THE SPECIAL JURIDICAL REGIME OF GENETICALLY MODIFIED ORGANISMS

Livia Mocanu
Valahia University of Târgoviște
Faculty of Juridical, Social and Political Sciences
mocanulivia@yahoo.com

Abstract
Along with the reform of the mutual agricultural policy adopted in 2003, Europe abandoned the objective of increasing the production and started considering seriously, the environment protection. In such a context, the European Community adopted in the last 15 years a set of rules aiming at controlling the distribution in the environment and the trade of genetically modified products, for the purpose of protecting human health and the ecosystem.
The Romanian law took over the communitarian legislation in the matter along with the adoption of the Urgent Ordinance no. 43/2007, regarding the deliberate introduction of genetically modified organisms in the environment and on the market and of the Urgent Ordinance no. 44/2007, regarding the use of genetically modified micro-organisms within isolation conditions. Thus, a new special regime in the matter was instituted, and it has a complex content which includes objective and the application domain of the normative document, the institutional framework, the authorization procedure, the trans-border movement of the genetically modified organisms, bio-security measures and the responsibility for damages caused to human health and to the environment. In the present study we aim at analyzing the administrative authorization procedure of the activities regulated by the dispositions of the G.U.O. no. 34/2007, as a tool created by the legislator to act against serious pollutions and to reduce their level as much as possible. In this matter, the regulation documents specified are the authorization regarding activities with genetically modified organisms and the import agreement for genetically modified organisms, both conditioning the development of activities for which they are required from the point of environment protection. The issue, renewal, suspension, cease of the two categories of authorizations are submitted to a special regime, "of environmental law " whose coordinates arise from the specific legal dispositions, in which context we will emphasize them related to the common law in the matter, that is the administrative law. Our investigation aims at determining the specific mechanisms of these authorizations which provides them, mainly, the special status of specific documents of environmental law and secondly, that of individual administrative documents. This is a procedure requiring a special institutional framework made up of institutions with attributions that are strictly regulated by the law in the progress of the stages composing it, the evaluation of the impact on the environment, the public consultation and the responsibility for the damage caused to human health and to the environment.

Key words: genetically modified organisms, caution, operator, authorization, agreement

1. INTRODUCTION

Adopted from the perspective of preparing Romania's adherence and integration into the European Union, the Urgent Ordinance no. 195/2005 regarding the environment protection [1] institutes the general juridical regime concerning genetically modified organisms. In the meaning of the law, the genetically modified organism represents any organisms, except human beings, in which the material was modified in a way which does not happen naturally by breeding and/or natural recombination (art. 2 of the G.U.O. no. 195/2005).
Just like any framework–regulation, the normative document stipulated that all activities involving genetically modified organism (GMO), obtained through the techniques of modern biotechnology are submitted to a regulation, authorization and administration regime, thus as to take place only while observing the conditions of environmental protection as well as people's and animals' protection. These activities include: - the use within isolation conditions of genetically modified micro-organism; - the deliberate introduction in the environment and on the market of genetically modified organism; - the import of genetically modified organism/micro-organisms.
Related to the stipulations comprised in the framework-law regarding the environment protection and to achieve the total transposition and the correct implementation of the communitarian acquis in the field[2], a special regime in the matter was instituted in the internal law once with the elaboration of the

Urgent Ordinance no. 43/2007 regarding the deliberate introduction of the GMO[3] in the environment and on the market and respectively, the Urgent Ordinance no. 44/2007 concerning the use of genetically modified micro-organism within isolation conditions.[4]
Based on the preoccupations manifested at communitarian level, the two normative documents institute, by special dispositions, a set o rules concerning the control of the distribution into the environment and trade of genetically modified products, for the purpose of protecting human health and the ecosystem. The necessity of these regulations is obvious as, after 10 years of cultivation and trade, genetically modified organism occupy nowadays 102 millions ha in the entire world and, although they increase productivity, they are disputed, as until present no long-term tests were made to determine whether they involve any risk for human health.

1. The authorization of the activities regarding the deliberate introduction of genetically modified organisms in the environment and on the market

1.1. General obligations

In accordance with the principle of caution, to avoid adversary effects on human health and on the environment, the G.U.O. no. 43/2007 institutes a series of general obligations, which are actually prohibitions and procedural requirements.
Thus, the law prohibits: - the deliberate introduction in the environment of a genetically modified organism for the purpose of research-development or for any other purposes than the introduction on the market, without an authorization issued by the competent authorities [art. 3 line (1)] or without observing the conditions imposed in that authorization [art. 3 line (2)]; the introduction on the market of any genetically modified organism, per se or as part of a product, without a legal authorization issued by another member state [art. 4 line (1)] or the use of a product which does nor observe the conditions in the respective authorization [art. 4 line (2)], or which does not observe the label and package requirements in this [art. 4 line (3)]; the introduction on the market of a product obtained from a genetically modified organism deliberately introduced into the environment, without observing the legal requirements [art. 4 line (4)]; making any trans-border movement of genetically modified organism, per se or as part of a product, if made without observing the conditions imposed by the law [art. 4 line (5)].

1.2. The institutional framework

The main institutional actors that participate and collaborate to create the national bio-security framework are: the central public authority for the environment protection; the National Agency for the Environment Protection; the Commission for biological security; the National Environmental Guard; authorities involved, as: the central public authority for agriculture, the central animal health authority and for food safety, the central public authority for health, the central public authority for the consumers' protection and the central public authority for education, research and innovation.

2.3. The authorization procedure

The authorization of the activities carried out in this field is the result of a procedure comprising several staged, such as: notification, authorization proper, and the appraisal of the Commission for Biological Security and of the involved authorities, the public reference, and taking the decision.

2.3.1. Notification

According to law, all operators, before the deliberate introduction of a genetically modified organism or of a combination of such organisms in the environment in Romania, or previous to the introduction of a genetically modified organism or of a combination of such organisms on the market, for the first time, per se or as part of a product, must previously send a notification to the competent authority in order to receive the authorization, notification whose content is set by the law. Along with the notification or no later than 5 days from its approval, the entity sending the notification must provide witness-samples of the

genetically modified organism or of a combination of such organism, as well as the detection method, to the legal representative of the control authority and/or the competent authority or to a laboratory accredited to make such analysis.

The competent authority can accept that the deliberate introduction of a GMO or a combination of such organisms in the environment, in the same location or on different locations, made for the same purpose and for an established period, can make the object of a single notification; in case the activity which made the object of a previous authorization restarts, the entity sending the notification must send a new notification (art. 14).

2.3.2. Standard authorization procedure of activities regarding the deliberate introduction of genetically modified organisms in the environment, for other purposes than their introduction on the market

One must distinguish here the following stages: acceptance/refusal of the notification, appraisal from the Commission for biological security (CBS), consultation of the public and taking the decision.

As for the notification, the competent authority will decide within 15 days from its registration; the absence of an answer does not mean the tacit acceptance of the notification;

Once accepted, the notification is registered in the registry and the competent authority informs in writing the entity sending the notification and communicates it the registration number of the notification, as well as the number of copies of the notification file, necessary for the authorization procedure, which must be submitted to the competent authority within maximum 7 days.

In case the notification is not accepted, the competent authority notifies the entity sending the notification on the reasons for being rejected, in writing, and this entity must complete the missing information in the notification file, within 10 days. If the entity sending the notification cannot fulfill this duty, the authorization procedure is suspended, without denying it the right to fill a new notification file.

According to law, the authorization procedure starts the date the competent authority notifies the entity sending the notification on the file acceptance and sends it the registration number of the notification. Within 10 days from the beginning of the procedure, the competent authority will send:

- a copy of the notification, accompanied by the appraisal application, for each one of the authorities involved and to the Commission for biological security, which issues an appraisal ;
- the notification summary in English, at the European Commission.

Within 60 days from the beginning of the procedure, the Commission for biological security sends the appraisal scientifically substantiated to the competent authority and to each of the involved authorities. The authorities involved send their appraisal to the competent authority within 15 days starting the date of receiving the appraisal of the Commission for biological security.

Within 5 days from the date of beginning the authorization procedure, the competent authority starts the procedure of consulting with public, which takes 30 days, starts in the 6^{th} day and ends in the 36^{th} day from the procedure start (art.17).

The information destined to the public is published on the internet address of the competent authority, as well as at the siege of the agency for environmental protection in the region/county or of the local council from the place where the deliberate introduction will occur. The public can send its comments to the competent authority by e – mail or by mail with registered letter, and can see the notification file, except for undisclosed data, based on an application send to the competent authority.

Within 10 days from the end of the public consultation procedure, the competent authority elaborates a synthesis of its rematks, which is then send to the central public authority for environmental protection, to the involved authorities and to the Commission for biological security.

The decision on the authorization is taken within maximum 90 starting the beginning of the procedure; this is based on the scientifically substantiated appraisal of the Commission for biological security, the appraisal of the involved authorities, the synthesis of the public consultation and the results of consulting the member states.

According to art. 18 line (3) of the G.U.O. no. 43/2007, the decision can be:

a) *favorable.* The competent authority issues the authorization, which sets the conditions of the deliberate introduction in the environment, and the entity sending the notification must observe them or

b) *unfavorable.* The competent authority rejects the authorization application, if the introduction proposed does not accomplish the conditions imposed by the law. The competent authority informs the entity sending the notification, by registered letter, regarding the decision taken and, if applicable sends the authorization, which is then published on its internet address and a copy is forwarded to the central public authority for environmental protection. The entity sending the notification can start the deliberate introduction in the environment only after receiving the authorization, on condition that this is observed.

The authorization regarding the deliberate introduction in the environment is issued into Romanian and English and has a compulsory content.

In accordance to the law, the authorization regarding the deliberate introduction in the environment cannot be transferred to other people, which mean it is issued after considering the person of the entity sending the notification, thus having a personal character.

2.3.3. Simplified procedures

In the context of accomplishing certain criteria, stipulated in annex no. 5 of the G.U.O. no. 43/2007, for the genetically modified organisms in whose case a sufficient experience was obtained on the occasion of its introduction in certain types of systems – one can apply to simplified procedures.

In such cases, the competent authority, with the approval of the central public authority for environmental protection, can present the European commission a motivated proposal concerning the application of a simplified procedure, based on the favorable appraisal of the Commission for biological security and of the involved authorities, if applicable. The proposal must be the object of a decision of the European Commission, which sets the minimum quantity of technical information, necessary to evaluate any predictable risks after their introduction in the environment (art.19).

The competent authority waits for the decision of the European Commission for 90 days starting the date of the proposal transmission, to which one must add the period when the European Commission receives the competent authorities' comments of the other member states, the public observations and the communitarian scientific boards' appraisals.

2.3.4. Review, suspension or cancellation of the authorization

Any change /changes, deliberate or not of the authorization conditions regarding the deliberate introduction of a genetically modified organism or of a combination of such organisms in the environment, with consequences on human health and on the environment, creates for the entity sending the notification the obligation to properly review the measures specified in the notification.

When the competent authority encounters new information with possible impact on human health and the environment, it requires the appraisal of the Commission for biological security and of the involved authorities, it publishes this information on the internet address and sends it to the control agency of the central public authority for environmental protection, along with the evaluation of the Commission for biological security. Based on these appraisals, the competent authority, after consulting with the entity sending the notification, at its request, can ask for the review, suspension or cease of the deliberate introduction in the environment and informs the public regarding this on its internet address.

According to the dispositions of art. 24 of the G.U.O. no. 43/2007, the competent authority can suspend or withdraw the authorization regarding the deliberate introduction in the environment issued to the entity sending the notification, in the following cases:
- the conditions imposed in the authorization are not or are no longer accomplished and no alternative solution could be found for the suspension /cancellation of the authorization. If applicable, the appraisal of the Commission for biological security will be previously asked;
- one noticed that the data based on which the authorization was issued are founded on incorrect or false information.
The suspension/cancellation of the authorization is made after prior notification, by which a term to accomplish the obligations can be given, according to the authorization requirements, and during the suspension period it is forbidden to carry out the activity.

2.3.6. The standard authorization procedure of the activities aiming at introducing genetically modified organisms on the market, per se or as part of the a product

According to the law this procedure does not apply to genetically modified organisms per se or as part of a product in the following categories: those authorized according to the communitarian legislation and to medicament products for human or animal use.
The competent authority will decide regarding the notification acceptance within 20 days starting with its registration; the absence of an answer does not equal a tacit acceptance of the notification.
In case the notification is accepted, the competent authority registers it, informs the entity sending the notification in writing, communicates the notification number and mentions the number of copies in the notification file necessary in the authorization procedure, file the it must send to the competent authority within maximum 7 days. A delay in sending the documentation leads to the extension of the other terms, adding the delay duration.
In case the notification will be rejected, the competent authority communicates its reasons to the entity sending the notification in writing and displays the missing information. The entity sending the notification must complete the missing information within maximum 10 days, and in case the entity sending the notification will not complete the notification file within due time, the authorization procedure will be suspended without reducing the its right to submit a new file.
The authorization procedure starts the date the competent authority announces the entity sending the notification about the file acceptance and communicates it the registration number of the notification.
Within 10 days from starting the procedure, the competent authority transmits:
a) a copy of the notification accompanied by the appraisal issue application, to the Commission for biological security and the authorities involved, that issue an appraisal ;
b) the notification summary in English, to the competent authorities of the other member states and to the European Commission.
Within 75 days, calculated starting with the date of beginning the procedure, the Commission for biological security will issue a scientific appraisal, as well as the rapport drawn up with this occasion. The appraisal is send to the competent authority, into Romanian and English, and to each of the authorities involved into Romanian. When issuing its appraisal, the Commission for biological security considers strictly scientific arguments, with updated references to the specialty literature. In addition, the Commission for biological security acknowledges the comments enunciated by the competent authority and the public's observations regarding the bio-security aspects, including the observations of the other member states.
Besides, within 5 days starting with the beginning of the authorization procedure, the competent authority starts the consultation and participation procedure of the public in taking the decision.

The public can send its comments within 30 days and can see the notification file, except for the secret data.
At the end of the term set for receiving the public's comments, the competent authority elaborates their synthesis which is then sent to the central public authority for environmental protection to decide on organizing public debates or not.
Within maximum 90 days from starting the authorization procedure, the competent authority, based on the appraisal of the biological security Commission, of the authorities involved, of the information destined to the public and of the public's consultation synthesis, of the risk management measures, elaborates an evaluation rapport of the notification, which can be:
a) *favorable* and decides motivated that the genetically modified organism/organisms can be introduced on the market and in what conditions;
b) *unfavorable* and decides motivated that the genetically modified organism/organisms cannot be introduced on the market.
In all cases the evaluation rapport will be send to the European Commission after consultation with the central public authority for environmental protection.
In order to facilitate the public' participation, the competent authority publishes the evaluation rapport on its internet address, on the date of its communication and starting this date the public has 30 days to send its comments. Within 10 days after receiving the comments, the competent authority sends them to the Commission for biological security and to the involved authorities.
The competent authority informs the entity sending the notification by registered letter about the decision taken and sends it the authorization. The authorization is given for a period of maximum 10 years, calculated starting the issue date, and its existence conditions the introduction of the mentioned genetically modified organisms on the market.
The authorization can be renewed in the conditions and according to the procedure regulated by the law.
In accordance with the law, a genetically modified organism which constituted the object of an authorization concerning the introduction on the market, per se or as part of a product, can be used without any other notice on the territory of the Community, as long as the specified conditions for use and the geographic and/or environmental areas specified in the respective authorization are observed (art. 38).

2.4. The trans-border movement of the genetically modified organisms

According to the dispositions of art. 41 line (2) of the G.U.O. no. 195/2005 regarding the environment protection, the import on the territory of Romania and the export of a genetically modified organism can only be made by juridical entities. The holders of these activities must ask for and get the import agreement for genetically modified organisms. In the meaning of the law, the import agreement for genetically modified organisms is the technical-juridical document issued by the competent authority for the environment protection, which gives its holder the right to carry out the activity of import with genetically modified organisms/micro-organisms and sets the conditions in which they can run, according to the in force legislations.

2.5. Conclusions

The legislation in the domain of genetically modified organisms confirms the fact that one of the modern techniques, currently used to prevent or limit the damage caused to the environment, consists in the obligation to get a previous special authorization (*lato sensu),* to run certain activities or to use the products or service including an ecological risk.
Both the authorization for activities with genetically modified organisms and the import agreement for genetically modified organisms are individual administrative documents, by which rights and/or obligations are set, determined for the subject to which they address to. They are «half-free authorizations», meaning that they are issued based on an assessment right of the environmental authorities, though conditioned by an objective element – the evaluation of the

impact on the environment – and another subjective subject – conclusions deduced after public debates and the public's consultation. All these confer an irrevocable character to them, but one which must be motivated and substantiated.

The authorization concerning activities with genetically modified organisms has an exclusive character because, by its issue procedure, coordination and a synthesis of all the other appraisals are achieved. It authorizes the activities which produce an impact on the environment as a result of a control about the cause and all the consequences to the environment generated by these activities. Based on the authorization, the holder gets the right to carry out the respective activity in the offing of the environment protection requirements.

The environment agreement has an intermediary position between appraisal and authorization, with a specific juridical profile because of its purpose and because of the applicable juridical regime. A feature of the environment agreement is that compared to the environment authorization it is issued parallel to the other regulation documents issued by the competent authorities according to law.

Certainly, both the authorization regarding activities with genetically modified organisms and the import agreement for genetically modified organisms, are issued subject to the third parties' rights and they do not create the gained right to pollute. In all cases, the polluter must assume contravention, civil or criminal responsibility of its deeds, as applied, and will not be able to hide behind the administrative authorization which was issued to it to justify about a damage caused to the environment.

2. REFERENCES

[1] Published in the Off. G no. 1196 of 30th December 2005, G.U.O. no. 195/2005 was approved by Law no. 265/2006.

[2] Directive 2001/18/CE regarding the deliberate introduction of genetically modified organism in the environment and Directive 90/219/CEE regarding the use of genetically modified micro-organism within isolation conditions. Published in JOCE no. L 106 of 17th April 2001, Directive 2001/18/CE has already suffered a series of changes by: Decision of the Commission no. 2002/623/CE of 24th July 2002, Published in J.O.C.E. no. L 200 of 30th July 2002, Regulation no. 1829/2003/CE of the Parliament and the Council of 22nd September 2003 and Regulation no. 1830/2003/CE of the Parliament and the Council of 22nd September 2003, published in J.O.C.E. l 268 of 18th October 2003.

[3] Published in the Off. G. no. 435 of 28th June 2007 and approved with modifications by Law no. 247/2009.

[4] Published in the Off. G. no. 438 of 28th June 2007.