

LEGAL FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS IN CROPS PRODUCTION: THE EU PRACTICES

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ABSTRACT

The use of genetically modified organisms in food manufacturing in the course of growing agricultural produce is considered an efficient method to raise the yield and increase the amounts of the grown crops. This is of special importance for agricultural crops manufacturers in terms of increasing their profits. Nevertheless, regardless of the obvious advantages, the use of such organisms is not always safe for life and health of humans as well as the environment in general.

In legislative acts, the issue of genetically modified organisms is treated with particular attention within the context of the international integration processes due to the present-day acute problem of state regulation of development and use of genetically modified organisms. As a result, the constant increase in the areas sowed with genetically modified plants and the spread of biotechnologies all over the world is currently observed.

In this connection, the analysis of legal framework concerning the issues of legal support for genetically modified organisms in crops production is of utmost importance for consequent forming of an efficient management system.

Keywords: GMO, Agricultural Produce, International Law, International Standards.

INTRODUCTION

According to the Constitution of Ukraine, “everyone is entitled to environment safe for life and health and to reimbursement for the damage caused by violation of this right. Every person is guaranteed the right of free access to information on the state of environment, on the quality of foodstuffs and household goods, as well as the right to spread such information. Nobody can make this kind of information secret” (Art. 50) (The Constitution of Ukraine, 1996).

The Law of Ukraine “On Consumers’ Rights Protection” establishes “one of consumers’ rights is the right for obtaining the necessary, accessible, true, and timely information on a product to ensure a possibility of a conscious and competent choice”. Information is to be provided for a consumer prior their purchasing a product or ordering some work (a service). Product information is not considered advertising. Product information should include:

1. The name of the product, the name or reproduction of trademark for goods and services under which they are sold;
2. Data on the product’s main features, nominal amount (weight, volume, etc.), the terms of its use;
3. Information concerning the presence of harmful substances provisioned by legal acts, and warnings as to the use of individual products if precautions are provided by legal acts; data on the price (tariff), conditions and rules of purchasing the product;
4. The manufacturer (seller) in case of discovering inaccurate information on the product (if it does not have an adversary effect on consumer’s life, health or property) withdraws this product from the market within a week and brings the relevant information in accordance with its actual properties unless the law or corresponding technical regulations prescribe other procedures for the manufacturer (the seller) in such cases;
5. The date of production;
6. The information on storage;

7. The manufacturer's (contractor's) warranties;
8. The rules and conditions of efficient and safe use of the product;
9. The service life (term of service) of the product (work outcomes), information on the necessary course of action by the consumer following the term's expiration, as well as about possible consequences of failure to perform such actions;
10. The name and location of the manufacturer (contractor, seller) and the enterprise which operates on behalf of them concerning responding to the consumer's claims and carries out repairs and technical maintenance, as well as;
11. A marking on the presence of genetically modified organisms in the product (2. On Consumers' Rights Protection, 1991).

The Law of Ukraine "On State System of Biosafety in Transforming, Testing, Transporting and Using Genetically Modified Organisms" of May 31, 2007 No 1103-V (3).

On State Biosafety System at Transforming, Testing, Transporting, and Using of Genetically Modified Organisms, 2007) determines the procedure of handling genetically modified organisms, as well as distinguishes the two types of corresponding systems: the open and the closed systems. Also, it provides the definition of genetic safety, describing it as "the state of human activities environment wherein there is not any kind of unnatural impact on the human genome, or any kind of unnatural impact on the biosphere objects' genomes, as well as not any uncontrolled impact on the genomes of agricultural plants and animals, industrial microorganisms which leads to development of adverse and/or undesirable properties in them".

The issues of handling genetically modified organism are also regulated by the Ministry of Public Health of Ukraine Order "On Approval of the Nomenclature of Food Products to be Controlled for the Presence of Genetically Modified Organisms" of 09.11.2010 No. 971; the Decree by the Cabinet of Ministers of Ukraine "On Approval of the Procedure for Labelling Food Products Containing Genetically Modified Organisms or Manufactures with the Use of Them and are Placed in the Market" of 13.05.2009 No. 468; the Law of Ukraine "On Children's Nutrition" of 14.09.2006 No. 142-V; the Ministry of Agricultural Policies and Foods of Ukraine Order of March 16, 2011 No. 78 "On Taking Samples of Seeds Brought in Ukraine to Determine the Presence or Absence of Genetically Modified Organisms", etc.

As to the genetically modified organisms in crops production itself, one should mention the Decree by the Cabinet of Ministers of Ukraine of July 23, 2009 No. 808 "To the Issues of Approbation (Testing) of Genetically Modified Organisms of Agricultural Plants' Species". This document contains the Procedure for state approbation (testing) of the genetically modified organisms of agricultural plants' species in the open system (determines the sequence of measures to be undertaken within the procedure of state approbation (testing) of genetically modified organisms in agricultural plants' species in the open system) along with the Procedure for state registration of genetically modified organisms in agricultural plants' species in the open system (determines the procedure for entering the relevant information to the State Register of genetically modified organisms in agricultural plants' species in the open system).

It is doubtless that in the last two decades the progress in molecular biology and genetic engineering has offered scientists new ways to improve plants and animals which were difficult to imagine previously. A possibility has appeared of bypassing traditional selection methods to obtain new genotypes nonexistent in nature before. That is why, becoming ever more perfect, multi-purpose, and safer with every passing year, transformed plants and animals have begun to influence noticeably agriculture, medical industry, and other human activity areas (Marchenko, 2017).

Currently, more than 100 lines of transgenic plants are grown worldwide on industrial scales, including technical species like tobacco and cotton. Among the most widespread food crops are soya, corn, rapeseed, beetroot, and potato, the unconditional leader being soya, the share of which amounts to 98% of all the GM plants. Unlike the vulnerable natural soya, its GM counterpart is resistant to pest insects and survives chemical treatment that kills all kinds of

weeds, which enabled increasing its production by several times (Hetman & Lozo, 2011).

One of the main international documents regulating the issues of GMO handling at the international level is the Cartagena Biosafety Protocol of January 29, 2000, supplementing the UN Convention on Biological Diversity enacted on September 11, 2003, Ukraine being one of the parties to sign it. This document enumerates the potential risks and establishes the priority of the caution principle concerning the GMO, outlines the responsibility area for violating the norms of GMO handling.

In 2002, Ukraine joined the Cartagena Protocol on Biodiversity (the Law of Ukraine No. 152-IV of 12.09.2002), attesting to its recognition and support of the need in applying coordinated measures directed at ensuring the due protection level in the area of safe transportation, circulation, processing, and transborder moving and use of genetically modified organisms obtained through the use of modern biotechnologies and which can negatively affect the preservation and non-extensive use of biodiversity with taking into account the risks for human's health. The full implementation of international obligations by Ukraine concerning the Cartagena Protocol on Biosafety calls for conceptual establishing of the state policies foundations in the area of genetically modified organisms' biosafety, as well as determining the long-term principles for its implementation (Grigorova, 2015).

It should be noted that the international legislation limits the spread of GMO and provides for informing the consumer about the presence of GMO in this or other product. In the European Union countries, trans border moving of GMO in the process of growing agricultural plant crops can be limited due to the fact that the EU legislation provides that the member-states can take measures to protect their territory from GMO by a prescribed procedure. For Ukraine, as a party in the Cartagena Protocol, it is actual to regulate the issue of information provision concerning trans border moving of GMO as prescribed by the Protocol. The UN Convention on Biological Diversity for the first time proclaims at the international level the need in careful attitude to living transformed organisms obtained through biotechnology in order to ensure a due protection level in terms of safe transportation, processing, and use of living transformed organisms obtained by means of modern biotechnology, which may unfavorably affect the preservation and sustainable use of biodiversity, with taking into account the risks for human health (Pavliuchenko & Savchuk, 2018).

LITERATURE REVIEW

At the legislative level, a genetically modified organism is defined as “an organism (with the exception of humans) whose genetic material has been transformed in a way impossible under natural circumstances in the process of breeding and (or) natural recombination” (Art.2 of the Directive 2001/18/EC of March 12, 2001 on deliberate release of GMO into environment (Codex Alimentarius, 2002).

In specialized literature, a GMO is defined as “an organism whose genotype was transformed by means of genetic engineering methods resulting in introduction of changes to the genetic structure of organisms. GMO are comprised of the three groups of organisms: genetically modified microorganisms, animals, and plants. Genetically modified products are products obtained from transgenic (genetically modified) organisms” (Marchenko, 2017).

In agriculture, a genetically modified organism in a process of growing agricultural crops is a plant organism (or its part, including seeds), in which genetic material has been transformed in a way that is impossible in natural conditions in the process of natural recombination, to be used in order to increase the yield of agricultural crops, or to improve the quality indicators of agricultural crops (Meniv, 2016).

The GMO transformation method supposes a change in the genetic structure of plants,

microorganisms, or animals to the effect that obtain new properties, become, for instance, more resistant to pests or illnesses. Owing to this, the organism is imparted a desired characteristic which it did not have previously. The main argument of the genetic modification supporters is improved characteristics of plants, microorganisms, and animals thus obtained. Therefore, genetically modified plants are more resistant to infectious diseases agents, can be stored for a longer period of time, and are more stress-resistant to the environmental factors. Genetic modification of animals enables simplifying their keep, speeding up their growth, and improving the taste of meat and dairy products.

The opponents, on the other hand, point to the fact that the outcomes of consuming the GMO have been studied insufficiently and, in renowned specialists' opinion, may induce diseases in humans. Genetically modified products may cause allergies, metabolic disorders, and stomach diseases. Of the long-term consequences, the mutagenic factors may pose a threat. Officially, GMO-containing crops are not grown in Ukraine. Because none genetically modified cultures are registered in Ukraine, their bringing in and cultivation in Ukraine are illegal. Nevertheless, according to business insiders' information, the Ukrainian agriculture is not free from GMO. Such organisms find their way to Ukrainian foodstuffs mainly from the agricultural raw materials imported to Ukraine, and from genetically modified crops cultivated in Ukraine (Marchenko, 2017).

It should be noted that the native legislation provides for the use of GMO in the process of agricultural crops cultivation both in the closed and in the opened systems. In the agricultural sphere, an example of GMO application in the closed system can be the cultivation of genetically modified agricultural plants in laboratories, on the covered soil, in greenhouses, in particular in the course of carrying out relevant research (Meniv, 2016).

The EU legislation also provides for growing GMO-containing agricultural produce in the closed system. This issue was regulated by the EU Directive 90/219/EC concerning the limited use of GMO, followed later on by the European Parliament and Council Directive 2009/41/EC of 16.06.2009 on the limited use of genetically modified microorganisms in the closed system.

According to the mentioned regulating acts, the limited use of GMO is defined as any activity in the course of which microorganisms are subjected to genetic modification, or in the process of which such genetically modified organisms are grown, stored, transported, destroyed, removed, or used in any other way, and regarding which special protective measures are applied as to limit contact with them as well as to ensure a high safety level for the population and the environment.

The corresponding subject (operator) is to carry out an assessment of the limited use of GMO considering the risks for human health and environment that can be caused by these types of limited use. The record of such an assessment is registered by the operator and forwarded in the due form to the competent authority as a part of the notification procedure or if required by the authority. According to the Directive 2009/41/EC this "assessment supposes distinguishing of four classes of GMO limited use: class 1 – activities with zero or insignificant risks; class 2 – low risk activity types; class 3 – moderate risk level activity types; class 4 – high risk level activity types". On the grounds of this classification, the corresponding restriction levels are established concerning the GMO use (levels 1–4) in order to protect the human health and environment (Meniv, 2015).

It is reasonable to agree with O.I. Meniv opinion, who thinks that "Ukrainian also should provide for similar provisions. Therefore, agricultural crops manufacturers should be liable to carry on assessment of the GMO limited use considering the risks for human health and environment" (Meniv, 2015).

RESEARCH METHODOLOGY

The structure of the research is expressed in the standard observation descriptive analysis of obligatory components for the state, and also results of researches by the leading scientists in this area.

The methodological basis of the research includes system analysis, comparison, theoretical and legal forecasting.

Research Objectives

The authors of the paper were guided by the goal of conducting a comprehensive comparative analysis of the legal regulation of the genetically modified organisms in plant production in accordance with national legislation and international standards.

DISCUSSION

Referring to the issue of the use of GMO in an open system, it should be noted that it has been regulated by the Law of Ukraine “On State Biosafety System at Transforming, Testing, Transporting and Using Genetically Modified Organisms” of May 31, 2007 No. 1103-V - (para. 13 part. 1 art. 1) and the Cabinet of Ministers of Ukraine Decree of 2.04.2009 No. 308 “On Approving the Procedure for Granting Permission for Carrying out State Approbation (Testing) of Genetically Modified Organisms in the Open System”, the Cabinet of Ministers of Ukraine Decree of 23.07.2009 No. 808 “To the Issues of Carrying out State Approbation (Testing) and Registration of Genetically Modified Organisms of Agricultural Plants’ Species”.

Unlike the agricultural plants’ species formed on the GMO basis, in Ukraine up to now have not been approved either the Procedure for carrying out state approbation (testing) of protection means for plants obtained with the use of genetically modified organisms, or the Procedure for their state registration, which cannot be considered acceptable. Counter to this, in the EU, as described in scientific literature, prior to placing on the market any GMO or prior to their deliberate release in environment, laboratory and greenhouse personnel carry out preliminary research and preparatory work. These issues are dealt with by the Directive 2001/18/EC of March 12, 2001 on deliberate release of GMO in environment (Marchenko, 2017), according to which, the subject (notificator) is to submit a notification containing technical information specified in Annex III to the Directive along with the environmental risks estimation. Among other things, technical information is to contain data concerning the interaction between the GMO and the environment. The relevant authorities of the EU member-states are to approve or to reject the notification within 90 days from receiving it, following which the notificator is to forward to the relevant authorities an account on the outcomes of the release regarding all the risks to humans’ health or to the environment. This procedure has enabled European researchers to conclude that the Directive on deliberate release from many points of view ensures stricter environment protection than the Directive 2009/41/EC on limited use. Apart from this, the established procedure provides significant powers to the member-states, while in the matters of products placing on the market, the control is exercised mostly on the EU level (Meniv, 2016).

The following main features concerning the procedure for handling the GMO in the EU are mentioned in scientific literature: “on the territory of the EU there is a so called licensing system, which means that for activities related with the use of GMO it is necessary to obtain a special permission issued by a competent authority; the procedure of granting a permission is preceded by carrying out risk assessment for all kinds of GMO to the environment, human health, etc.” (Strutynska-Struk, 2005).

A reasonable proposal was offered by another scientist as to the need in forbidding the cultivation of genetically modified agricultural plants' species on lands designated for growing organic foods and raw materials, as well as on lands having the special zone status for growing children's nutrition and diet products (Meniv, 2016).

Transgene organisms, that are nowadays widely spread and used, have been created in the recent 15-20 years. According to the current Ukrainian legislation, transgene plants' species pass state testing during 3-4 years (that is, on general terms set for usual plants' species). This period is sufficient for detecting short-term and medium-term consequences of possible negative impact caused by such plants on human health and the state of environment. Nevertheless, this time is insufficient for detecting the remote consequences of such organisms' impact. Therefore, the majority of scientists recommend to prolong monitoring such plants' species concerning their possible negative impact on human health, the environment and its components following the state registration. This requirement should definitely be reflected in regulating acts. Contrary to this, Ukraine's current legislation does not provide for obligatory continued monitoring of the mentioned GMO-plants following their state registration (Barchuk, 2015).

As demonstrated by the international experience, planting of genetically modified materials for mass production does not give considerable advantages to consumers or small farmers in developing countries. Even widespread reports of "indirect advantages", that is, decrease in the amounts of herbicides and pesticides applied in the course of production, are unsubstantiated. The only beneficiaries are international agrochemical corporations that control the industry of genetically modified plants and chemicals as well as sub-products linked with using them (Vlasenko, 2014).

CONCLUSION & RECOMMENDATION

Therefore, having analyzed the current legislation of Ukraine and the international law enables making the following conclusions. The road taken by Ukraine to adapting the national legislation to the European norms is indisputable, hence the introduction of already "working" and efficient procedures of implementing the issue in question. In this connection, the Ukrainian legislation should make it obligatory for agricultural manufacturers operating in crops production to carry out an assessment of the limited use of genetically modified organisms in agriculture concerning the risks to human health and environment. The authors also think it expedient to introduce changes to the related legislation as to a possibility of applying genetically modified organisms in the process of their limited use and deliberate release in the environment, thus changing the outdated, from the authors' point of view, norms concerning the two types of systems (the closed and the open systems).

Also, it is deemed urgent to develop a procedure concerning utilizing, destruction, and neutralizing the GMO-containing materials, as well as to provision responsibility for non-compliance with the norms of current legislation in this area.

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