to the environment, and warns of negative consequences for the health of farmers from the use of pesticides and saves time (since 1996 around the world began to use 286 million kg less pesticides on the area, where GMO crops are grown, reducing the impact of herbicides and pesticides on the environment by 15%)[8];

- Reducing the amount of land needed for processing, it reduces greenhouse gas emissions (on a global scale, in 2006, this reduction was equivalent to removing 6.56 million road cars per year[9]);

- the issue of increasing farm incomes using GM technology is still debatable. The USA[10] 2016 report states that "GM crops that are currently used do not increase the capacity of 118[11] crop yields of hybrid varieties. (...) However, protecting plants from individual parasites, GM crops[12] can prevent yield loss compared to non-GM hybrids, especially when the level of infection with parasites is high. This effect is especially important for Bt cultures". Although, GMO opponents argue that GM technology is inadequate. In addition to the question human health (eg possible allergic reactions) and the environment (eg, crossing with conventional plants, which may be risky for biological diversity), there are also supply issues for seeds, since GM seeds protected by patents and restrictions applicable to the storage of seeds. It is also worth mentioning, that developing countries, if they want to benefit from genetic modifications, it is important to have access to GM technology and GM seeds at affordable prices. There are some fears that with the world of GMO

[6] There is currently no GM wheat on the world market. In 2004, the American biotech company Monsanto abandoned its plans to remove GM wheat into the market through strong opposition from consumer groups, as well as US farmers who were afraid of losing the EU market. However, today, there are those who, through the food crisis, are in favor of GM's permission for wheat to overcome hunger in developing countries.

[7] James Grubel's Report of September 3, 2008 Accessible: www.int.iol.co.za, 13 March 2018

[8] Graham Brookes and Peter Barfoot of the UK consultancy PG Economics, Global Impact of Biotech Crops: Socio-Economic and Environmental Effects 1996 – 2006, AgBioForum 2008.

[9] Ibid

[10] Jorge Fernandez-Cornejo and Margriet Caswell, The first decade of Genetically-engineered Crops in the United States, USDA 2016.

[11] Harvest of cultivars in favorable conditions

[12] Nicolia, A., Manzo, A., Veronesi, F., & Rosellini, D. (2014). An overview of the last 10 years of genetically engineered crop safety research. Critical Reviews in Biotechnology, p.7 Accessible: http://www.agrobio.org/bfiles/fckimg/Nicolia%202013.pdf , 17 April 2018

distribution, the highly concentrated agro-biotechnology industry will dominate the food sector in the world. This can lead to high prices for GM seeds, as farmers become more dependent on its supply.

Work is also under way on the development of second-generation GM plants that are straightforward consumed by people in the form of food (GM rice, wheat, fruits) and bring benefits industrial sector. This is a wheat-stomach safe[13] for people who are allergic to gluten (the research program for her is under development), yes called "golden rice" enriched with vitamin A, is tested for many years, but still not is grown through a skepticism about possible health risks[14]. Also, fruits with a longer shelf life and Amylopectinous Amflora potato that waiting for an EU permit, designed to deliver more starch for the process production.

The third generation of GM plants is even further from commercialization than the second one, however already explored. It covers modified plants that can produce valuable Pharmaceutical, Vaccine and Bioluminescent for Production or Enzymes for improvement of animal feed. This technology is called biopharming. Biotechnology as a business activity was becoming more and more interesting for private manufacturing in connection with the strengthening of the protection of intellectual property rights in the US, mainly during the 1970s and 1980s. Consequently, private investment in the study of varieties of crops and their development grew fourteen times between 1960 and 1996 (with inflation taking place), while public spending did not change much.[15] GM seeds are protected by patents, which give their owners exclusive rights to increase their quantity and sales. A patent holder may require a patent fee from farmers who use GM seeds and crops and prosecute them for legal breach. This means that legal liability also occurs in the case of contamination by neighboring GM crops (unintentional pollution).[16] See, for example, the case of Percy Schmayzer of Canada, who faced Monsanto's lawsuit after his plants were contaminated by her GM rape in 1996. The Federal Court of Justice ruled that Schmayzer could no longer own its seeds and plants, since they have the patented GMO genes (2001). The Supreme Court of Canada ruled that Monsanto's patent for genes was valid, but Schmayzer did not have to pay Monsanto anything because he did not benefit from the presence of GM rape on his field (2004). In March 2008, according to an out-of-court decision, Monsanto agreed to the cost of cleaning Schmayzer

[13] DeFrancesco, L. (2013). How safe does transgenic food need to be? Nature Biotechnology, 31(9), 794-802.

[14] Wolfenbarger L.L. & P.R. Phifer (2000). 'The Ecological Risks and Benefits of Genetically Engineered Plants' Science 2088, 2092.

[15] Jorge Fernandez-Cornejo and Margriet Caswell, The first decade of Genetically-engineered Crops in the United States, USDA 2006.

[16] Schmayzer vs Monsanto, Article Accessible: www.gmfreeireland.org/interviews/schmeiser.php www.taz.de/nc/1/zukunft/umwelt/artikel/1/monsanto-zahlt-schadenersatz , 16 March 2018

fields that were affected by GM rape (Schmayzer argued that when the company owns and controls the gene, it is also responsible for the uncontrolled spread of GMOs). Thanks to the TRIPS Agreement[17], the World Trade Organization for Biotechnology is becoming easier to protect intellectual property rights in developing countries[18].

1.2Regulatory system of Ukraine

The system of regulation of GMO products in Ukraine is relatively new. The basic law is the law "On the state system of biosafety during the creation, testing, transportation and use of genetically modified organisms"(hereinafter referred to as the Biosafety Act) was adopted on May 30, 2007. However, it should be noted that in recent months the legislators of Ukraine finally regulated many important issues, including the key mechanisms for registration and marking of GMOs. Recent efforts of the Cabinet of Ministers of Ukraine regarding Regulation of GMOs in Ukraine give hope that the system will be in the near future work.

In accordance with the Law on Biosafety, the powers of control and regulation in the GMO sphere is distributed among five central executive authorities: The Cabinet of Ministers, the Ministry of Education and Science, the Ministry of Defense of the Environment, the Ministry of Health and Ministry of Agrarian Policy. The Cabinet of Ministers is primarily responsible for the development of regulatory and legal frameworks acts for the implementation of the Biosafety Act, as well as coordinates in the field GMO management. The Ministry of Education and Science approves activities in the field of genetic engineering in a closed system, while the Ministry of Environmental Protection approves GMO testing in an open system.

Conducting ecological examinations of GMOs belongs to the authority of the Ministry environmental protection, while the Ministry of Health Defense conducts sanitary and epidemiological examination of GMOs before drinking the decision on their state registration.

In general, there are three stages of development and application of GMOs: research in the closed environments (laboratories, special greenhouses), tests (eg, landing GMOs in open systems within the experiment) and, ultimately, organization of production (commercialization). The GMO law

[17] The Agreement on Trade-Related Aspects of Intellectual Property Rights is Annex 1C to the Marrakech Agreement Establishing the World Trade Organization, signed at Marrakesh, Morocco, on April 15, 1994.

[18] Gaskell, George , Nick Allum and Sally Stares (2003). 'Europeans and Biotechnology in 2002: A Report to the EC Directorate General for Research from the Project "Life Sciences in European Society" ', QLG7-CT-1999-00286, Euro-barometer 58.0, 2nd edn, 21 March, Accessible: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_177_en.pdf , 10 April 2018

covers all three stages (see below), but some important details need to be clarified in the normative and legal acts of the Cabinet of the Ministers.

A company that intends to explore and study GMOs in a closed system in Ukraine has to submit an application for a permit (license) to the Ministry of Education and Science of Ukraine according to a procedure to be adopted by the Cabinet of Ministers of Ukraine. According to the Article 12 of the GMO Law, every company that carries out genetic engineering activities has created a commission from their own staff, whose mission is to provide preliminary risk assessment. On the basis of these data the company receives a license or refusal to provide it. Upon obtaining a license, the company may begin the study. She can do this request permission to import unregistered GMO products to the Ministry of Education and Health science in accordance with a certain procedure[19]. Permission is granted on the basis of scientific- technical expertise, as well as recommendations from the Interdepartmental Commission on Biosafety at Ministry of Education and Science. In accordance with this procedure, it is also possible to obtain an import permit unregistered GMO products for the purpose of public[20] trials in an open system.

But first, a company that intends to carry out pilot studies, gets permission for this. The permission that is issued by the Ministry of Environmental Protection for each GMO on the basis of environmental expertise, which holds this Ministry. The permit specifies the terms and conditions conducting state tests of GMOs. Appropriate procedure was approved The Cabinet of Ministers in April 2009[21]. The test is subject to control The Ministry of Environmental Protection and the Ministry of Health Protection that controls the compliance of the company with the necessary biological and genetic security measures.

If the test results in the open system are positive, the company can decide to monetize GMOs. In accordance with Articles 15 and 16 of the GMO Act, only registered GMOs can be released in the environment, produced, entered into whether imported or imported into Ukraine[22]. So, the next step is to register the appropriate GMO, which is carried out on the basis of conducted sanitary and epidemiological expertise Ministry of Health of Ukraine, as well as on the basis of test results. If this GMO is recognized biologically and genetically safe, it may be registered.

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[19] The procedure is regulated by the Decree of the Cabinet of Ministers No. 734 dated August 20, 2008 "On approval of the procedure for issuing a permit for the import into the customs territory of Ukraine of unregistered genetically modified organisms for research purposes or state approbation (tests)»

[20] In addition, the law on biosafety contains an article on "state" testing and the permission of companies for "State" GMO test (Article 7). However, in this case, the test is not conducted by the state.

[21] Decree of the Cabinet of Ministers No. 308 dated April 2, 2009 "On Approval of the Procedure for Granting the Permit for the State Approbation (Testing) of Genetically Modified Organisms in an Open System", which entered into force on June 1, 2009.

[22] There are two exceptions to this rule: unregistered GMOs can be imported into Ukraine for research purposes or state approbations (tests) and released into the environment for the purpose of testing (respectively, Articles 16 and 13 of the Biosafety Act).

According to the Biosafety Act, the State Register of GMOs is a specialized directory GMOs that have been registered with the definition of their further economic using. GMO registration must be carried out by ministries in accordance with the planned method of using GMOs or type of product (food, feed, cosmetics, food products, etc.). As a result, one and the same GMO has to undergo several registration procedures conducted by different ministries. So, for example, a GMO food source - the Ministry of Health, and that most GMOs, but the source of feed - the Ministry of Agrarian Policy. For the sake of transparency and cost reduction, registration should be carried out by one authority, whatever consulted by the competent authorities on specific issues (for example, Ministry of Agrarian Policy for Seeds of Genetically Modified Plants, Ministry of Environmental Protection on environmental issues GMO and Ministry of Health Expert Examination on the Impact of GMOs on Health human) In addition, it would be desirable to adopt a norm according to which GMOs that is used as a source of food and can be a source of feed allowed only at the same time for both areas of use. That way, it would be possible to avoid a situation where GMOs permitted only for feed are contained in foodstuffs[23].

The Biosafety Act states that the official register of GMOs and GMO products should be posted on the site of the relevant ministry, as well as regularly published in the media. According to the legislation of Ukraine, they are not subject to disclosure of confidential data, but the law clearly states that the information on the impact of GMOs on human health and the environment[24] in any one the case is not confidential[25]. In accordance with Article 14 of the Biosafety Act, the first one Registration is valid for 5 years and can be renewed. This article provides the possibility of refusing registration of GMO or GMO products by the competent authority, in case of obtaining scientifically substantiated information about their health hazard man or the environment.

The timing for consideration of statements by the authorities is beneficial for the interested parties companies - 120 days for registration of GMOs and 45 days for refusal or permission of the given activities that require such a permit[26], including the period of the relevant activities expert assessments (sanitary-epidemiological and ecological expertise). It should be noted that the

[23] For example, the case of Starlink corn in the USA. In September 2000, seeds were genetically modified corn known as Starlink was found in the stuffing of cakes sold for human consumption, even though permission for the use of this raw material was for feed only.

[24] Blakeney Michael (2015). Blowing in the Wind: Adjudicating the Impact of GM Crops on Organic Farming in the Courtroom', 21(1) International Trade Law & Regulation 91-100, ISSN: 1357-3136

[25] However, in Resolution No. 114 of February 18, 2009, "On Approval of the Procedure for the State Registration of Genetically Modified Organisms for Sources of Food Products, as well as Food Products, Cosmetic and Medicinal Products containing or derived from such organisms," states that information in the documentation submitted by the company for the state registration of GMOs is confidential and cannot be used without the consent of the applicant.

[26] Importation of unregistered GMOs for research, research and testing, import of GMO products for study and research, transit through Ukraine of unregistered GMOs and release of GMOs into the open environment.

Resolution "On approval of the procedure for issuing a permit for import into the customs territory Ukraine of unregistered genetically modified organisms for scientific research goals or state approbations (tests) "determines other terms for granting permission. It differentiates the terms according to the risk that may cause that or that another GMO on human health and the environment. Yes, permission is granted within 90 days, provided that the test requires certain precautions and 270 days, provided the ministry requests additional information.

These provisions do not comply with the provisions of the Biosafety Act, which clearly states that the relevant procedure cannot exceed 45 days. In this case, you need to be guided by the rules of the law. In the end, Ukraine introduced a mandatory GMO labeling of food (see below), as well as monitoring of GMO food and feed that has guarantee that only registered GMOs are used in their production (Article 10 and 11 of the GMO Act).

Procedure for consideration of GMOs

On February 18, 2009, the Cabinet of Ministers adopted Resolution No. 114 "On Approval of the Procedure for State Registration of Genetically Modified Organisms sources of food products, as well as food products, cosmetics and medicines means containing such organisms or derived from their use ". This is a decree that is used for GMOs - sources of food products, as well as food products cosmetics and medicines containing GMOs or produced with their use.

The Ministry of Health is responsible for the state registration of these products and for maintaining the relevant GMO register. According to the Resolution, the application for state registration of a GMO product shall state:

- commonly used product name;
- the trade name of genetically modified organisms in the language producer country, in English and in Ukrainian;
- purpose, types and methods of application of products;
- name, surname, first name and patronymic of the applicant with indication location, place of residence, telephone, telefax and e-mail address; for the foreign applicant, in addition - the registration number, for the domestic - the code according to "EDRPOU[27]";
- the name / surname, name and patronymic of the manufacturer of the products from location, place of residence, telephone, telefax and e-mail addresses; for a foreign manufacturer, in addition, the registration number, for domestic - code according to "EDRPOU". The application must be submitted to the Ministry of Health together with the

[27] EDRPOU - Ukrainian "Unified Register of Businesses and Organizations"

following documents: conclusion of the state sanitary and epidemiological examination and, if necessary, also the state ecological expertise;

- information about the results of examination of registration materials (registration dossier) for the medicinal product and its quality control carried out at determined by the MOH order.

The Resolution explicitly states that the Ministry of Health cannot require any other supplementary documents not provided for by the repealed Regulation relevant provisions of the Biosafety Act. Deadline for reviewing documents submitted for the state registration to the Ministry of Health, should not exceed 120 days from the date of their receipt, including the term of the state environmental and / or sanitary and epidemiological expertise.

The resolution does not clearly state that the results of examination of registration materials refer only to the registration of medicines. In addition, the registration procedure is not yet adopted by the Ministry of Health, which may be a barrier to registration of GMOs in Ukraine, at least for the registration of medicines. The reason for refusal of state registration of products is:

- negative conclusions of the state environmental and / or sanitary-epidemiological product expertise;
- negative results of examination of registration materials (registration dossier) for a medicinal product;
- the receipt of scientifically substantiated information on the hazards of products for human health or the environment if used for the intended purpose.

The Resolution came into force on June 1, 2009, that is, since this date, it is possible to register GMO products of domestic production in Ukraine. The import order is that imported products have not yet been approved. Other procedures have not been approved by the Cabinet of Ministers registration, determined by the Law on Biotechnology (registration of GMO sources of feed, fodder supplements and veterinary preparations containing GMOs or derived from them the use of plant protection products obtained using GMOs varieties agricultural plants and animal breeds created on the basis of GMOs). It is worth noting that the already approved procedure for registration of GM plants in Ukraine. If registration is successful, such plants can be grown on the territory of Ukraine. The procedure was approved by the Cabinet of Ministers Decree "On Approval of Temporary order of import, state testing, registration and use transgenic plant varieties

in Ukraine[28]" since 1998, that is long before the entry into force of the Law on Biotechnology. The regulation provides for the following registration procedure:

1. To obtain permission to import experimental samples of transgenic plant varieties the applicants submit to the State Commission for Testing and Protection of Plant Varieties at the Ministry of Agrarian Policy (hereinafter - the Commission) a statement containing information on the origin of the variety and its characteristics;
2. The Commission for conducting the examination shall forward the application to the Institute of Agroecology and Agriculture Biotechnology of the Ukrainian Academy of Agrarian Sciences;
3. In the presence of a positive expert opinion, the Commission agrees with Interdepartmental Council for Testing, Registration, and the use of transgenic plant varieties submits proposals to Ministry of Agronomic Production for import of prototype transgenic plant varieties;
4. The permit is issued by the Ministry of Agrarian Policy only for the received GMOs a positive conclusion of the Interdepartmental Commission on Biosafety under the Ministry education and science. To this end, the Interdepartmental Commission on Biosafety is evaluating risk
5. GMO varieties of plants are included in the state program for testing varieties plants;
6. State testing of transgenic plant varieties is under control State Commission for Testing and Protection of Plant Varieties, as well as under control Interagency Council on Testing, Registration and Use Regulation transgenic plant varieties;
7. The sanitary-hygienic examination is carried out by the Scientific-research institute Ministry of Health. For this the commission sends to the institute samples of GM plants.
8. In the case of a positive conclusion transgenic plant varieties are approved;
9. Such transgenic plant varieties are entered in a special section of the state register varieties of plants of Ukraine.

The registration process is very complicated and takes a long period of time (3-4 years). In general, there was submitted for consideration of the application for 5 varieties of agricultural crops (in 1997- 1998): Bt Monsanto Potato (3 varieties), Bt Corn and Syngenta Monsanto, Bayer Rape and Roundup Ready Monsanto Corn. All the above varieties of the farm plants have been tested, but none of them have received final approval.

[28] Decree of the Cabinet of Ministers of Ukraine No. 1304 dated August 17, 1998 "On Approval of Temporary order of import, state testing, registration and use transgenic plant varieties in Ukraine .

In Ukraine, no GMOs have been approved / registered yet. As mentioned above, several GM crops have been tested in accordance with Decree No. 1304, but not received approval. It seems that the state authorities were not able to take responsibility for such a decision. Since another registration decree (No. 114).

Genetically modified organisms in Ukrainian reality

Considering the fact that no GM crops are approved in Ukraine, cultivation, as well as the import of GMOs into Ukraine is considered illegal. However, according to information provided to us by businessmen surveyed in the framework of this study, Ukraine's agriculture is not free of GMOs. GMO falls into food products in Ukraine mainly through the batch of imported GMO products. Except that, GM potato was diluted in Ukraine back in the 90's. Under the conditions that existed in those years, it was impossible to provide "limited use" (contained use) distribution product, which led to the introduction of GMOs into the food chain products.

As a result, GMOs are grown in Ukraine and are consumed by GMOs for food products Ukrainian producers of agricultural products have enough open to biotechnology and, above all, see the benefits of GMOs (higher levels yield due to resistance to herbicides). There is no such official data for such data statistics, but according to entrepreneurs' calculations, about 50% - 80% of soybeans grown in Ukraine is genetically modified. In addition, the State Committee on Technical regulation and consumer protection confirms that 45% of soy processed in Ukraine, as of 2005, is GM soybean[29]. Experts explain this by the fact that Ukrainian soybeans consumed inside the country, and not exported. In case of export, active Traders in the Ukrainian market would have intervened and would control purchases.

Potatoes, corn and brewer's barley, as well as cotton, also contain GMOs, but in much less. Obviously, the lack of surveillance programs for the fields and the systematic control of seed sold encourages agricultural production manufacturers to use the illegal (for today) technology. In addition, it is estimated that about 30% of food products in Ukraine contain GMOs. First, it is a GMO soybean[30] of domestic production (in 80% of cases), which is used by the food industry of Ukraine as a popular food additive.

As a result, sausages, canned goods, pastries, chocolate and products from chocolate contain GMOs. As noted above, only from July 1, 2009 GMOs food products in Ukraine are subject to special labeling. However, it should be noted that some food industry producers in Ukraine began

[29] Dong W., L. Yang, K. Shen et al., (2008).“GMDD: a database of GMO detection methods,” BMC Bioinformatics, vol. 9, article 260

[30] Bertheau, Y., Davison, J. (2011). Soybean in the European Union, status and perspective. In: Recent trends for enhancing the diversity and quality of soybean products, 3-46. INT: InTech - Open Access Publisher., DOI: 10.5772/18896 Accessible https://prodinra.inra.fr/record/269289 , 12 March 2018

to mark their own products that do not contain GMOs on their own initiative, without appropriate legislative framework. The first one in this was the company Conti, which is one of the largest confectionery companies in Ukraine. The process of marking its own products with the words "without GMO" started in the middle of 2008, thus referring to consumers' rights to safe products and reliable information.

In the absence of systematic testing of agricultural products on GMOs, marking products that do not contain GMOs is just a marketing tool. However, this indicates that the GMO issue in food is becoming important for Ukrainian consumers. Otherwise, private companies would not start this way GMO action.

The current state of discussion on GMO labeling in Ukraine concerns, above all, the price point policy (who will bear the cost of labeling and how it will affect the price of food), as well also lack of necessary capacities in laboratories to detect GMOs. Without existing laboratories and the use of the latest technology will be impossible implement relevant legislation in Ukraine, especially when it comes to GMO marking. Today in Ukraine there are four laboratories that have the opportunity to identify GMOs in Food and Other Products: 2 of the laboratories are located in Kyiv (National Agrarian University and Ministry agricultural policy of Ukraine - veterinary services) and two smaller ones - in the Kyiv region. However, theirs power is not enough to meet the needs that would arise if properly implemented legislative norms. Moreover, the issue is the lack of laboratories for the detection of GMOs is used as the main argument against the mandatory introduction marking The President acknowledged this problem by his June decree[31] ordered the Cabinet of Ministers to ensure the creation of a network of laboratories capable of to detect GMOs in food before September 1, 2009. As regards to GMO seeds, its potential distribution in rural areas, the economy, subject to legalization, may hinder the low level of protection of rights[32] Intellectual Property in Ukraine. Companies that produce seeds can be reluctant sell patented GMO seeds, because they will be afraid that farmers will not pay license fees for using this seed. Mainly this concerns wheat and rape (the so-called hybrid maize and soybean stored, already on the market).It is also worth noting that the procedure for registration of new plant varieties in Ukraine is greater does not require information on GMOs. This item was excluded two years ago and today, applicants are expected to receive relevant information on GMO content under the "special criteria" clause.

[31] Presidential Decree No 466/2009 "On Stimulating the Development of Entrepreneurial Activity in Conditions global financial crisis "

[32] Drahos P., (2002). “Negotiating Intellectual Property Rights: Between Coercion and Dialogue”, Global Intellectual Property Rights: Knowledge, Access and Development 2002, 161-182.

2. TWO OPPOSING REGULATORY SYSTEMS. MAJOR DIFFERENCES IN EROPEAN SYSTEM VERSUS USA

European Union and the United States have introduced a very different one regulation in the field of approval, sale and sale, import and labeling genetically modified organisms. This difference is due to different degrees of confidence consumers to regulatory bodies, public organizations, interests and the strategy of the agricultural biotechnology industry, the behavior of farmers in the EU and in the US, volumes of grain trade of own production in world markets and other factors[33]. Speaking in general, the EU demonstrates a policy "better to be safe" than "to regret it", based on the principles of prevention[34] while US policy follows the principle of essential equivalence[35]. The principle of prevention says that there is the case where the proposed activity, such as the release of GMOs in the environment can be harmful to the environment, but if such damage is not fully proved, then such activity cannot be allowed. Present principle is also reflected in the Cartagena Protocol on Biosafety[36], but the World Trade Organization does not support it and allows restrictive measures in relation to trade only in case of risk verification by research[37]. According to the principle of substantial equivalence in the United States, GMO products and feeds that are sufficient similar to their usual counterparts, can be considered equally safe for food and do not require a comprehensive biosecurity examination.

[33] Kym Anderson and Lee Ann Jackson, 2003 why are the US and EU policies towards GMOs so different, University of Adelaide; and Thomas Bernauer and Philipp Aerni, 2008, Trade conflict over Genetically Modified Organism, in Kevin Gallagher, Handbook on Trade and the Environment

[34] The precautionary principle is enshrined in the so-called EU general food law contained in Regulation EC / 178/2002 of 28 January 2002 laying down general principles and requirements of the law on food introduced by the European Food Safety Authority and defines it order in the field of food safety.

[35] Guehlstorf Nicholas P., Lars K. Hallstrom (2005). The role of culture in risk regulations: a comparative case study of genetically modified corn in the United States of America and European Union Accessible: http://www.sciencedirect.com/science/article/pii/S1462901105000535, 26 April 2018

[36]The Cartagena Protocol on Biosafety was adopted on 29 January 2000 as an additional treaty to Convention on Biological Diversity. The protocol regulates the international trade of live modified organisms (LMOs) to protect human health and the environment from possible harmful effects. The protocol entered into force on September 11, 2003 and today ratified 147 countries. The USA and Argentina - the main exporters of GM crops - are not members of the Protocol. Australia and Canada, China, India, Ukraine and the European Community have ratified the Protocol. The main feature of the Cartagena Protocol is the early informed consent procedure. In accordance with this procedure, exporters are obliged to agree terms with the importing countries before the first movement of LMOs, which are intended for release into the environment (for example, seeds for sowing). In this case, all necessary information on safety assessment should be provided, at the basis of which the decision to import is taken. Based on the principles of prevention, the importing country can impose a ban on imports in the absence of scientific certainty. This principle is reflected in the introductory part of the Protocol, its objectives and Annex 3 on risk assessment.

[37] Under the WTO treaties, a country which intends to impose a ban or reject imports, justifying it security issues, should provide certain evidence of risk. Otherwise, she will be charged with deliberately creating barriers to trade. Ratio of the Cartagena Protocol and treaties WTO see Simonetta Zarrilli, International Trade in GMOs and GM Products: national and multilateral legal frameworks, UNCTAD 2005.

Consequently, US rules on GMOs are quite liberal in contrast relatively restrictive EU laws. Today only a small number is approved in the EU genetically modified plants for commercialization, and the total area under GMOs the cereals amounted to 108,000 ha in 2016, while in the United States a large number types of biotech crops were grown by 62.5 million hectares in 2016. In addition, in EU number of tests for new GMOs was significantly lower than in the United States, but rigid the EU labeling policy has led to the fact that today it sells very little amount of GMO food products[38]. In the following chapter, we are exploring the regulatory systems of Russia, Europe and America, focusing on the approval procedure, as well as on the labeling provisions. Polarization in question of the GMO between the EU and the US is considered in more detail.

2.1European Union Regulatory System

The European Union considers genetically modified organisms as a result special production process. Therefore, a separate, special system was developed rules for handling GMOs, which came into force in the early 90's. Until 2004 in the EU has had an unofficial moratorium on the approval of new GMOs[39]. Under the pressure of trading partners, especially the US, in 2004, the EU has replaced the moratorium on the revised a regulatory system covering GMO safety, labeling and traceability[4041], creating the world's strictest GMO code of laws[42].

[38] EU companies are trying to avoid the use of GM ingredients. and hence the need for their marking, taking into account the risk of losing their consumers, who are not primarily GMO supporters. According to the last review, 27 labeled GMO foods are available for sale in the Czech Republic, 18th – in The Netherlands and Estonia, 6 in Spain, 3 in England and 1 in Poland. Marked GMO products are not in Germany, Sweden, Greece and Slovenia. This market overview does not cover all EU countries. Accessible: www.transgen.de/aktuell/986.doku.html, 14 March 2018

[39] The approval rules have been in force, but in the EU during the period from June 1999 to mid-2004, there was no GMO approved. The US and other countries called it "de facto a moratorium" or "Informal moratorium".

[40] Davison, J., Bertheau, Y. (2007). EU regulations on the traceability and detection of GMOs: difficulties in interpretation, implementation and compliance. CAB Reviews Perspectives in Agriculture Veterinary Science Nutrition and Natural Resources, 2 (77), 14 p. , DOI : 10.1079/PAVSNNR20072077 Accessible: https://prodinra.inra.fr/record/24169 , 16 April 2018

[41] Major types of legislative acts in this area: Directive 90/219 / EEC supplemented by Directive 98/81 / EC on the controlled use of genetically modified microorganisms – regulates research and industrial activities using GM microorganisms (GM viruses, bacteria) in closed environment (eg laboratories); Directive 2001/18 / EC on pre-prepared release in the environment of genetically modified organisms - regulates experimental release GMO in the environment (testing) and placement of GMOs in the market; EU Regulation 1829/2003 on genetically modified food and feed on the market - regulates the turnover of GMO products food and feed; EU Regulation No 1946/2003 on transboundary movements of GMOs with the exception of intentional Movement within the framework of Feminism - regulates the movement of GMOs between the EU and third countries of the world; EU regulations No 1830/2003 on traceability and labeling of GMOs and product and feed traceability are produced from GMOs - regulates GMO marking and tracking of GMO residues.

[42] Endres Bryan (2000). 'Regulation of Genetically Modified Organisms in the European Union' 44 American Behavioral Scientist 378, 418-23.

Only approved GMOs can be marketed in the EU (including imports). Each case is considered separately. The approval / authorization procedure is very complex and requires the participation of all EU member states, as in the case of GMO approval can be placed on all 27 national markets of EU member states during the next 10 years. There are two legislative acts on the approval of GMOs in the EU:

- Directive[43] 2001/18 / EC on deliberate release into the environment Genetically Modified Organisms (Regulation of Part C of the Directive) regulating placing GMOs on the market (GMOs defined as GMO products contain or a combination of GMOs) for cultivation, import and processing in industrial products;
- Regulation[44] of 1829/2003 on genetically modified foods and feeds placed on the market 1) GMO for use in food and feed[45] and 2) GMO food and feed defined as foods and feed containing, composed or produced from GMO[46] for cultivation, import and processing in food / feed industrial products.

If food or feed contains or consists of GMOs, the application for authorization is filed in accordance with Regulation 1829/2003. Then an environmental risk assessment (according to Directive 2002/18 / EC) is carried out simultaneously with an assessment of the safety of food products and feed.

Approval of seed of plant varieties must first be approved if GMO plant in accordance with Directive 2001/18 / EC. Only after these kinds of seeds, obtained from this GMO plant, may be submitted for approval in individual member states of the EU. For this purpose, there is a test, but some safety issue products are not subject to consideration as these procedures were carried out during approval of GMOs at EU level. After approval and introduction into the national the catalog of plant varieties is subject to commercial use on the territory of the given variety EU Member State. Only if it is made by the European Commission to the Common Catalog of Varieties of Agricultural Plants[47], it can be put into circulation and grown throughout the EU. If the grain is to

[43] Adopted by the Council together with the European Parliament or the Commission separately, the directive refers to member countries. Its main purpose is to harmonize the national legislation of the EU member states. Directive binds all member countries to the result that will be achieved, but leaves them with a choice as to form and the method that they choose to realize the goals of the community within the framework of their domestic law. The directive defines the minimum standards in this area.

[44] Adopted by the Council, together with the European Parliament or the Commission separately, the regulations are general an intersection in all its parts. The regulation is a document of direct action, which means that it is in fact a law that has immediate effect in all member countries as a national instrument, without any further interference by public authorities.

[45] In accordance with Article 2 of Regulation 1829/2003, GMOs for the use of food and feed means GMOs that can be used as food and feed or as a source for food and feed production, for example Sweetcorn

[46] Ex. Corn Starch

[47] The EU Common Catalog on Varieties of Agricultural Plants is based on national catalogs of EU member states. If the types of seeds are listed in the national catalog (Member State), The European Commission is obliged to bring this

be used in food or feed, the GMO must be approved in accordance with the Regulation 1829/2003. According to Directive 2001/18 / EC, the application (so-called notification) is submitted for consideration to the authorized body in the Member State where the GMO is first introduced to the market (see figure below). The application must contain the information provided for in Article 13 of the Directive, including environmental risk assessment[48], performed by the applicant (company). The information is considered by the body in accordance with the Directive. Within 90 days from date of receipt of the application by this body, a decision is made in the form of a report on checked and sent to the applicant. In the case of a negative evaluation, the statement is rejected[49], but the applicant has the right to submit a new application to the authorized GMO on the above-mentioned GMO a body of another EU member state.

If the report does not contain any objections, the institution concerned shall send it together with the application to the European Commission, which will forward this information to the European Commission within 30 days' relevant authorities of other member states (report turnover). Within 60 days the Commission and the relevant national authorities have the right to request additional information, comment on this question and make objection to placement on the market of this GMO. In addition, the Commission's task is to create an open one access to the inspection report to receive comments from within 30 days the public.

If the Commission or other EU member states have no objections, the authority that performed an expert examination, provides written approval for placing on the market the corresponding GMO. The permit is valid for 10 years and can be renewed at the next 10 years subject to certain conditions. All products obtained from the approved GM plants are subject to demanding EU marking and labeling regulations tracking.

Figure 1. Procedure for granting GMO permits in accordance with the Directive 2001/18 / EC

type to the Common Catalog of the EU. To date, the number of the recorded species is 30,000, including the species Bt maize MON 810, which was approved for cultivation in the EU.

[48] The subject of an environmental risk assessment is to identify and assess the potential harmful effects of GMOs on human health and the environment, taking into account the cumulative and long-term effects that may be the result of placing GMOs on the market. Evaluation methodology according to which the company must carry out the tests set out in Annex 2 of Directive 2001/18 / EC.

[49] In this case, the European Commission, on its own initiative or at the request of the Member States, advises EFSA on the results of the examination (Article 28 of Directive 2001/18 / EC)

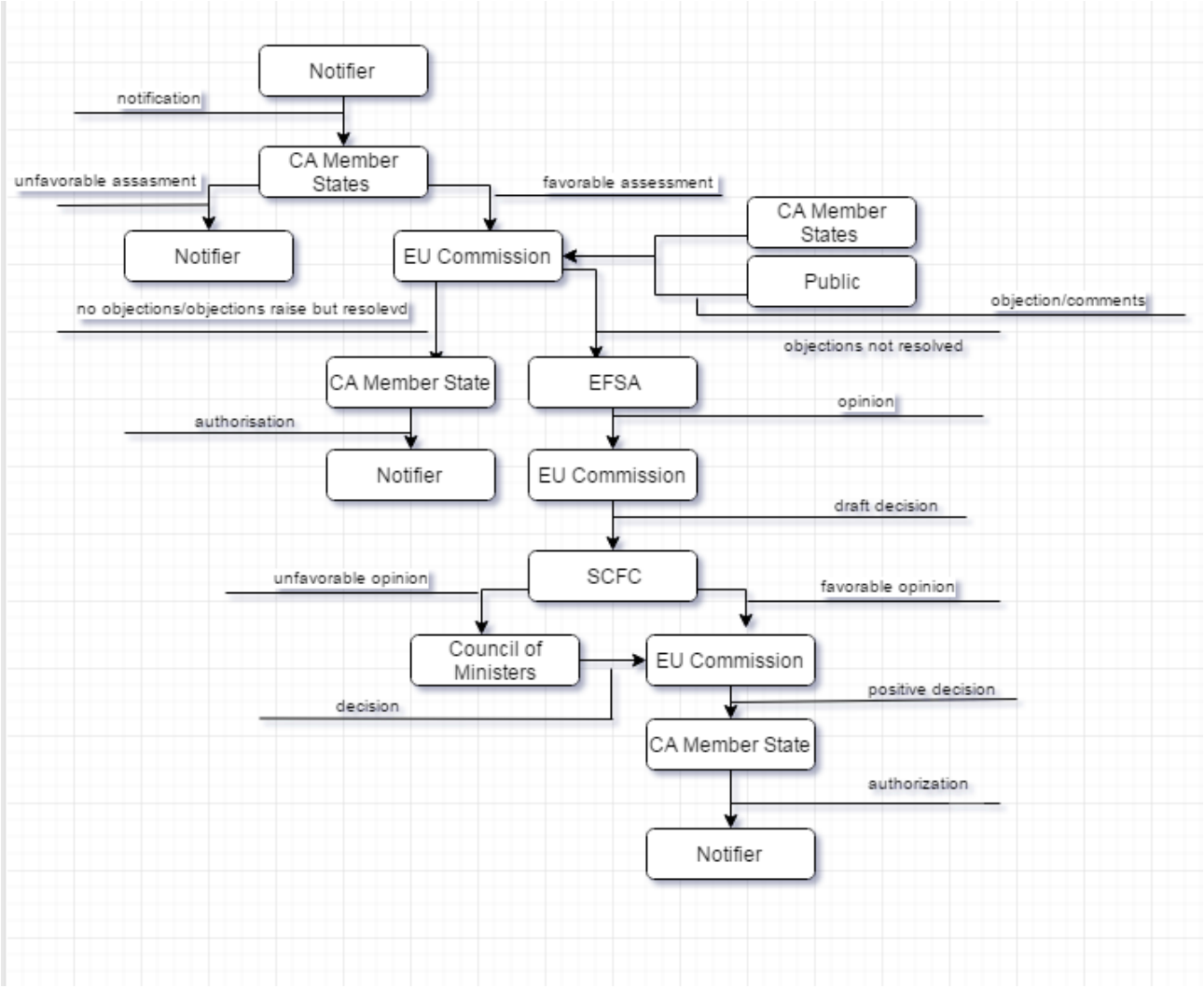

Figure1 Procedure for granting GMO permits in accordance with the Directive 2001/18 / EC
Source: author's own analysis based on Directive 2001/18 / EC

EFSA - European Food Safety Authority
CA – Country of Application
JRC - Joint Research Center
SCFC- Standing Committee on Food and Veterinary Affairs

To obtain permission under Regulation 1829/2003, the company planning to implement GMO, must submit an application to the authorized body of the EU member state in which the product is first introduced to the market (see chart below). The application must contain data provided for in Article 5 (3) of the Regulation, first of all, the materials confirming that this product 1) has no harmful effects on human health, animals or on the environment; 2) do not mislead the consumer; 3) does not differ from those the food to be replaced, to the extent that it is nutritious the value for the consumer is lower than normal consumption.

The authorized body must confirm receipt within 14 days in writing statements and inform the European Food Safety Authority (EFSA), that after checking the completeness of the submitted

documentation[50] informs other EU member states, The European Commission and the public. EFSA is responsible for assessing the scientific risk, for preparation of which is allocated 6 months. This period can be extended if necessary in additional information. EFSA submits a request to the Joint Research Center (JRC) [51] with a request to approve the method of defectoscopy and identification of GMOs, proposed by the applicant. If the application refers to GMOs for seeds or other plant material, EFSA applies to the National Authorizing Officer the body based on Directive 2001/18 / EC on environmental expertise risk EFSA makes its assessment of GMOs to the European Commission, the member states and the applicant, including a report on the assessment of the product and its justification. EFSA is doing this an evaluation available to the public with an opportunity for public discussion. For the European Commission is obliged to take 3 months from the date of the EFSA assessment develop a draft decision to grant or reject a permit and submit it Standing Committee on Food and Veterinary Affairs. Article 7 of the Regulation allows the Commission's decision to refer both to the scientific assessment of EFSA and to "others." legislative factors "on this issue. Consequently, the Commission's decision may differ from EFSA's estimate - written in this case justification of the final decision on the statement is taken on the basis of the above Comitology procedures as defined in Article 5 of Decision 1999/468 / EC. Message the applicant receives from the European Commission the decision taken. The decision is official published in the Government Magazine of the EU.

Figure 2: Procedure for granting permission for GMOs in accordance with the Regulation 1829/2003

[50] During the final inspection, EFSA verifies that all the necessary parts / materials have been submitted by the applicant. Only in case of submission of the complete package of documents the application is valid.

[51] 42 Joint Research Center (JRC) is a research center of the European Commission, consisting of Includes various institutions located in five member countries, each with its own field of research.
The Institute for Health and Consumer Protection is part of the OEC, with its location - Ispra, Italy. The Institute's activities are scientific and technical support for policy development within the framework of EU legislation on GMO and the development of biotechnological expertise in the fields of health and consumer protection. JRC manages the EU Reference Laboratory for GMOs for food and feed. Regarding applications for GMO approval, the center approves analytical methods for detecting quantification of GMOs in raw materials and processed products, while the EFSA GMO Group studies toxicity and safety issues. Accessible: http://ec.europa.eu/dgs/jrc/index.cfm and http://ihcp.jrc.ec.europa.eu, 12 March 2018

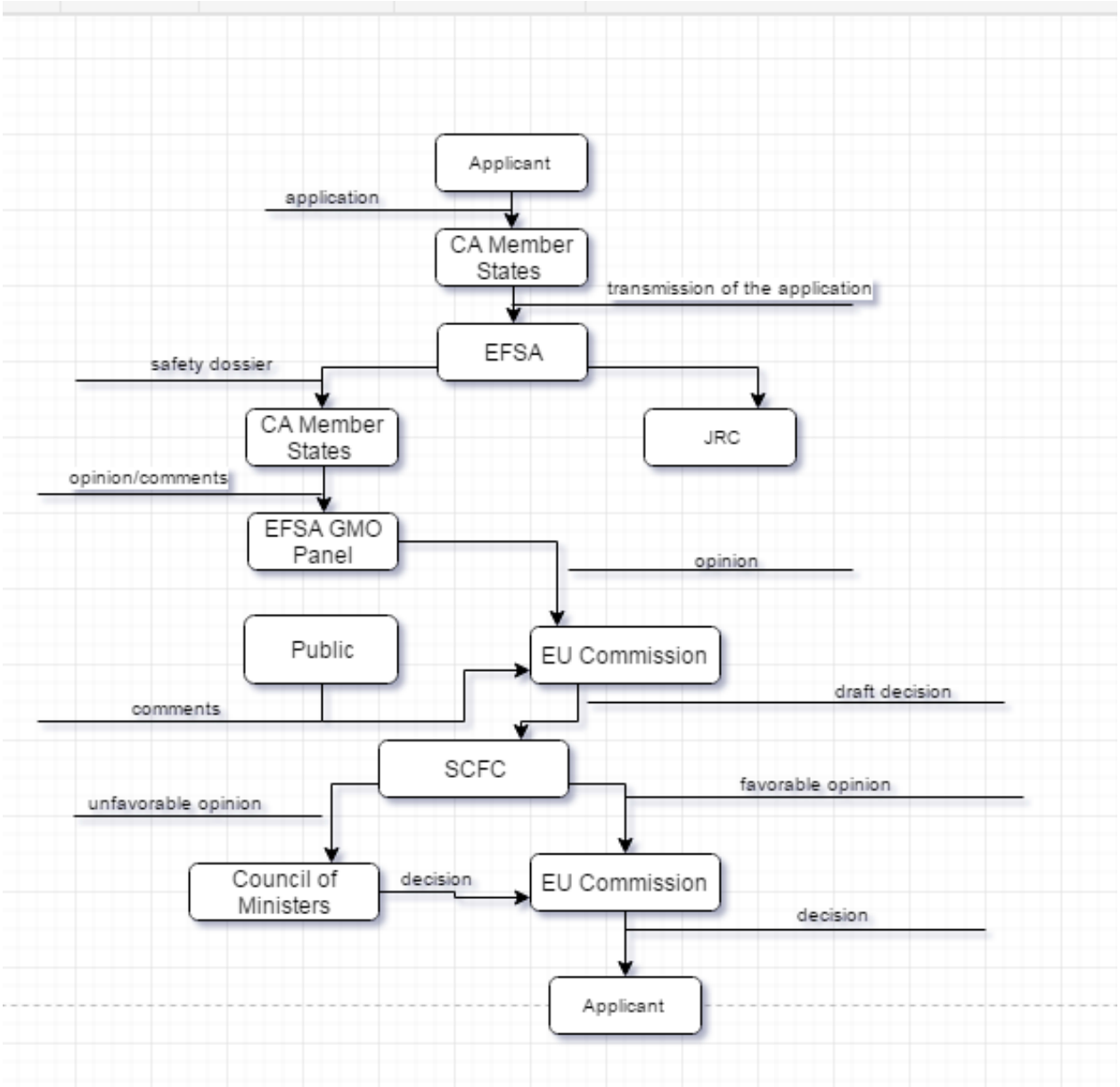

Figure 2: Procedure for granting permission for GMOs in accordance with the Regulation 1829/2003
Source: author's own analysis based on Regulation 1829/2003

EFSA - European Food Safety Authority
JRC - Joint Research Center
SCFC- Standing Committee on Food and Veterinary Affairs

It is worth noting that EU legislation provides for mandatory monitoring after release of products to the market of approved GMOs on the market, including monitoring of the long-term impact of GMOs on the environment. Monitoring has to be held by the holder of the permit in accordance with the conditions specified at approval of GMOs (Article 20 of EU Directive 2001/18). Based on the results report monitoring decision is made on renewal.

As of June 2009, the Official Register of GMOs for Food and Feed[52] contained 27 products (GM maize, cotton, soybean, rape, sugar beet and GM micro-organisms), authorized in the EU, and 5 products to be withdrawn from circulation. Today, in the EU it is allowed to grow two types of GM crops: corn-resistant insects Monsanto MON 810 and herbicide-resistant corn T25 Bayer Crop Science. Only the first variety is actively used in agriculture. Beginning in 1998

In the year, no new type of biotech grain was allowed into the EU market for cultivation. At the moment, there is a process of updating the data of two approvals[53]. Cotton approved only for use in food and fodder, sugar beet too. Soya, cotton, sugar beet and rape are approved for use exclusively in food and feed (authorized importation and processing, but not growing).

Labeling of GMO

The main objective of labeling GMO products is to provide consumers with the necessary information for selecting GMO products and common products. In general, labeling of genetically modified organisms may be voluntary and obligatory. In the case of mandatory labeling, the object of the rules is the presence of GMOs in finished products (only products where traces of GMOs are found to be labeled) or GMO technology as a production process, where any product is derived from GMOs to be labeled, regardless of whether it contains GMOs or none[54].

The EU has imposed strict binding standards for marking[55], and its system is based on the process production, rather than on the product and includes a wide range of products with a small amount of exceptions and a very low threshold. In addition, there are voluntary rules in the EU concerning the labeling of products without GMO[56]. EU labeling requirements apply for foods, feeds, nutritional supplements, flavor enhancers, foods, based on GMOs, as well as food products trading networks and restaurants[57]. According to EU legislation, labeling subject to:

- GMO products that are GMOs or consist of GMOs (this may be, for example, tomatoes or GM salmon);

[52]The register is established in accordance with Regulation (EC) 1829/2003, Accessible: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm, 14 March 2018

[53] In accordance with Article 17 of Directive 2001/18 / EC, after filing an application for renewal of the permit, the company may continue to place GMOs on the market under the terms of the previously issued permission to acceptance of the final decision on renewal.

[54] More details on labeling GMOs: G. Gruere and S.R. Rao, A review of the international labeling policies of Genetically modified food to evaluate India's proposed rule, AgBioForum 2014

[55] EU first introduced GMO labeling in 1997. In April 2004, new labeling requirements entered into force.

[56] 47 In February 2008, Germany approved the GMO mark in a new biotechnology law. Except in Poland and Sweden, there are local regulations on the "no GMO" sign.

[57] 48 In the case of gastronomic properties, food and beverages should be labeled if they are made up, whether it's a month or produced from GMOs. Such products should be allocated to the end consumer I saw whether the menu or the buffet is a distinguishing sign. But there are several exceptions for dining.

- products, ingredients or additives produced from GMOs (eg, oil from GMO soy or canola, sugar - from GMO sugar beet, lecithin - from GM soya, starch - from GMO corn);
- products, ingredients or supplements containing GMOs (this may be, for example, yogurt with GM bacterium or wheat beer with GM yeast);
- feed produced from GMOs

The main categories of products that are not subject to mandatory labeling are meat and animal products derived from animals that have been fed GMO feeds. Such products are considered products produced by GMOs. Also, not labeling is required for supplements, flavor enhancers and vitamins manufactured for with the help of GM microorganisms (such as vitamin B2 - riboflavin or aspartame, which is used as a substitute for sugar), provided that the GM microorganisms are absent in food and / or supplements. The labeling is not subject to products whose GMO content is less than 0.9%. Threshold level[58] is established by Article 12 (2) of Regulation 1829/2003 on genetically modified organisms modified food and feed, refers to the percentage of "ingredients a product that is considered separately or a product consisting of one ingredient". The threshold level is valid only for GMOs approved in the EU (i.e. recognized as safe) and if GMOs are accidentally or technically exposed inevitably). In the case of deliberate mixing of GMOs, marking is always required. This labeling approach requires the existence of a GMO tracking system as well as GMOs food products and feed produced from GMOs at all stages of production, processing and distribution. Regulation 1830/2003[59] introduced this a system that is mandatory for all manufacturers and suppliers of products food and feed that must ensure that information on GMO products and products produced from GMOs, as well as a unique identifier, assigned to each GMOs (code helping to identify GMOs) are provided in writing to operator's markets receiving this product (Articles 4 and 5 of the Regulation).

It should be noted that the deliberate use of GMOs in organic farming banned in the EU. In accordance with Article 9 (1) of Regulation 834/2007 of 28 June 2007 Organic production and labeling of organic products, GMOs and products, produced by GMOs or using GMOs are not used as products food, feed, technological additives, plant protection products, fertilizers, soil remediation, seeds, materials for vegetative reproduction, microorganisms and animals in organic production. However, insignificant traces of GMOs in organic products are allowed. Acceptable level is accidental or technical inevitable content of GMOs in organic products is set at 0.9%, as

[58] Setting a threshold level is necessary, given the fact that during the production process, transportation and processing of agricultural products, mixing / mixing between different fields and batches of goods is difficult to prevent. As a result, even if it was planned that the product GMO does not contain GMO traces.

[59] Regulation 1830/2003 on the control and labeling of genetically modified organisms control of food and feed produced from GMOs.

for ordinary products. This means that the organic products, which GMO does not reach of this level, are not subject to mandatory labeling.

2.2United States Regulatory System

The American approach to genetically modified organisms is based on the product, as well not in the production process and considers biotechnology to be safe in nature, and its products as not differing from unmodified products[60]. As a result, in the US, no separate GMO law has been adopted and is being used the legislation that was adopted for conventional products. So, GMO is regulated by The Plant Protection Act, the Federal Law on Food Products, and Medicines and cosmetics, the Federal Law on Insecticides, Fungicides and Rodenticides and The Law on the Control of Toxic Substances. In the United States[61], there are three federal agencies: The Office for the supervision of food US Food and Drug Administration (FDA), Department of Agriculture, USA (USDA), the United States Environmental Protection Agency (EPA), are endowed powers to regulate GMOs. Their usage obligations individual products are set by the Federal Regulatory System for Biotechnology that operates since 1986. Under this system, the USDA regulates the cultivation of GMO plants in accordance with the Plant Protection Act. EPA regulates pesticides according to Federal Law on Insecticides, Fungicides and Rodenticides (FIFRA) and Federal Food, Drug and Cosmetic Act (FFDCA), also GM microorganisms in accordance with the Law on the control of toxic substances. FDA regulates the use in food and feed of all products made from GMO plants. In addition, each department has been published rules specifying in which part of their mandate they cover GMOs, as well as guidelines for enterprises for GMOs.

USDA-APHIS regulates the introduction into the environment of GMO plants and other GMOs, which may pose a threat in the epizootic sense. These GMOs are called "Regulated products"[62], their introduction includes import, intercity transportation and release into the environment.

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[60] Hallman, W. K., Hebden, W. C., Aquino, H.L., Cuite, C.L. and Lang, J.T. (2003). Public Perceptions of Genetically Modified Foods: A National Study of American Knowledge and Opinion. (Publication number RR-1003-004). New Brunswick, New Jersey; Food Policy Institute, Cook College, Rutgers - The State University of New Jersey., Accessible: https://ageconsearch.umn.edu/bitstream/22058/1/sp03ha05.pdf , 10 April 2018

[61] McHughen A, Smyth S. (2008). US regulatory system for genetically modified [genetically modified organism (GMO), rDNA or transgenic] crop cultivars. Plant Biotechnol J, 6, 2–12.
Moynihan Maura (1994). "The European Biotech Directive -- An End in Sight?' Patent World, 24 at 26.

[62] According to USDA-APHIS, a regulated product is a genetically engineered organism (through technology of recombinant DNA) from the donor organism, recipient organism, vector or vector agent that is the pest contains harmful substances for the plant. Other genetically engineered organisms can be regulated products, if they have been genetically engineered using unclassified or if the director of the Biotechnological and Scientific Service (BRS – APHIS program) indicates that A genetically engineered body is an adjustable product.

USDA-APHIS approves biotechnology tests crops in accordance with the permit procedure or the notification procedure[63] was introduced for tomatoes, tobacco, corn, soybeans, cotton and potatoes as an alternative to a permission in 1993, which is four years later, it also began to apply to all non-planting plants "Regulated toxic weed"[64] and storms in the territory of release of GMOs in environment. In practice, about 90% of tests are approved Notification[65]. In accordance with this procedure, the company that plans to conduct the test in the open system, simply inform USDA-APHIS about the place carrying out of harvesting and characteristics of GMO plants. In case of agreement agency of compliance with the planned release criteria for the notification procedure, a letter of confirmation is sent to the applicant, which means the opportunity to start the trial. The entire procedure lasts up to 30 days[66] from the date of notification, including 5 days for comments to the appropriate state body where it has to pass the test. Agreed notification is valid for a year from the date coordination.

As a rule, permission is required for GM plants requiring more severe control, for example, for use in pharmaceuticals and industry[67]. The procedure is more stringent than notifying, and therefore requires more time to review. The plant developer applies for the approval of the test to the USDA-APHIS. The statement contains certain information based on which the decision is made on the permission to open system test. This information contains information about biology The GMO plant under consideration is the way in which genetically modified is obtained a plant, information about the potentially harmful properties of the plant, a test plan (location, size and duration), as well as measures to restrict distribution culture and its utilization after the test[68]. Deadline for review and statement the USDA-APHIS decision is 120 days[69] from the filing date. First, the preliminary assessment is done. After that, the application and preliminary assessment are submitted to the agricultural authority questions about the state where the planned tests will take place. This body is within 30 days gives his comments, in particular, that he may recommend additional terms test, however, these comments have no binding character for USDA-APHIS,

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[63] See the USDA-APHIS Recommendation on Notification from May 2008, Accessible: www.aphis.usda.gov/brs/pdf/Notification_Guidance.pdf , 10 March 2018

[64] The list of relevant species of these plants is constantly updated by USDA-APHIS. Management explains Notification as a quick procedure for authorization of biotechnological plants that are considered as plants lower risk and in relation to which management has extensive regulatory experience in the past.

[65] Michael Taylor, Jody Tick, Diane Sherman, Tending the fields: state and federal roles in the oversight of Genetically modified crops, PEW Initiative on Food and Biotechnology, December 2004

[66] 10 days for notification of import and inter-state transport.

[67] See APHIS recommendations for permission for carcasses or carriage of organisms that used in Pharmaceuticals and Industry in 2008 Accessible: www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf. 1 March 2018

[68] From: Michael Taylor, Jody Tick, Diane Sherman, Tending the Fields: State and Federal Roles in the Oversight of Genetically modified crops, PEW Initiative on Food and Biotechnology, December 2004

[69] In the case of environmental assessment, APHIS makes a decision within 180 days. If granting of permission for import and interstate transportation, the term of consideration is 60 days.

which accepts the final decision to approve or reject the application about testing the trial should begin within one year from the date of submission permission. It should be noted that the authorization and the notification procedure are also used to approve the import and intern mental movements of biotechnological plants. During the trial, the applicant must comply with all the conditions provided approval. USDA-APHIS is responsible for carrying out inspections to ensure this matching. The management is trying to control at least 10% of the notified tests and all tests for which permissions are obtained[70]. In case[71] of violation conditions of testing, the management may issue recommendations for correction or written caution, or to start a lawsuit against the applicant. Tests and their control by the USDA are the main features of the US system, therefore that it is based on the test results that a decision is made on whether to provide the plant has a status that is "not regulated", which means permission for it commercial use. The cultivation of such plants is not controlled by USDA-APHIS (no additional permits or notifications are no longer required). When the developer of the plant has gathered enough evidence to confirm its harmlessness, agriculture and the environment, he can file a petition for "status determination" as such is not regulated "(cancellation of state regulation) of a plant[72].

First, USDA-APHIS is considering a petition that, among other things, should include the relevant experimental data and work. After that, the scientific information provided is evaluated the developer of GMO plants, regarding the implications of introducing GMO plants for the environment and its impact on endangered species, and those that are under as well as the impact on useful non-target organisms. Assessment of the impact on the environment the medium is published in the Federal Register together with the notice on receiving public comments on the petition and its evaluation. In the end, USDA-APHIS recognizes that the plant under consideration does not cause more damage, compared to equivalent to non-GMO organisms[73], and the plant becomes regulated. The Office publishes the "definition of status as non-regulated" in The Federal Register. The period of full consideration of the petition is 10 months and longer. In the future, USDA-APHIS does not monitor plants with this status. In the case of USDA-APHIS consideration of plants modified for production pesticides (for example, Bt cereals), pesticide substances[74] (eg,

[70]Michael Taylor, Jody Tick, Diane Sherman, Tending the Fields: State and Federal Roles in the Oversight of Genetically modified crops, PEW Initiative on Food and Biotechnology, December 2004

[71] McEowen, Roger A. (2015). "Developments in GMO patent infringement cases," Decision Maker Newsletter: Vol. 8: Iss. 9, Article 2. Accessible: http://lib.dr.iastate.edu/agdm/vol8/iss9/2, 3 April 2018
Accessible: www.aphis.usda.gov/brs/pdf/usergen8.pdf , 12 March 2018

[73] Grossman Margaret Rosso (2003). Genetically modified crops in the United States: federal regulation and State tort liability Env. L. R, 5(2), 86-108

[74] EPA calls pesticides derived from GMO plants "plant protection products" (PIP).

Bt toxin) also subject to ERA risk assessment[75]. This assessment under normal conditions lasts for 18 years months or longer and is concentrated on toxicology, food perception and allergic potential of the pesticide under consideration. Message is posted to The Federal Register with the involvement of the public to discuss it. If ERA determines that the pesticide does not cause unnecessary harmful effects on health humans and the environment, a pesticide is recorded that allows it commercial use in the environment.

According to FFDCA, the EPA is responsible for determining the permissible limits for pesticide residues in food. However, a possible deviation from the established limits if it is proved that security standards can be respected, even in the event of such a deviation. Today, such an exclusive status has 11 Bt proteins EPA then approves tests for pesticide plants in a larger than 10 area acre using the Experimental Use Permit (EPU). The purpose of EPU is to collect the necessary data for registration not yet registered for use of pesticide. Public Notification of the approved EPU is required by Federal Register.

According to the FFDCA, the FDA is empowered to request a pre-market review and approval of any nutritional supplements to protect the health of the population. The term "food additive" refers to non-pesticide substances and do not have the GRAS status ("generally recognized as safe"[76] qualifications scientific experts). In such cases, food manufacturers have scientifically substantiated that the new substance in food is safe. Currently, the market monitoring of GMO products was conducted only once in 1992 for counteracting the gene marker Kanamycin tomato variety Flavr Savr. After security assessment of the genetic material that was added to the tomato, the FDA stated that given tomato is essentially equivalent and safe as a regular tomato. and granted permission to its commercialization. This is the first product that was commercialized in the United States, however subsequently withdrawn from the US market in 1996 due to concerns about its safety the FDA's primary tool for product safety is voluntary donor consultation procedure on the use of GMOs in products food[77]. The reason for such a loyal approach (voluntary nature) lies in because the FDA relies on the food industry's commitment to manufacturing and selling safe food (also safe GMO products food) in accordance with the general legislation on product safety food. In accordance with the consultation procedure, food producers provide management with a

[75] Slovic, Paul (1987). 'Perceptions of Risk', Science 236: 280-285 Accessible: http://www.jstor.org/stable/1698637 April 14 2018

[76] According to US law, a substantiated GRAS substance must be sufficient the number of published works (or equivalent), and there must be a preponderant majority among them scientific circles about product safety.

[77] In 2001, the FDA proposed to make the notification process binding. "Premarket review of the bioengineering product, "the FDA required notifications of GMO product manufacturers' visas feeding at least 120 days prior to their commercial distribution, obtained from bioengineering plants intended for human and animal consumption. However, this initiative has not been proven by the end of.

conclusion on the properties of its GMO product. These actions are available voluntary, and the FDA does not make any additional evaluations. This is voluntary nature does not stipulate any requirements for notification in the Federal Register or public discussion. The FDA does not grant permission / approval, but only informs manufacturer who has no additional comments on the data received and reminds him about the commitment to sell safe food. FDA regularly publishes a list of completed consultations containing the name of the manufacturer, entered product property, source and description of all introduced genes, and year of completion consultations, it may happen that the FDA acknowledges during the consultation process a product that contains nutritional supplements and in this case, will require a separate permission before placing on the market (pre-market inspection).

In 2006, the FDA introduced a special procedure for new proteins (excluding pesticides) in new plant species that are used in food industry[78]. It is anticipated that plant developers will inform the FDA regarding the safety of new proteins at a rather early stage of research. The purpose of this procedure is to evaluate the protein before the development stage, where it can accidentally get into food products. In general, the concept of "new protein" covers any protein that is not a pesticide and is part of a new variety of plants that is new for this type[79]. However, the procedure is voluntary. The FDA advises the developer, who collaborated with the agency on new protein, to participate in the process FDA consultations, since this procedure allows for a thorough evaluation food safety.

Thus, in the United States, the authority for products depends on a particular method their use, and some products are regulated by more than one control. Bt Corn is an example of a product that is regulated by three departments. USDA is considering Bt corn as a regulated product, until it receives the status of "no subject to regulation "of the product. The EPA considers Bt as a pesticide, so the developer of this product must register it at EPA. After all, the developer can consult the FDA with a voluntary consultation procedure product safety.

Labeling of GMO

In the United States, there are no special requirements for labeling GMO products as a separate class because GMO products are not considered to be less safe than ordinary products[80]. However,

[78] See FDA Industry Guide - Recommendations for early evaluation of food safety new pesticide-free proteins derived from new plant species for use in products Eating out in 2014 Accessible: www.cfsan.fda.gov/~dms/bioprgu2.html , 14 March 2018

[79] Or the natural protein of plants, produced in substantially larger quantities, or natural protein, a part of a plant that under normal conditions is not consumed in food, and will be used as a part plants that are consumed in food and which was not the subject of completed biotechnological research either completed FDA food safety assessment.

[80] "The FDA has no reason to argue that the bios-invented food products vary considerably

GMO products are subject to mandatory standards markings requiring the labeling of any products that result in particular risks to health and the environment. It may be, such as the presence of allergen or changes in food properties. In this case the product label must be true and not mislead the consumer. If, for example, there is a new product, for example, an allergen, the contents of which consumers do not know, then the information on it should be on the label. If the GMO product is different from its not a GM equivalent so that the common or common name is definitely not describes it, it needs to be changed. FDA publishes voluntary recommendations for marking GMOs and non-GMO products. According to some estimates, almost 75% of food produced in the United States contains some GM ingredients[81]. It should be noted that US national standards for organic products have been established USDA, exclude genetic engineering from organic farming.

from other food or that the food obtained with the use of new technologies is of greater interest to the question of safety than food derived from traditional crop production. " From the Draft Recommendation on voluntary labeling of products that are invented or not invented by the Biosphere, 2001

[81] Margaret R. McLean An Introduction to the Ethical Issues in Genetically Modified Foods *Santa Clara University April 15, 2005.* Accessible: www.scu.edu/ethics/practicing/focusareas/medical/conference/presentations/genetically-modified-foods.html , 5 Mrach 2018

3. UKRAINE'S CHOICE IN REGULATING GMO: BETWEEN EU AND US

3.1 Between regulatory systems of EU and US: Ukraine's choice

To put it simply, the issue of GMOs and their permissions relates to access to the market. The regulatory regime can severely restrict access to the foreign market products, so the US is challenging the EU regime on GMOs. But while he is not revised, foreign products (US, Ukraine) must meet internal requirements EU[82], including those relating to the criteria for granting permits and limits for the presence of GMOs to gain access to the market and further expand its market share. The more intensive the trade is[83], the greater the need for compliance standards of trading partners. Ukraine aspires to EU membership. Obviously, the path to membership implies closer ties trade ties, investment and economic cooperation between Ukraine and the bloc.

The EU is one of the main importers of Ukrainian agriculture products. The EU uses imported soybeans to produce oil products food, nutritional supplements and ingredients, cattle feed. Corn also used as livestock feed. Rape is used for production biodiesel. The United States is not important for Ukraine as an import market, because they themselves are the world leader in corn, soybean and rapeseed production.

As for the EU market, if the GMOs are not allowed by the EU are found in the batch of imported the EU may apply protective measures, starting with additional requirements testing and certification and ending with a temporary suspension of import problem product in case the consignment contains GMOs, but only those authorized in the EU, they must be appropriately marked. If, for example, Ukrainian corn, one of the main export grain types of Ukraine will contain GMOs, as in the case with soybeans consumed in the domestic market, the country may come across serious problems during export to the EU. Moreover, it is very likely that corn which does not contain GMOs will also not be accepted if it is not used appropriate measures: GM pollen should not be a fertilizer for plants, but GMOs and not GMOs products must be isolated from each other during transportation.

Although EU GMO legislation has so far had a very limited impact on Ukrainian exports, opportunities for economic growth can to face serious threats in the future. Thanks to increase in

[82] Grossman, Margaret Rosso (2009). Protecting Health, Environment, and Agriculture: Authorization of Genetically Modified Crops and Food in the US and the EU, 14(2) Deakin Law Review 257-304, Australia

[83] Jackson Lee Ann (2005). What's behind GM food trade disputes? 2009, World T.R., 4(2), 203-228

domestic production Ukraine has a large share in exports other agricultural products, if the EU remains one of the main import markets of Ukraine, it has to take care of the conformity of its products requirements of the EU. Consequently, economic reasons suggest the choice of the EU approach to GMO path to EU membership also requires the incorporation of the acquis communitarian[84] - all areas, which are legally harmonized at the EU level. Harmonization means that the law was created at the EU level, and EU member states no longer make decisions on the issue individually. In fact, they are losing their autonomy in this area. As described above, the issue of GMOs is a harmonized zone, and the EU member state may deviate from European Commission decision on GMOs only if it provides new scientific conclusions (safety note).

In the Partnership and Cooperation Agreement of 1994, Ukraine has already promised to bring it closer its legislation to EU norms, especially in the priority areas that are listed in Art. 51[85]. Legislative approximation to EU norms is also stipulated by Law No. 1629 of March 18, 2004 "On the National Program of Adaptation of Ukrainian Legislation to the legislation of the European Union "; there is also a separate Department in Ministry of Justice of Ukraine, which deals with adaptation of legislation (State Department for Adaptation of Legislation). Ukraine has already reached significant progress in this direction. Ukraine is expected to intensify its efforts to establish an in-depth free trade area with the EU. The problem of the lack of a regulatory framework for GMOs is explicitly mentioned in the Presidential Decree No. 1072 of September 14, 2000 "On the Program of Ukraine's Integration into European Union ". This document provides a number of mechanisms to be applied in Ukraine in this aspect, including the development of regulations to be consistent with relevant EU laws.

Nine years later, several aspects of the Ukrainian regulatory system for GMOs were brought into compliance with EU requirements, in particular:

1) In 2002, Ukraine ratified the Cartagena Protocol, a great supporter which is the European Union[86]. That is, Ukraine took a precautionary principle like the basis of its approach to GMOs;

[84] EU Legislation to be adapted by candidate countries for EU membership. Per: summary the main norms and requirements of the EU.

[85] Partnership and Cooperation Agreements read: "Approximation of laws has to be extended on such areas, especially on: the customs law, the law on enterprises (companies), banking laws, accounting and taxes in companies, intellectual property, protection of workers in the workplace, financial services, rules of competition, public procurement, protection of the health and life of people, animals, plants and the environment, consumer protection, indirect taxation, technical rules and standards, nuclear laws and directives, transport ".

[86] It is expected that the Cartagena Protocol will have a greater impact on GMO trade than it once did impose responsibility for international trade in GMOs, in accordance with the decision made at conference by the parties who signed the protocol in May 2008 in Bonn. The plaintiff will be the one who has evidence that harm to biodiversity was caused by the use of GMOs. If successful plaintiff will be able to prove that he will be able to claim compensation

2) Like the EU, Ukraine has developed a special legislation on the use of GMOs;
3) Like in the EU, Ukraine's approach to GMOs is procedural (the product is considered GMO product, if production technology involves the use of GMOs on any stages of the production process);
4) Like the EU, Ukraine has introduced mandatory GMO labeling. The threshold for marking - GMO in the amount of more than 0.9% - completely coincides with the corresponding threshold of the EU. Moreover, as in the EU, non-food products GMOs, but produced using GMOs are to be labeled in Ukraine. As in the EU, in Ukraine provides for voluntary labeling of non-GM products.
5) Like the EU, Ukraine has introduced GM food and feed monitoring after their introduction on the market;
6) Ukraine has introduced mandatory public information on use of GMO Art. The 20th Law on GMOs guarantees the availability of this information to the public, and this complies with EU law. In addition, according to Art. 14 of the Law, the registers of GMOs and GMOs products should be published on the website of the responsible central authority and in the media. Only confidential information, according to Ukrainian legislation may be concealed. But the law clearly specifies that the information regarding the GMO's impact on human health and the environment can not in any case considered confidential. However, EU legislation is a step ahead: the EU should consult the public during the process of granting a GMO permit that offered to the market;
7) Finally, the planned changes and additions to the legislation on GMOs, the consideration of which is expected in the Verkhovna Rada, refer to the relevant EU norms. Example, Draft Law No. 3037 dated August 1, 2008 "On Amendments and Additions to Law of Ukraine "On the state system of biosafety during the creation, testing, transportation and use of genetically modified organisms "offers obligatory labeling of GMO products, tracking and risk classification.
8) Additionally, the implementation of Directive 98/44 / EC in the national legislation of Ukraine is stipulated by the Decree of the Cabinet of Ministers of Ukraine dated March 4, 2015, No. 164-p "On Approval of Plans of Implementation of Some Acts of EU Legislation Developed by the Ministry of Economic Development and Trade."

from who has been harmed by this damage. Specific provision as an annex to art. 27 protocols should be prepared for the next conference in Japan in 2010.

The question of tracking, which is one of the most important components of regulation in the EU, put up for the first time. It should be noted that the introduction of tracking system will increase the ability of Ukrainian food producers to capture and to expand the market share in the EU.

As you can see, Ukraine has already used important elements of the EU regulatory system GMO, the first three, listed above, are especially important as they are the basis for the relevant legislation. Introducing a precautionary principle and development special legislation means that Ukraine does not accept GMO products the same safe as well as non-modified. In the end, the GMO regulation is based on the production process itself creates important prerequisites for the introduction obligatory marking of GMOs. From this it follows that to this day Ukraine tried to go through the EU, at least at the level of legislation. Most likely, the rules for marking GMOs and their compliance will serve litmus test paper to confirm Ukraine's aspiration to follow the EU. Mandatory labeling of GMOs is one of the most important elements of EU policy on GMOs, and in the United States there are no mandatory GMO labeling requirements. Marking proposed in Ukraine in 2007, was in line with EU norms regarding it mandatory character and threshold, but was canceled by the Cabinet of Ministers, and since then has not been introduced again. Difficulty with introducing mandatory marking illustrates the existence of disputes between Ukrainians executive and legislative authority (lobbyists and business sector) on GMO issues. Introduced in 2009, the marking is in line with the EU mandatory standards character and threshold value. Whether Ukraine will adhere to the decisions on these issues depend to a large extent on the choice of the appropriate model: the EU or the United States. At present, the EU model prevails in Ukraine, at least in the legislation. But open the question remains about the completeness of political will to make the necessary legislation and enforcement. In particular, it is necessary to introduce monitoring system and equip new laboratories. The Union, which affects trade relations between the EU and the leading exporter of transgenic products, is the United States. At the same time, 35 countries have adopted laws or regulations on the mandatory labeling of products containing transgenes. The Cabinet of Ministers of Ukraine dated August 1, 2007, No. 985, which provided for the mandatory labeling of food products, was temporarily canceled. In connection with the entry of Ukraine on February 4, 2008, the issue of marking of transgenic food products will again arise in the WTO. The Law of Ukraine "On the State Biosafety System for the Establishment, Testing, Transport and Use of Genetically Modified Organisms" No. 1103-V dated May 31, 2007, criticizes the fact that the scheme for the implementation of its separate provisions is unclear and confusing the work and interaction of various bodies central executive power. Therefore, it is necessary to rationally approach the division of responsibility between state authorities and research centers (first of all, the institutes of the National Academy of Sciences of

Ukraine and the Ukrainian Academy of Agrarian Sciences) concerning cooperation in the creation, testing, registration and use of genetically modified organisms).

First of all, it is necessary to determine at the state level the use and distribution of GMOs. The prohibition on the use and distribution of transgenic plant varieties in Ukraine should be in line with market economy conditions. The implementation of certain provisions of the Law on Safety should not mean automatic and uncontrolled permission to use transgenic plants and their ingredients after the formal registration procedure. The state (including the Ministry of Agrarian Policy) must know which GM varieties and which crops, on which fields and on what scale they are grown and for what purpose, and after accurate and complete information about this, to make an informed decision about the future strategy of behavior. It is necessary at the expert level to determine which varieties of transgenic varieties and with what signs are needed in Ukraine and whether they are needed at all, where and to what extent the state is ready to enter depending on the world's producers of seeds, and where to maintain their own breeding science, including the creation of their own GM varieties. A significant part of the domestic market of varieties.

3.2 Exclusion of patentability biotechnological inventions under Directive 98/44 EC based on public order and morality

Ethical issues and case laws on patenting living forms

One more very important aspect is the ethical question arising from the society – whether patenting and adopting the legislation to the requirements of the EU is worth it. Although in Ukraine people are not aware of the GMO inner workings, however it is rather perceived negatively by the society. That can be explained due to the overall Orthodox Religion Institute in Ukraine that has a big influence on the mass society and prohibits puts any form of interaction with subjects that were created artificially[87] (meaning – not created by the power of the Lord).

To justify whether or not patenting of the living forms is ethical, we can refer to the very beginning of the GMO patenting. The first patented object, obtained on the basis of human material, in 1906 was the hormone adrenal adrenaline. Almost immediately, the possibility of issuing such a patent was contested in court. The process of Park-Davis versus Mulford (Parke-Davis versus Mulford)[88]

[87] Hitchcock Julian (2014). Should patents determine when life begins? E.I.P.R., 36(6), 390-398

[88] Jon M. Harkness. (2011) "Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in Parke-Davis v. Mulford" ExpressO Accessible: http://works.bepress.com/jon_harkness/1/ , 13 March 2018

for a long time was considered the first precedent that raised the question of the legitimacy of obtaining exclusive rights to use something created not by man, but by nature. However, detailed analysis of historical documents showed that decision that dedicated and purified adrenaline is no longer a creation of nature, but a product created by man (and therefore it is subject to patenting) was not made in the course of the process. In reality, the essence of the litigation was reduced to the conflict between the two producers, which almost simultaneously produced very similar drugs on the market. Nevertheless, they are very fond of referring to this process in discussions about how justified and reasonable the practice of patenting of bio objects is.

The first patent[89] for deoxyribonucleic acids was obtained in 1980: Stanford University affirmed the right to use the technology developed by Stanley Cohen and Herbert Bauer Laboratories to create recombinant DNA, which allowed making various changes in the genomes of living organisms.

In the same year, the famous Diamond versus Chakrabarty process took place, following which the US Supreme Court decided that living organisms could be subject to patenting if they were changed by a person. The reason for the proceedings was a patent obtained by the American microbiologist of Indian origin Ananda Chakrabarty on the genetically modified bacteria Pseudomonas he created, which could split the crude oil. Different instances made decisions in favor of the scientist, then against him, but the final verdict was significant for future processes.

The court's conclusion (adopted by five votes to four) stimulated the boom of patenting all sorts of genetically modified organisms: from viruses and bacteria to plants, animals and cell cultures. The last step was the patenting of genes - DNA sections, encoding those or other proteins of the body[90].

One of the most famous processes involved in challenging the rights to cells was the John Moore process against the University of California[91]. In 1976, Moore was diagnosed with a rare type of leukemia and, in order to save his life, removed the spleen. Doctor David Gold managed to get a line of cancer cells from the diseased organ, capable of endless division and received a patent for it. Cells became popular among biologists and clinicians, who acquired a line from patent holders.

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[89] Deoxyribonucleic acids patent, Accessible: http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4237224.PN.&OS=PN/4237224&RS=PN/4237224 , 14 March 2018

[90] Gryson, N. (2010). Effect of Food Processing on Plant DNA Degradation and PCR-Based GMO Analysis: Analytical and Bioanalytical Chemistry, 396, 2003-2022 Accessible: http://dx.doi.org/10.1007/s00216-009-3343-2 , 26 April 2018

[91] John Moore, v. The regents of the University of Califoria 51 Cal.3d 120, July 9, 1990, Accessible: https://patents.google.com/patent/US4438032 , 12 April 2018

Moore tried to challenge the extradition of this patent, but the court found that his claims were not substantiated.

It wasn't soon until the regular people that are far from biotechnology, found out that their genes had long belonged to someone, in the early 2000s, when the processes on patents for the BRCA1 and BRCA2 genes began. Mutations in these genes significantly increase the risk of breast and ovarian cancer in women. Biotechnological and diagnostic company Myriad Genetics in 1998[92] and 2000[93] respectively patented these two genes, as well as their mutant variants and methods for detecting mutations. And already in 2001, the laboratories engaged in diagnostic testing for changes in the BRCA genes received letters demanding the termination of all work or the payment of Myriad's due deductions.

Addressees of letters, as well as human rights and public organizations with such a statement of the issue did not agree and filed a lawsuit against the company. The trials lasted for many years, with most of the decisions being made in favor of Myriad. The plaintiffs persistently challenged the verdicts, and another round of hearings ended on August 17, 2012. The Court of Appeal reiterated that the patent rights of the biotechnology company for the BRCA1 and BRCA2 genes are legitimate.

The idea of assigning rights to someone's genes looks wild and, moreover, the laws of most countries explicitly forbid patenting what was created by nature (and the laws of nature too). These arguments have been repeatedly voiced in the courts and public discussions, but so far the patent lobby has successfully repelled all attacks. Arguments of those who believe that the rights to use genes within us or whole living organisms can be staked out with the help of any documents are not devoid of logic and even some grace.

Even though under the religious matters the patenting of living forms[94] might not be justified, however there are a lot of doubts in the society whether patenting living forms can cause the patenting of useful inventions and cause major troubles in legal aspect. To clarify, one thing that can be done is the educating the people on GMO, e.g. it can be justified that man introduced certain changes in the genomes of the creatures (most often patents are obtained for genetically modified organisms), hence, in nature they do not exist, but are the creations of people. This consideration was used even at the time of Louis Pasteur: in 1873 he patented the yeast strain, saying that "yeast

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[92] Gene patents by Myraid Genetics, Accessible: https://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=5747282&KC=&FT=E&locale=en_EP , 12 March 2018

[93] Ibid Accessible: https://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&II=23&ND=3&adjacent=true&locale=en_EP&FT=D&date=20000307&CC=US&NR=6033857A&KC=A , 13 March 2018

[94] Wells Angus J. (2004). Patenting new life forms: an ecological perspective, 2004, E.I.P.R. 2004, 16(3), 111-118

free from all parasites and infections is an industrial product.[95]" In the opinion of the proponents of the alienability of the rights to use biological objects, the basic US patent law is on their side, in paragraph 101 of which (in the interpretation of the American Congress[96]) it is asserted that the object of patenting can be "everything that is under the sun and created by man."

While in Ukraine we are not having any cases of granting patents to GMO, it is commonly used in Europe and US. By 2005 it was a formed trend[97] that the patented DNA fragments are extremely unevenly distributed across the genome: areas with unknown function or genes not related to health are of no interest to anyone, and to the other pieces of the genome there are already two dozen patents. The record holders of BMP7 and CDKN2A genes were the number of papers issued on them. The product of the BMP7 gene is a so-called osteogenic protein that can stimulate the formation of cartilage and bones, and the protein encoded by the CDKN2A gene suppresses tumor growth. In the case of gene sequences encoding pharmacologically important targets, as well as with the three-dimensional structures of the target proteins themselves, the potential of the usefulness is quite obvious: this includes diagnostics, the development of new drugs and much more. The burden of proving utility lies with the applicants, and if, for example, the US patent office recognizes that the application has novelty, non-obviousness and utility, there is no reason not to issue a patent.

Companies that own such patents for me significant DNA fragments can set any prices for the diagnosis of the corresponding deviations. In its appeal issued after the announcement[98] of the next verdict of the court in the case of Myriad Genetics, the firm stresses that the prices for analyzes of mutations in the BRCA1 and BRCA2 genes are not "prohibitive" at all. In numerical terms, this means three thousand dollars for analysis (in the US). The test can partially or completely cover medical insurance, but not all companies agree to include this analysis in the proposed package.

This hinders the research on the effect of the genetically modified organisms and their effect on the environment and human body.

Such tensions are creating the “villain” perception for the average people. The assume that big corporations are hiding the information, while on practice patenting[99] of some living forms by

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[95]Patenting the yeast strain, Accessibel: https://www.uspto.gov/sites/default/files/web/offices/com/sol/notices/utilexmguide.pdf , 14 march 2018

[96] Alienability of the rights to use biological objects, paragraph 101, US Law, Accessible: https://www.uspto.gov/sites/default/files/web/offices/com/sol/notices/utilexmguide.pdf , 16 March 2018

[97] Deacon Charles A. & Emilie K. Paterson (2001). Emerging Trends in Biotechnology. Litigation, 20 Rev. Litig. 589-622

[98] Appeal of the verdict of the court for Myraid Genteics, Accessible: http://investor.myriad.com/releasedetail.cfm?ReleaseID=700880 , 11 March 2018

[99] Crespi, R. (2000). An analysis of moral issues affecting patenting inventions in the life sciences: A European perspective 2007 Science and Engineering Ethics, Vol.6(2), 157-80

business sector by patenting and revealing the patent details help scientist all over the world to build more researches on the topic, therefore stimulating safer environment.

Regarding the Ukrainian case law, there was no cases on the patents so far. Post-Soviet countries including Russia are "playing it safe" due to the lack of research laboratories and finances to integrate for the conducting of more long-term resources.

Regulating the ethical issues under Directive EU 98/44

As far as the directive itself is concerned, it is also necessary to understand and analyze the most controversial rules of the EU Directive 98/44 and their implications.

At the first consideration, it may be noted that the objects are traditionally divided into patentable patents and non-patentable inventions.

The directive contains a condition according to which the human body at various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a human gene, is not patentable in the invention[100], but is isolated from the human body or otherwise produced by a process, including a sequence or partial sequence of a gene, may be a patented invention[101].

That is, in accordance with the provisions of the Directive, the patentability of a biological element in patent and non-patent discovery, as well as the transformation of discovery in the invention, is conditioned by the isolation of such sentences from their natural environment and their production in a technological manner.

But one can point out the following contradictory points:

- the study of any object is possible only after its removal from the natural environment;
- if an element is considered to be isolated, it still retains its natural component;
- EU Directive 98/44 does not contain definitions and performance criteria which should be consistent with the ways in which isolation and production of biotechnological products are carried out, which requires a broad interpretation of the methods used in biotechnology.

It can be concluded from the foregoing that, in this way, the Directive leaves out of consideration whether the technical method is to meet the patents' criteria and, if there are not any conditions, for the product to be able to obtain the status of a patentable product in the result of such a process.

[100] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, p.14-18

[101] Ibid

In my opinion, it is also necessary to pay special attention to such an important point as an exception to the patentability, on the basis of moral.

The European Parliament rejected the adoption of the original version of the directive, which did not contain restrictions on the exclusion from the patentability of inventions on the basis of morality. The adopted text of the Directive includes a number of articles specifically devoted to the ethical issues of patenting biotechnological inventions.

Thus, on the basis of Article 6 of the Directive, inventions cannot be patented, the commercial use of which is in contrary to public order and morals. In clause 2 of Article 6 of the Directive there is also provided the non-exhaustive list of offenses that cannot be patented on the basis of public order and morals:

- processes of cloning human beings;
- processes of modification of the germline genetic identity of human beings;
- use of human embryos for industrial or commercial purposes;
- processes for the modification of the genetic identity of animals that can cause them suffering without significant medical benefit to humans or animals, as well as animals themselves, which are the result of such processes.

Article 6 of the Directive reverses the non-patent application of inventions whose commercial use is contrary to public policy and morals. It is logical to admit that it would be contrary to morality and the public order of the use of inventions, when the invention itself would be contrary to the morals and public order.

This position was also supported by all members of the EU in the patent convention[102], for example, the patenting of embryos for commercial use is controversial to public order and morality, and hence our claim is contrary to public order and morals. Since the laws do not contain the criterion of morality, the moral standards applied by the patrimonial agencies can be found in other branches of law. This is, first and foremost, the constitutional right which protects the basic rights and freedoms of citizens, establishes the basic principles of the right of the state[103].

However, it can be noted that in practice the reference to constitutional law is a rather complicated process, since the principles of constitutional law of different countries are based on rather different cultural and religious traditions. The patent specification for biotechnological inventions has already fluttered in the attitudes of EU Member State legislatures to the patenting of stem

[102] The Guidelines for Examination in the European Patent Office are general instructions, for the examiners working at the European Patent Office (EPO), Accessible: https://www.epo.org/law-practice/legal-texts/guidelines.html , 4 May 2018

[103] Plomer Aurora (2012). 'After Brüstle: EU Accession to the ECHR and the Future of European Patent Law' 2(2) QMJIP 110, 123-124

cells[104] (cell delivery to uninterrupted division and transformation into any cell of the body). The method of extracting such cells occurs at the embryonic stage of fetal development for about 4-5 days of life, resulting in destruction, which became the main cause of protests, which led to the prohibition of patenting in Germany and Denmark, as opposed to Sweden and the United Kingdom[105].

In this aspect, an important role is played by the message of the Directory itself on the enacting legislation of the EU member states, insofar as it introduces restrictions on the basis of morality: "In order to ensure that the ethics or moral principles are recognized in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of discoveries in this field and their inherent relationship with living matter; whereas such ethical or moral principles supplement the standard legal examinations under the patent law, regardless of the technical field of the invention; ".

In other words, Directive requires the correspondence between the exceptions from patentability on the basis of morality and public order established by the EU law and the right of individual EU member states.

According to this, it can be concluded that the adoption of legal parameters and guidelines for the interpretation of the concepts of morality and public order at the pan-European level is contrary to the Directive itself to require the interpretation of these concepts in accordance with the national law of each Member State of the EU. In my opinion, it is necessary to resolve the issue in favor of the preamble of the Directive through the following actuaries

- the criteria for the introduction of moral and public policy inventions should not be developed at the European level because of the lack of a commonly accepted values and the impossibility of artificially creating norms and standards for different legal systems
- the purpose of harmonization of EU law is to create a single market as a way to establish principles for the free movement of people, goods and services, but the quotation of notions in the sphere of morality, culture, religion belongs to the internal competence of the state itself.

One can conclude that the inclusion in the directive of an approximate list of inventions that cannot be patented on the basis of morality and public order is a rather unsuccessful attempt to extend the EU competence to interpret abstract and uncertain concepts of morality and public order.

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[104] Nordberg, Ana and Minssen, Timo, (2015). A 'Ray of Hope' for European Stem Cell Patents or 'Out of the Smog into the Fog'?: An Analysis of Recent European Case Law and How It Compares to the US IIC 2016, 47(2), 138-177

[105] Herrmann, J.R. and M. Rowlandson (2008), 'The Role of Ethics and Morality in EU Law', Journal of International Biotechnology Law, 5 (6), p.243

In my opinion, the function of patent law should remain purely for regulating economic relations and should not touch complex philosophical questions and try to establish their criteria, even if they directly or partially affect the rights and obligations of the subjects of such relations.

Taking into account the existing cultural and historical differences between the relevant provisions of their respective laws, harmonization within the EU framework in the framework of the establishment of unified patent exemptions is not an expedient and feasible task.

Summing up, one can say that the nuances of the Directives were due to the need to harmonize EU patent law in order to promote EU biotechnology excellence. Due to the complexity of the adoption of the Directive and, subsequently, the process of implementation in national legislation, the crash of the EU member states suggests that the European community is still far from accepting the phenomenon of "patenting biotechnological inventions"[106] for both ethical and socio-economic reasons.

Significant differences in national patent laws that are not eliminated today, despite the considerable pressure from EU institutions, confirm the need for a more balanced and detailed analysis of the developed norms in developing countries.

Ukrainian legislation should take into account the gaps and shortcomings described in the legal regulation of the patenting of biotechnological inventions in the EU. In particular, Directive would have been consolidated in Law of Ukraine on December 15, 1993 "On the protection of the rights to inventions and utility models", the prohibition of the patenting of sequences or partial sequences of a gene isolated from its natural environment. However, this does not mean that all the compounds that were subjected to genetic engineering maneuvers[107] should not be the object of patent protection in general. If as a result of such activity there will be substances of a material that differ significantly from natural ones, then they can be patented if other patentability criteria are met, and if their patenting is not recognized as contrary to the public order and morals.

The prohibition on the patenting of isolated sequences or partial sequences of the gene will be able to resolve the question of exactly where the boundary between patentability of inventions and non-patent discoveries occurs, thus making it possible to freely transfer valuable information contained in the genes to scientists, while encouraging inventive activity.

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[106] Plomer Aurora (2009). 'Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on. Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds), Embryonic Stem Cell Patents: European Law and Ethics 187-189

[107] Pew (2002). 'Environmental Savior or Saboteur? Debating the Impacts of Genetic Engineering' , Pew Initiative on Food and Biotechnology, Accessible: http://merid.org/en/Content/News_Services/Food_Security_and_AgBiotech_News/Articles/2002/02/04/Consumers_Evenly_Divided_Over_Environmental_Benefits_And_Risks_Of_Genetically_Modified_Food_And_Biotechnology.aspx , 4 February 2018 stem

3.3Problems in compliance of the Ukrainian legislation on GMO

Today, there is a lot of problems concerning the compliance of Ukrainian legislation on GMO to EU regulatory system. Firstly, for the population of Ukraine, there is no information on the quantity of seeds imported abroad, food products, and genetically modified ingredients. In fact, there is no control over the genetic nature of the products and the seeds imported on customs territory.

In Ukraine, it is illegal, but completely free to use soy concentrates and purified soybeans, feed additives in poultry farming. Parties import sweets, dairy products, other products, raw materials that are not checked for GMO content. In recent years, no product has been registered for the contents of the HMD. In 1997-1998, MONSANTO Corporation supplied about 400 tons of genetically modified potatoes to Ukraine. Under pressure from the public, the Ministry of Agrarian Policy prohibited in 1999 the industrial cultivation and sale of genetically modified potatoes and obliged Monsanto to dispose of produced potatoes, which, since September 1998, were lying in refrigerators, waiting for a landing permit in 1999. Genetically modified potatoes from five areas were brought in with. Note that experiments with genetically modified potatoes were carried out at the Ukrainian Potato Institute. After a month of storage, it turned into a yellow-brown mass. The reasons for this phenomenon cannot be called scientists. In spite of this, Monsanto continues to test the New Letter potato in Ukraine.

Officially, genetically modified crops are not cultivated in Ukraine, and, according to unofficial data, potatoes, corn, rape, soybeans are grown on private plots and small farms. A member of one of the centers involved in testing agricultural products, asking not to name his name, has unofficially confirmed this information: "Of course, we are genetically grown modified plants and soy, corn and rape. There are plenty of it. True, most of it goes to animal feed, and special panic do not need to grow".

According to environmentalists in stores, unmarked products containing GMOs are sold massively. Regarding the huge scale of the illegal distribution and use of plant and food products containing GMOs in Ukraine, there are sharp discussions in the mass media. There is no official information about it. Neither the government nor the Ministry of Agrarian Policy "On the state system of biosafety during the implementation of genetic engineering activities". In February 2002, it was adopted in the first reading with the changed title: "On state security system in the creation, testing and practical use of genetically modified organisms."

After that, the adoption of this law was delayed for 5 years. It came into force only on May 31, 2007. One of the reasons for delaying the adoption of this law is the lack of the required number of laboratories that could cover seeds, ingredients, and foodstuffs throughout Ukraine.

Only on January 15, 2007, a laboratory of molecular genetic research was set up in Kyiv to monitor food and food raw materials for the presence of GMOs, as well as develop a method for their determination, which spent 500 thousand UAH. Tests are carried out in accordance with international standards. The first test of 45 samples of food products (sausage wares, fish products, baby food products) showed that almost 50% of sampled supermarkets in Kyiv contained samples of GMOs.

The second laboratory, which was established at one of the Odessa research institutes, will not monitor the GMOs that are present in food and raw materials sold through retail enterprises to the population. She will conduct research on GMOs. Another reason for such a situation is the lack of funding, relevant scientists, trained for such work professionals. These circumstances, as well as others, can explain why the Resolution of the Cabinet of Ministers of Ukraine "Issues concerning the circulation of food products containing genetically modified organisms and / or microorganisms", which provides for mandatory labeling of food products containing more than 0,9% GMOs, and, in addition, it is prohibited to use GMOs in infant food products. Who and how it has to do is not defined. In order for this ruling to come into effect, it is necessary to have laboratory data on the content of GMO products. One laboratory cannot execute the order of the manufacturers of goods to carry out such definitions. It is known that analyzes are expensive and to carry out tests of such products, accredited laboratories have been tested and approved in accordance with the established procedure methods. No one, no other in Ukraine yet. The United States refuses to accept the Law on the labeling[108] of products containing modified genes and proposes to abolish the labeling as contradicting the provisions of the WTO, as well as to impose sanctions on European countries.

What is not in compliance?

Based on the analysis made above, it is possible to conclude that the level of the responsibility for the use of genetically modified organisms in Ukraine is not significant, namely:

1. National law does not contain a law that would regulate the legal status of the use, movement and control of genetically modified genital mutilation that is contradicting to Clause 2 of Article 2 of the Cartagena Protocol on Biosafety to the Convention on

[108] Goldman, Karen A. (2000)."Labeling of Genetically Modified Foods: Legal and Scientific Issues." Georgetown International Environmental Law Review 12.3, 717-60

Biological Diversity and does not oblige the effective regulatory legal form this sphere.

2. Based on the laws of Ukraine regulating the legal aspects related to food and creatures and safety, food manufacturers do not take into account the requirements of the Cartagena Protocol on Biosafety on Biological Diversity and the Directive No. 90/219EU of 23 April 1990 on the limited use of genetically modified organisms, contain no reservations regarding the use of GMOs (in the wording of Article 51 of the Law of Ukraine "On Creature Reception" No. 2894-W on December 13, 2001, which, however, is quite a sparse nature and has not found its solution). Among the laws of Ukraine in the investigated sphere, the highest coherence with the international and European legislation is only the Law of Ukraine "On Infant Nutrition" No. 142-V of September 14, 2006.
3. Despite the absence of its own law, in Ukraine, the basic elements of biosafety systems, concerning transgenic plants, have practically been formed. They include the Biosafety Commission under the Ministry of Education and Science (biological and environmental safety), the relevant structures of the Ministry of Health of Ukraine (sanitary and hygienic and nutritional assessment), and the State Commission of Ukraine for Testing and Protection of Plant Varieties of the Ministry of Agrarian Policy (testing and registration varieties). At the same time, the "Interim Procedure for the Import and Testing of Transgenic Varieties of Plants" (Decree of the Cabinet of Ministers of Ukraine of August 17, 1998, No. 1304) does not actually function, because it does not foresee the logical distribution of responsibility of the key ministries within the framework of state control over GMOs in Ukraine. For the further functioning of this system, it is necessary to streamline the interaction of these structures with the Ministry of Economic Resources.
4. Separately it is necessary to note the lack of development of the conceptual apparatus in the field of GMO use in national legislation, which requires the introduction of appropriate changes and additions to the laws of Ukraine that regulate the legal relationships in the researched sphere.
5. There are no norms in national legislation regarding which a person guilty of violating the order of safe transfer, processing and use of living organisms obtained in the process of using modern biotechnologies, which makes it necessary to introduce the corresponding changes in the Criminal Code of Ukraine and the Code of Administrative Offenses.

6. In Ukraine, there is no special authority for which the law would be responsible for exercising control over the use of GMOs, which contradicts the requirements of Clause 1 of Article 11 of Council Directive 90/219 of 23 April 1990 on limited use of modified organisms.

Harmonizing national law in regards to Directive 98/44 EC

Another valuable question is the compliance of the Ukrainian patent laws to European legislation that is still not fully complied is that Article 158 of the Association Agreement stipulates that the Parties shall ensure the proper and effective fulfillment of obligations under the international intellectual property treaties to which they are party, in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights contained in Annex 1C to the WTO Agreement, and the provisions of Chapter 9 "Intellectual Property" of Section IV "Trade and Trade-Related Issues" of the Association Agreement supplement and specify the rights and obligations of the Parties under the TRIPS Agreement[109] and other international agreements Agrarian agreements in the field of intellectual property.

That puts the reasonable goal to change definition of the concept of "invention" set forth in Article 1 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" as follows: "invention is the result of intellectual activity of a person in any sphere of technology having an inventory level, in comparison with the existing before the date of filing an application with the level of technology has significant distinctive features and is progressive". Such a definition of the concept of "invention" contained in the current law does not fully comply with article 27 of the TRIPS[110], according to which patents are issued for any inventions, regardless of whether they are products or processes in all areas of technology, provided that they are new, have an inventive step and are industrially suitable. Similar provisions are contained in Article 3 of Directive 98/44 / EC, which states that new inventions of an inventive step and suitable for industrial use are patentable, even if they relate to a product consisting of or containing biological material or a process by which a biological material is produced, processed or used. However, the proposed addition to the concept of "invention" proposed above does not contain a requirement regarding the industrial suitability of the invention[111]. As already mentioned in the work, the implementation of Directive 98/44 / EC into the national legislation of Ukraine is stipulated by the Decree of the Cabinet of

[109] Verma S.K. (2005). TRIPs and plant variety protection in developing countries 2005 E.I.P.R. 17(6), 281-289

[110] Arup C. (2007). TRIPs: across the global field of intellectual property , E.I.P.R. 2007, 26(1), 7-16

[111] Shanker D. (2002). "The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration on the TRIPs Agreement" 36 Journal of World Trade 721 at 726.

Ministers of Ukraine dated March 4, 2015, No. 164-p "On Approval of Plans of Implementation of Some Acts of EU Legislation Developed by the Ministry of Economic Development and Trade". In the part of the exclusion from the scope of the patent protection of the methods of surgical or therapeutic treatment of the organism of humans or animals and the methods of diagnosis, the draft Law does not contradict part three of Article 27 of the TRIPS Agreement, according to which Member States may not permit the patenting of diagnostic, therapeutic and surgical methods of human treatment, or animals.

Legal relations related to the regulation of utility models are not covered by the Association Agreement and EU law, but are determined at the level of national legislation of the EU Member States. Also, the draft Law proposes to supplement the third part of Article 6 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" with the provisions contained in Article 5, first paragraph, of Directive 98/44 / EC concerning the exclusion from the list of non-proprietary technology objects. Legal protection "of the human body at various stages of its formation and development, as well as the simple discovery of one of its elements, including sequences or parts of the gene sequences." However, the other provisions of Directive 98/44 / EC, in particular the provisions of the second and third paragraphs of Article 5, as well as the exclusions provided for in Article 6 of Directive 98/44 / EC (similar provisions are contained in Article 221 of the Association Agreement) are not included in the current law. Consequently, another drawback of the bill is that it does not provide for an integrated regulation of issues in the field of intellectual property, but proposes only the introduction of partial changes.

Conclusion

To conclude, the aim of the research, namely – to reveal the essence of the legal provision of the use of GMOs in the cultivation of agricultural products of plant origin in Ukraine in comparison with the legal provision of this activity in the EU, as well as to analyze what exact points of Ukrainian legislation need to be compiled to the requirements of European Union as one of the main tasks for Ukraine is European integration – was achieved.

We managed to analyze, that European Union and the United States have introduced a very different regulation in the field of approval, sale and sale, import and labeling genetically modified organisms. This difference is due to different degrees of confidence consumers to regulatory bodies, public organizations, interests and the strategy of the agricultural biotechnology industry, the behavior of farmers in the EU and in the US, volumes of grain trade of own production in world markets and other factors. Speaking in general, the EU demonstrates a policy "better to be safe" than "to regret it", based on the principles of prevention while US policy follows the principle of essential equivalence. The principle of prevention says that there is the case where the proposed activity, such as the release of GMOs in the environment can be harmful to the environment, but if such damage is not fully proved, then such activity cannot be allowed. Present principle is also reflected in the Cartagena Protocol on Biosafety, but the World Trade Organization does not support it and allows restrictive measures in relation to trade only in case of risk verification by research. According to the principle of substantial equivalence in the United States, GMO products and feeds that are sufficient similar to their usual counterparts, can be considered equally safe for food and do not require a comprehensive biosecurity examination. Consequently, US rules on GMOs are quite liberal in contrast relatively restrictive EU laws.

We established that industrial production and introduction into circulation of GMOs, as well as products produced using GMOs, is prohibited until their state registration in Ukraine. This issue is regulated by the Law of Ukraine "On the State Biosafety System for the Establishment, Testing, Transport and Use of Genetically Modified Organisms". Unfortunately, so far, no GMO registry and products produced with their use have been created in Ukraine, so there is a possibility that agricultural producers will try to import for the introduction of GMOs and related products illegally. Since Ukraine has signed and ratified the Association Agreement with the European Union, the European Atomic Energy Community and their member states and is currently working on unifying its own legislation with the EU legislation, it is proposed to provide for simplified

registration of GMOs and products produced in their territory on the territory of Ukraine, subject to their registration in the European Union. In this case, the mentioned simplified registration procedure will be determined by the Cabinet of Ministers of Ukraine.

As shown above, Ukraine has developed a special legislation on GMOs that covers a number of issues from GMO research to their commercialization, and introduces several important mechanisms. We can also conclude, that the system is not fully operational. The fact that Ukraine began to regulate GMO and GMO products only in 2016, led to a situation in which reality does not conform to the principles enshrined in the relevant legislation. In this situation, it is very important for Ukraine to complete the legislative work on the organizational norms on the use of GMOs and implement them. The corresponding derivative legislation will determine the effectiveness of the system. It also showed which GMO regulation model is more beneficial for Ukraine: EU or US. From the political and economic point of view, author made a conclusion that considering the desire of Ukraine to receive EU membership, Ukraine is better to follow the EU on GMO issues. Therefore, it will send a clear signal to your trading partners, which is especially important for a "dual" world where the EU and the US have no consensus on GMO issues, and where the EU does not want to change its GMO policy.

The fact that Ukraine follows the EU, developing its biosafety system does not guarantee such same level of efficiency. Causes of ineffective work on GMO approval in the EU have a structural (European Commission v. Council of Europe) and emotional character (consumers' concerns regarding GMO food). Even if Ukraine accepts EU principles and high standards in the management of GMOs, its system can to function more coherently with regard to the approval of GMOs through another institutional arrangement. However, this requires transparency, consistency and comprehensiveness the structure of legislation regarding the registration of GMOs, as well as the positive attitude Ukrainian consumers.

It should be noted that as a WTO member, Ukraine cannot impose a ban on the import of GMOs, as this would be contrary to WTO rules. However, there are other possible ways for restrictions on the use of GMOs in the country, for example, permits to create regions and zones without GMOs, and financial support for organic production, where the use of GMOs is forbidden. Basically, the main problem in Ukraine regarding legislation is that it practically doesn’t exist compared to EU or USA. In Ukraine, the cultivation and circulation of genetically modified products is regulated by the Law of Ukraine "On the State Biosafety System for the Establishment, Testing, Transport and Use of Genetically Modified Organisms" approved by the Verkhovna Rada in 2007. Based on the comparative analysis, we managed to identify the lacking legislative norms to comply with EU legislation, namely:

1. National law does not contain a law that would regulate the legal status of the use, movement and control of genetically modified genital mutilation that is contradicting to Clause 2 of Article 2 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and does not oblige the effective regulatory legal form this sphere.
2. Based on the laws of Ukraine regulating the legal aspects related to food and creatures and safety, food manufacturers do not take into account the requirements of the Cartagena Protocol on Biosafety on Biological Diversity and the Directive No. 90/219EU of 23 April 1990 on the limited use of genetically modified organisms, contain no reservations regarding the use of GMOs (in the wording of Article 51 of the Law of Ukraine "On Creature Reception" No. 2894-W on December 13, 2001, which, however, is quite a sparse nature and has not found its solution). Among the laws of Ukraine in the investigated sphere, the highest coherence with the international and European legislation is only the Law of Ukraine "On Infant Nutrition" No. 142-V of September 14, 2006.
3. Despite the absence of its own law, in Ukraine, the basic elements of biosafety systems, concerning transgenic plants, have practically been formed. They include the Biosafety Commission under the Ministry of Education and Science (biological and environmental safety), the relevant structures of the Ministry of Health of Ukraine (sanitary and hygienic and nutritional assessment), and the State Commission of Ukraine for Testing and Protection of Plant Varieties of the Ministry of Agrarian Policy (testing and registration varieties). At the same time, the "Interim Procedure for the Import and Testing of Transgenic Varieties of Plants" (Decree of the Cabinet of Ministers of Ukraine of August 17, 1998, No. 1304) does not actually function, because it does not foresee the logical distribution of responsibility of the key ministries within the framework of state control over GMOs in Ukraine. For the further functioning of this system, it is necessary to streamline the interaction of these structures with the Ministry of Economic Resources.
4. Separately it is necessary to note the lack of development of the conceptual apparatus in the field of GMO use in national legislation, which requires the introduction of appropriate changes and additions to the laws of Ukraine that regulate the legal relationships in the researched sphere.
5. There are no norms in national legislation regarding which a person guilty of violating the order of safe transfer, processing and use of living organisms obtained in the

process of using modern biotechnologies, which makes it necessary to introduce the corresponding changes in the Criminal Code of Ukraine and the Code of Administrative Offenses.

6. In Ukraine, there is no special authority for which the law would be responsible for exercising control over the use of GMOs, which contradicts the requirements of Clause 1 of Article 11 of Council Directive 90/219 of 23 April 1990 on limited use of modified organisms.

Regarding patentability and exclusion of the patentability of the biotechnological inventions within the prism of the public order and morality, under Directive 98/44 EC, author made the conclusion that due to the complexity of the adoption of the Directive and, subsequently, the process of implementation in national legislation, the crash of the EU member states suggests that the European community is still far from accepting the phenomenon of "patenting biotechnological inventions" for both ethical and socio-economic reasons. Significant differences in national patent laws that are not eliminated today, despite the considerable pressure from EU institutions, confirm the need for a more balanced and detailed analysis of the developed norms in developing countries. It is possible to conclude, that Ukrainian legislation should take into account the gaps and shortcomings described in the legal regulation of the patenting of biotechnological inventions in the EU. In particular, Directive would have been consolidated in Law of Ukraine on December 15, 1993 "On the protection of the rights to inventions and utility models", the prohibition of the patenting of sequences or partial sequences of a gene isolated from its natural environment. However, this does not mean that all the compounds that were subjected to genetic engineering maneuvers should not be the object of patent protection in general. If as a result of such activity there will be substances of a material that differ significantly from natural ones, then they can be patented if other patentability criteria are met, and if their patenting is not recognized as contrary to the public order and morals. The prohibition on the patenting of isolated sequences or partial sequences of the gene will be able to resolve the question of exactly where the boundary between patentability of inventions and non-patent discoveries occurs, thus making it possible to freely transfer valuable information contained in the genes to scientists, while encouraging inventive activity.

From the research, the following proposals in regards to complying Ukrainian national Law to European Standards on regulating GMO can be made:

- to adopt appropriate changes and additions to the laws of Ukraine that regulate the legal relationships in the researched sphere to conclude the concept apparatus for GMO;

- to streamline the interaction of the Biosafety Commission under the Ministry of Education and Science (biological and environmental safety), the relevant structures of the Ministry of Health of Ukraine (sanitary and hygienic and nutritional assessment), and the State Commission of Ukraine for Testing and Protection of Plant Varieties of the Ministry of Agrarian Policy (testing and registration varieties) with the Ministry of Economic Resources to provide the logical distribution of responsibility of the key ministries within the framework of state control over GMOs in Ukraine;
- to put down a law to regulate the legal status of the use, movement and control of genetically modified genital mutilation that is contradicting to Clause 2 of Article 2 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and does not oblige the effective regulatory legal form this sphere;
- to adopt changes in the Criminal Code of Ukraine and the Code of Administrative Offenses in regards to violation of the order of safe transfer, processing and use of living organisms obtained in the process of using modern biotechnologies, as there are no presented penitentiary sanctions for the mentioned matter;
- to establish a government authority that law would exercise the control over the use of GMOs as it is required under Clause 1 of Article 11 of Council Directive 90/219 of 23 April 1990 on limited use of modified organisms.
- to acknowledge the gaps and shortcomings described in the legal regulation of the patenting of biotechnological inventions in the EU. In particular, Directive 98/44 EC would have been consolidated in Law of Ukraine on December 15, 1993 "On the protection of the rights to inventions and utility models", while adopting the legislation on the prohibition of the patenting of sequences or partial sequences of a gene isolated from its natural environment.

The applicability of the results obtained is that the conclusions, provisions, suggestions and recommendations formulated in work are a definite contribution to the theory of Ukrainian civil and agrarian law. The provisions and conclusions of the dissertation can be applied:

- in the field of research, for the further resolution of the problems of patent and agrarian law in terms of legal support for the use of GMOs in the cultivation of agricultural products of plant origin;
- in law-making activity - in working out of draft normative-legal acts, carrying out systematization of legislation regarding GMO, as well as harmonization the national Ukrainian legislation to comply the EU law on regulating trade and patenting GMO;

- in the field of law enforcement - to increase the effectiveness of the application of civil law in the field of legal regulation and patentability of GMO;

The work enables to continue the further research within drafting legislation on patentability of GMO in Ukraine, as well as providing the background for comparative analysis of the legal regulatory systems on GMO in USA versus European Union.

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