BRIEF PRESENTATION OF THE NATIONAL LEGAL REGIME OF THE GENETICALLY MODIFIED ORGANISMS

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Abstract
The current study starts from the fact that, in general, the modified genetic organisms has represented and still represents a very controversial subject from the ethical, moral, economic, financial and legal perspective. The GMOs are non-traditional organisms, whose spread can generate a modification of the ecosystems, which has determined certain researchers to speak about the so-called "genetic environmental pollution". In this context, an important role belongs to the law, which must face these new challenges and to answer by drafting norms adequate to the questions raised by the use of the modern bio-technologies.
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INTRODUCTION

In current times, in the context of the unprecedented scientific development, the artificial manipulation of the genetic material represents a reality, being without any doubt that the "genetics has become the main actor of the modern science, fascinating area, allowing the intervention of man in life processes" [1]. Thus, modern biotechnologies having as object for study the genetic modification, namely the genetic modified organisms, find their practicality in areas such as medicine, pharmaceutical industry, and frequently in agriculture and food industry.

According to the World Health Organization (WHO), the genetic modified organisms (GMOs) are organisms whose genetic material (DNA) has been modified by a procedure in which it does not emerge naturally, through "modern technologies", the so-called "genes' technology", also known as the "technology of the recombined DNA" or "genetic engineering" [2].

Even if the economic benefits obtained by these genetic engineering technologies are obvious, the possible negative consequences upon the environment and human

health cannot be neglected. Among the negative effects of the GMOs against the environment, mentioned in specialized studies, we refer to, as example: “the spread of the altered genes in the environment, to wild vegetation and to conventional cultures; the destruction or severe reduction of biodiversity; insufficient knowledge of the long-term effects of cultivating and using the GMOs in human and animal food [3], as well as “the negative effects upon the genetic dynamics and diversity of the species from that particular environment; the diminution of the resistance to pathogens; compromising the prophylactic treatment or the plant, veterinary or human treatment etc.” [4]. To all these, are usually added the ethical, moral or religious reasons.

For the purpose of minimizing the possible negative consequences of the modern biotechnology, simultaneously it had been developed the biosecurity, represented by the ensemble of the policies for biosecurity, the legal regulations, the scientific measures and the techniques necessary for the establishment of a balance in this area, especially emphasizing the precaution.

Regarding the supporters of the modern biotechnology, the main arguments brought are: the production is higher than the traditional culture, the storage and resistance to pests, the higher capacity of the culture to develop in limited environmental conditions, but also the possibility to harvest crops rich in proteins, gluten free, of plants without allergenic proteins (kiwi allergenic protein free), tomatoes with baking during transport, soybeans with an increased amount of lecithin etc. [5].

But, the increment and diversity of the sources of information of consumers with more and more “requirements” regarding the quality and safety of the products to be consumed makes the balance of pros and cons against the GMOs to lean against the GMOs.

If until 2007 Romania held one of the largest surfaces with GMOs in Europe, especially with genetic modified soybeans, after the adhesion to the European Union, our country has aligned with the European norms on GMOs. Thus, the communitarian block allows the cultivation of just two GMOs – MON810 corn, resistant to pests and Amflora potato with an increased level of starch, and in Romania the single GMO allowed being the corn.

LEGAL REGIME OF THE GMOs

The legal regime of the GMOs is presented by Chapter 6 of the G.E.O No 195/2005 on environmental protection [6]. Thus, Art 39 Para 1 of the normative act establishes that the activities referring to GMOs resulted using the modern biotechnology shall be subjected to special rules of regulation, authorization and administration.

In accordance with Art 39 Para 2 of the G.E.O No 195/2005, the category of activities referring to GMOs resulted using the modern biotechnology shall include:

a) The use in contained conditions of the GMOs;

b) The deliberate introduction in the environment and on the market of the vivid GMOs;

c) The import of the GMOs.

These activities may be performed only by legal persons based on the documents of regulation, issued by the competent authority and within the conditions of insuring the environment protection and the health of humans and animals.

In this meaning, Art 44 of the G.E.O No 195/2005 establishes a series of obligations in the burden of the legal persons exercising activities referring to GMOs, namely:

a) The obligation to request and receive the agreement for import for GMOs and/or the authorizations regarding the activities with the GMOs;

b) The obligation to comply with the agreements for import for GMOs and/or the authorizations for the activities with GMOs;

c) The obligation to cease the activity or switch the conditions for development, at the request of the competent authority, if new information is received regarding the environmental risks and for the human/animal health;

d) The obligation to be held responsible, according to the legislation in this area, for the damages caused by these activities;

e) The obligation to pay for the necessary measures for the prevention and/or the reduction of the consequences of the adverse effects generated by these activities;

f) The obligation apply the measures for the elimination of the waste resulted from activities regarding GMOs.

Also, for legal persons, owners of the agreements for import of the GMOs and of the authorizations for activities with GMOs have the obligation to comply with the legal exigencies regarding the insurance of the traceability, labeling, monitoring and reporting to the central public authority for environmental protection and to other authorities, of the results of the activity.

The competence for issuing the authorizations and agreements for import for activities regarding the GMOs belongs to the central public authority for environmental protection.

The authorization for activities related to GMOs is “the administrative act issued by the competent authority for environmental protection, according to the legal provision in force, which states the conditions for a deliberate introduction in the environment and/or on the market of the GMOs and for the use in contained conditions of the GMOs” [7].

For the deliberate introduction in the environment or on the market of the GMOs, as well as in the case of the import of the GMOs, the central public authority for environmental protection shall request the approvals of the central public authorities for agriculture, health, food safety, consumer’s protection as well as from other public institutions involved. Also, it shall consult the Commission for Biologic Security and shall insure the information and participation of the public.

Regarding the use in contained conditions of the GMOs, the central public authority for environmental protection shall apply the procedure established by the specific legislation in this area.

THE SPECIAL LEGAL REGIME GOVERNING THE GMOs

The rules governing the activities related to GMOs are stated by the G.E.O No 43/2007 on integration in environment of genetically modified organisms [8] and the G.E.O No 44/2007 on the contained use of the genetically modified microorganisms [9].

The objective of the G.E.O No 43/2007 on integration in environment of genetically modified organisms is represented by the insurance of the necessary legal and institutional framework, harmonized with the communitarian one, so that the activities with GMOs to be developed in compliance with the principle of precaution for the insurance of human health and environmental quality.

The object of regulation of the G.E.O No 43/2007 is represented by the following types of activities: a) the introduction in environment of the GMOs, for other purposes than the introduction on the market; b) the introduction on the market of the GMOs as such, or as part of other products; c) cross-border movement of the GMOs.

After defining the terms, the normative act enlists a series of general obligations in this area for the application of the general principle of the environment law. Therefore, Art 3-4 state the following interdictions:

- The prohibition of inserting in the environment of an GMO for the research development purposes or for other purposes than the introduction on the market, without an authorization issued by the competent authority or without complying with the conditions imposed by the authorization;
- The prohibition of inserting on the market of an GMO, as such or as part of another product, without authorization issued by the competent authority;
- The prohibition of using a product non-compliant with the conditions from the authorization;
- The prohibition of inserting on the market of an GMO as such or as part of another product, if the labeling or packaging is not compliant with the conditions of the authorization;
- The prohibition of performing any cross-border movement of GMOs as such or as part of another product, if this is non-complaint with the conditions mentioned by the normative acts in force;
- The prohibition of inserting on the market of a product resulted from an GMO deliberately inserted in the environment, without the compliance of the legal provisions.

Guaranteeing the compliance and application of the legal provisions in this area is achieved by the participation and collaboration of several public authorities/institutions, namely: the central public authority for the environment protection; the National Agency for Environment Protection; the Commission for Biological Safety; Office of Environmental Police & Assistance, as well as other authorities involved, for instance: the central public authority for agriculture, the central sanitary veterinary and food safety authority, central authority for health etc. all of them contributing to the establishment of the national framework for bio-security.

Regarding the introduction in the environment of an GMO or of a combination of such organisms, the legal provisions state that any legal person, before submitting a notification to the competent authority for the authorization shall, first of all, asses the risks on human health and environment describing the methods used and references to standard methods or internationally recognized ones, as well as bibliographical references.

It is necessary that the assessment to be fair and to take into consideration the possible side effects on human health and environment, directly or indirectly resulted from the transfer of genes from the GMOs to other organisms; it shall be performed for each particular case, before the introduction and shall take into consideration the nature of the organism introduced and the recipient environment, as well as the long-term cumulated possible effects, associated to the interaction with other GMOs and the environment [10].

The notification file, drafted according to Art 13 or Art 29 of the G.E.O No 43/2007, shall be submitted to the competent authority for examination, which shall establish if it can be accepted or not. During the decisional process, the competent authority shall request the approval of the Commission for biologic security and the authorities involved.

Also, the competent authority has the obligation to inform and consult the public. It shall receive the information from the Commission for biological security and the authorities involved and shall insure the transfer of information and of the decisions taken to the authorities involved, to the Commission for biological security and to the public. The transfer of information to the European Commission and the other EU Member States shall be made with the approval of the central public authority for environmental protection.

According to Art 9 of the G.E.O No 43/2007, any operator – legal person using GMOs or performing activities of introducing on the environment and/or on the market, import, export, transit, manipulation, transportation of such an organism or of a combination of GMOs, has a series of obligations among which we mention:

- The obligation to take measures for the activities performed to not generate side effects on human health, animals and environment;
- The obligation to bear the costs for the bio-security measures necessary for the safe development of the activities, as well as the costs for the bio-security measures

necessary for the reduction, repair or prevention of the consequences of the side effects generated by the use of the GMOs;

- The obligation to appoint a responsible for matters of bio-security or to insure the collaboration with an external consultant, trained in the area of bio-security, and to insure the training of the personnel and direct collaborators on the specific legislation regarding the GMOs, the legislation in force regarding the environmental protection and the legislation for labor security;
- The obligation to allow the access of the authorities for control, to collaborate with them and to present the documents proving the nature of the products being used, under the aspect of the genetic modification, for the verification of the compliance with the provisions of the agreement/authorization issued by the competent authority or for the ascertainment of the legality of the activity and of the means of compliance with the requirements regarding the traceability;
- The obligation to archive the documents regarding the activities developed, for 10 years since the conclusion of the introduction in the environment and/or on the market;
- The obligation to draft the emergency plans and to submit them to the authorities with responsibility for emergency situations and to all possible concerned parties etc.

Also, the G.E.O No 43/2007 details the rules applicable for the procedure of authorization of the activity of introducing the GMOs in the environment, for other purposes than the introduction on the market, the rules applicable for the activity of introducing the GMOs on the market, as such or as part of other products, namely the rules applicable in the area of the cross-border movement of GMOs.

G.E.O No 44/2007 on the contained use of the genetically modified microorganisms has as purpose the establishment of the proper measures of bio-security, necessary to be applied, for the use under contained conditions of GMOs, complying with the principle of precaution, for the protection of the human health and environment.

Its area of application is represented by the activities under contained conditions of the GMOs, given the fact that the genetic modification results at least from the use of the techniques stated by the annex of the normative act (Annex No 1, Part A).

Art 2 Pct 16-17 of the G.E.O defines the microorganism as being “every microbiological, cellular or non-cellular entity, able to replicate or to transfer material

genetic", and the genetically modified organism as being "a microorganism whose genetic material has been modified differently than the natural one, other than by cross-breeding or natural recombination".

Similarly to the G.E.O No 43/2007, the G.E.O No 44/2007 states a series of general obligations for each user, such as: the prohibition of using under contained conditions of the GMOs without authorization or non-complying with its provisions, the obligation to notify, the obligation to insure an internal system of bio-security, the obligation to alert the competent authority in case of accident etc.

The institutional framework for the use under contained conditions of the GMOs shall be guaranteed by the: central public authority for environmental protection, the National Agency for Environmental Protection, the central public authority for education and research, the central public authority for health, the central public authority for labor and social protection, the central public authority for agriculture, the Commission for biological security, the Office of Environmental Police & Assistance, as body of control under the public central authority for environmental protection, the National Sanitary Veterinary And Food Safety Authority, the National Customs Authority.

The G.E.O details the rules applicable for the complex process of using the containment conditions for the GMOs, starting with risk assessment, bio-security measures, the Register of the activities for contained usage of the GMOs, the notification procedure, the authorization procedure, import and export of the GMOs, labeling and packaging, the emergency plan and the accident management, reporting to the European Commission and concluding with the sanctions for non-complying with different provisions.

CONCLUSIONS

The legal regime applicable to GMOs stated by the G.E.O No 195/2005 on the environmental protection, the G.E.O No 43/2007 on the introduction of GMOs in the environment and the G.E.O No 44/2007 on the contained use of the genetically modified microorganisms, shall be completed by the Cartagena Protocol on bio-safety, by the Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms, as well as by the

provisions of the legislation regarding the products for protection of the plants and by those regarding the registration of the varieties and hybrids of genetically modified plants, the coexistence of the cultures of superior genetically modified plants with the ecological and conventional ones, the authorization of the cultivators of genetically modified plants.

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