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# REGULATIONS ABOUT THE INTRODUCTION OF GENETICALLY MODIFIED ORGANISMS IN THE MARKET FOR COMMERCIAL USE

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***Abstract***

*O.U.G. nr. 43/2007 on the introduction in the environment and market of genetically modified organisms took effect because of the need for full compatibility of the Romanian legislation with the EU Directive 2001/18/EC.*

**Key words:** genetically modified organisms market commercial use, human health, the competent authority, Community legislation

## INTRODUCTION

O.U.G. nr. 43/2007 on the introduction in the environment and market of genetically modified organisms took effect because of the need for full compatibility of the Romanian legislation with the EU Directive 2001/18/EC.

Article 1 of the O.U.G. nr.43/2007, which states that "the objective of this ordinance is to ensure legal and institutional framework, harmonized with the EU, such as activities with genetically modified organisms to take place with the principle of precaution, for ensure protection of human health and the environment.

## RESULTS AND DISCUSSION

Any legal person intending to market for the first time, a genetically modified organism or a combination of such bodies as or part of a product, must submit a prior notification to the competent authority. Notification is transmitted in electronic form in Romanian and English, and on paper, in two original copies by mail, with return receipt, or be submitted to the competent authority, which records the date of notification. The notification must contain:

a) application for a permit, which specifies the type of genetically modified organisms and the proposed use;

b) proof of payment of tariff notification dossier evaluation;

c) the technical dossier containing information that takes account of the diversity of locations where the use of genetically modified organisms as or components of products, data and results from introductions made to research and development, the impact on human health and the environment, including:
1. general information, including information on personnel and training;
2. information on genetically modified organisms;
3. information concerning the input and the potential receiver;
4. information on interactions between genetically modified organisms and the environment;
5. internal control measures, traceability, monitoring, remediation methods, waste disposal, contingency plans in case of emergency;
6. an annex containing any confidential data;
d) summary notification under national and Community legislation in force;
e) environmental risk assessment and health
f) the conditions for marketing the product, including the specific conditions of use and handling;
g) the duration proposed for approval, which may not exceed 10 years;
h) monitoring plan to identify the effects of GMOs on human health or the environment, including a proposal for the duration of the monitoring plan, this period may be different from the duration of the authorization;
i) the proposed labeling
j) proposal for packaging;
k) information to the public electronically and on paper;
l) a separate annex with confidential information
m) solemn declaration, completed and signed by the notifier, which assumes full liability for any harm human health or environmental material goods, which would result from the proposed marketing.

If, on the basis of the results of any introduction notified or on other important considerations, for scientific reasons, a notifier considers that the marketing and use of genetically modified organisms as or part of a product does not pose a health risk human and the environment, he may propose to the competent authority not to provide some necessary information listed above. Notifier included in this notification information on data and results of placing the same genetically modified organisms or the same combination of GMOs previously or currently notified notification and/or introduced by the notifier either inside or outside the Community.

Also, the notifier may refer to data or results from notifications previously submitted by other notifiers or submit additional information it deems relevant, whether the information, data and results are confidential or these notifiers have given their consent writing.

Notifier is required to provide blank samples from genetically modified organisms, the legal representative of the supervisory body and/or competent authority or an accredited laboratory to perform the analysis, with the service no later than 10 days after the acceptance notification .

Auth start after the competent authority notifies the notifier shall notify the acceptance of the dossier and the registration number of the notification. If notification is not accepted competent authority shall notify in writing the reasons and the notifier states that the missing information. Notifier is required that not later than 10 days to complete missing information in the notification dossier and if the notifier does not complete file notice within the prescribed period, be withdrawn authorization procedure without prejudice to its right to file a new file notification.

After beginning the procedure, the competent authority shall send a copy of the notice, together with the request for an opinion, the Commission for Biological Safety and the authorities concerned to give an opinion. A summary, in English, is sent to the competent authorities of other Member States and the European Commission. The transmission is made after consulting the central public authority for environmental protection. Biological Safety Commission takes note of comments made by the competent authority and public comments on issues of biosecurity, including comments from other Member States, by issuing a strictly scientific opinion, which I submit to all authorities involved. If the opinion needs information, the Commission shall notify the competent authority an application motivated.

The authorities concerned shall transmit its opinion to the competent authority within 15 days from the date of receipt of the Committee on biological safety.

Public consultation procedure is done by publication, by the competent authority, the Internet address and the media, within 5 days of the date of commencement of the proceedings of a summary of public notification may send its observations to the authority, for 30 days, by email or by mail, with return receipt and can see the file notification, excluding confidential data, based on an address to the competent authority. At the end of the set term for receiving public comments, the competent authority shall draw up a summary of them, which is transmitted central environmental authority to decide the organization or public debates.

Not later than 90 days from the start of the authorization procedure, the competent authority with the Commission for biological safety, the authorities concerned, public disclosure and the synthesis of the public, risk management measures, establish a evaluation report of notification.

The report can be:

a) positive and lays the ground that organism / GM can / may be introduced in market and under what conditions;

b) adversely and establish reasoned that organism / GM may / may not be introduced in market. The competent authority shall forward a copy of the report to the central public authority for environmental protection, body control, Biological Safety Commission, notified, if a positive report, the European Commission.

After streaming the report, the competent authority receives requests for information and comments or objections, motivated, on the marketing of genetically modified organisms in question, issued by the competent authorities of other Member States or the European Commission. If you do not receive a reasoned objection from another Member State or the Commission or if they reach agreement on any outstanding issues within the 105 days following the submission of assessment report the European Commission, the competent authority shall issue a permit for entry market. Shall inform the notifier by letter about the decision and provide authorization by this presentation of proof of payment of a charge. Authorization is granted for a maximum period of 10 years, counted from the date of issue, and the notifier may proceed with the placing on the market only after receiving authorization and under the conditions specified therein.

If renewal, no later than 9 months before expiry of the permit issued, if Romania is a Member State which received the initial notification, the notifier shall send the competent authority a notification of renewal. After receiving notification of renewal, shall check that the notification be accepted. Not later than 90 days after the start of the procedure for renewal, the competent authority, based on advice received and the results of the public, prepare an evaluation report. It indicates that: a) organism / GM may remain on the market and under what conditions; b) organism / GM may / may not remain on the market. The competent authority shall forward a copy of the report to the central public authority for environmental protection, Biological Safety Commission and the notifier and the European Commission after it is approved by the central government for environmental protection. In the absence of reasoned objection from a Member State or the Commission, within 60 days following the submission of assessment report, the competent authority issuing the decision to renew the marketing authorization and the following steps:

a) inform the notifier by registered post and send an authorization as proof of payment of a charge set;

b) shall permit, on paper, within 7 days of issue, the central public authority for environmental protection, the authorities involved, the oversight body and to the biological security;

c) inform the other Member States and the European Commission on the permit within 30 days of its issuance. Duration of validity of the authorization shall not exceed 10 years. Where are made by Member States or the European Commission inquiries, comments or any grounds, the competent authority and the Commission may discuss any issue dissenting, to reach an agreement within 75 days the date on which the European Commission evaluation report submitted by Member States and the purpose is:

a) if an agreement is reached, the competent authority issuing the final decision to send a notifier payment of a charge. Duration of validity of the authorization shall not exceed 10 years and may be limited, reasoned, in specific conditions;

b) if no agreement is reached and a competent authority of a Member State or the Commission formulate and maintain an objection, the Community procedure. If a positive decision was taken at Community level, the competent authority issuing the authorization for marketing the product or renew the authorization, send a notifier and inform the other Member States and Commission thereof within 30 days of permit issuance . The permit shall be submitted on paper and electronically, the central public authority for environmental protection, the authorities involved, the oversight body and the Commission for Biological Safety. After notifying the renewal of a permit, the notifier may continue marketing until the final decision on renewal, but with the conditions and period of validity specified in that consent.

A genetically modified organism that has been on the marketing authorization as or part of a product may be used without further notification throughout the Community as long as the specific conditions of use and geographical areas and / or environment specified in that consent. If the competent authority may have received new or additional information that became available after its release and affecting human health risk assessment or environmental, or re-evaluate existing information on new or additional scientific data and has reasonable grounds to believe that genetically modified organisms as or part of a product that has been notified and a valid permit issued in a Member State, present a risk to human health or the environment, this may limit the the validity of the authorization or may restrict or prohibit temporarily the use and/or sale of this body, as such

or component of a product, territory, after consulting the Commission for Biological Safety and the authorities involved.

The decision to initiate the procedure for applying the safeguard clause, belongs to the central public authority for environmental protection, the proposal of the competent authority.

The competent authority shall, in case of major risks, taking emergency measures such as suspension or termination of its placing on the market and provide information to the public, with the approval of the central public authority for environmental protection.

Before taking a decision, the competent authority gives consent holder can comply with the requirements described in the permit. Shall inform without delay the advice of public authority for environmental protection, European Commission and other Member States on actions taken and the reasons for its decision, sending reappraisal of risk to human health and the environment, indicating that the conditions of the permit must be revised as or where the intended cancellation of the permit and, where appropriate, new or additional information that is based that decision. The final decision on the application of the safeguard clause will be taken at EU level, within 60 days. In calculating this period does not take into account the period during which the Commission is awaiting information requested from the notifier or is seeking the opinion of the Scientific Committees have been consulted and the period during which the European Union Council acting in accordance with Community.

**CONCLUSION**

O.U.G. nr. 43/2007 on the introduction in the environment and market of genetically modified organisms took effect because of the need for full compatibility of the Romanian legislation with the EU Directive 2001/18/EC.

The text clarifies the responsibilities of all stakeholders in the field of GMOs and regulates increased sanctions for those who do not comply with the ordinance regulations.

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