Avosetta Meeting on GMOs (Siena, 29-30 September 2006)

Romanian Report

by
Dr. M.Józon, LL.M
Sapientia-Hungarian University of Transylvania

1. *Which is the national regulatory approach to GMO in the Member States? Is there a horizontal act on GMO or just sectoral regulations apply in the Member States?*

The current legal framework is based on a special framework law (Law no. 241 of 2002), which constitutes the primary legislation. Its provisions are further detailed through special environmental laws, and specific provisions governing the activities related to GMOs in consumer legislation, agricultural legislation, and health legislation.
The relevant legal framework mainly consists of:
a) Horizontal legislation: Emergency Ordinance no. 195 of 2005 *on environment protection*, which replaces the former Law no. 137 of 1995 on environment protection.
b) Specific legislation**:**

Government Decision no. 173/2006 *on the contained use and labelling of GMOs and traceability of food and feed containing GMOs*
Government Decision no. 256 of 2006 *on animal feed and food containing GMOs*
Ministerial Order no. 237 of 2006 *on the authorisation of GMO producers*
Government Decision no. 28 of 2006 *on cross-border transport of GMOs*
Ministerial Order no. 1295 of 2005 *on the notification requirements on the deliberate release of GMO in the environment, for other purposes than placing them on the market*
Ministerial Order no. 838 of 2005 *on approval of the Guidebook on the Monitoring Plan required by Law no. 214 of 20004*
Ministerial Order no. 923 of 2005 *on the approval of the notification form for placing on the market of GMOs or products containing GMOs*
Ministerial Order no. 606 of 2005 *on the approval of the notification form for the release of GMO plants in the environment for other purposes than their placing on the market*
Law no. 42 of 2005 *on Romania's accession to the International Convention on the vegetal genetic sources, adopted in Rome on November 3, 2001*
Law no. 878 of 2005 *on public access to information concerning the environment*
Law no. 214 of 2002 *on the approval of Emergency Ordinance 49 of 2002, on the legal regime of production, testing, use and distribution of GMOs, and of the products resulting from GMOs*
Government Emergency Ordinance no. 49 of 2000 *on the legal regime of production, testing, use and distribution of GMOs*
Law no. 59 of 2003 *on the ratification by Romania of the Protocol on Biosecurity and of the Rio de Janeiro Convention on Biodiversity*
Order no. 84 of 2003 of the Ministry of Agriculture on the approval of the regulation on testing and registration of new variety of agricultural plants
Law no. 58 of 1994 *on the ratification of the Convention on Biological Security*

Ministerial Order no. 684 of 2002 on the members of the Commission on Biological Security

2. Executive competencies in the Member States: which national authority is responsible for the area of Dir. 98/81 and Dir. 2001/18 and for the area of Reg. 1829/2003 and Reg. 1830/2003?

Environmental policy related to GMOs is implemented at central, regional (regional environmental agencies) and local level (county level environmental agencies). The coordination at horizontal level among the central public authorities is done by the Ministry of Environment and Water. Other central public authorities with competencies in the field of authorization, monitoring and surveillance related to GMOs are: the National Authority for Consumer Protection, the National Authority for Food Safety, the National Environmental Guard, and the Ministry of Agriculture, Forest and Rural Development.

In Romania the regulatory policy on GMOs is Environmental Ministry led, but the policies of and coordination with the Ministry of Agriculture, Forest and Rural Development have a decisive role on the effectiveness of the policies related to GMOs. It can be said that the Ministry of Agriculture, Forest and Rural Development is the most influent central public authority with its *de jure* and de *facto* role on the development of the Romanian legal framework on GMOs. However, this role is not benefic at all, as will be seen in the later sections of the Report, for the promotion of strong environmental values in the regulatory policy on GMOs.

The competencies at central level are as follows:

- The *Ministry of Environment and Water* is the central public authority in charge of issuance of authorizations and import licenses for GMOs and products containing or produced from GMOs (Art. 40 paragraph 1 of Emergency Ordinance no. 195 of 2005). Within its decisional process the Ministry requires approvals from the central public authorities for agriculture, health, food safety, consumer protection, and other institutions with competences concerning GMOs and takes into account the opinion of the Commission for Biological Security (Art. 40 paragraph 2).
  It implements its policy strategies and regulations through the National Agency for the Protection of the Environment and the regional and county level agencies (Art. 75.lit. k). The Ministry of Environment and Water appoints the expert commissions for the assessment of damages caused by genetically modified organisms (Art. 75 lit. l).
  The *central public authority for health* has the right to issue opinions in the process of authorization of activities related to GMOs and of import licences (Art. 82 lit. e.).
- The central public authority for education and research also has the competence to cooperate with the other central authorities in the elaboration of the programs and studies on the control of biotechnological products and processes for the prevention, reduction and elimination of risks related to the production and use of GMOs (Art. 85).
- The *Ministry of Agriculture, Forest and Rural Development* has the obligation to assure the protection and conservation of soil and of the agricultural patrimonium, to *assure the authorisation of the genetically modified plants*, to approve the locations and the surfaces designated for GMO agriculture, to cooperate within the authorisation process with the Ministry of Environment and Water, to assure through the national registry the monitoring of agricultural territories used for GMO production, to *apply*

the principle of co-existence of GMOs with other types of agricultural plants, and to report to the Ministry of Environment and Water the findings of its control and monitoring (Art. 87).

- The *Veterinary and Food Safety National Authority* contributes to the elaboration of regulations on GMOs, assures the identification and traceability of products, and cooperates with other authorities for the assessment of the potential risk in the process of authorization of GMOs, as well as in the elaboration of the criteria for the assessment of potential risks resulting from the use of genetically modified food and feed. The Veterinary and Food Safety National Authority has control competences as well.
- The National Authority for Consumer Protection has the right to be involved in the process of elaboration of regulations on GMOs and assures the control of implementation of such regulations, as well as controls the traceability and the labelling of GMOs in all stages of their introduction on the market (Art. 93).

The *Commission for Biological Security* is a scientific authority with consultative role in the process of decision making by the Ministry of Environment and Water. It is composed of 12 members, all well known specialists with academic titles: 3 members of the Romanian Academy, 3 members of the Romanian Academy for Agriculture and Forest, 3 members from the Academy of Medical Sciences, or/and institutions under their coordination, and 3 members from universities and other research institutions with biological, agricultural or medical profile (Art. 4 paragraph 2). Its decisions are based on unanimity.

3. Implementation and enforcement of Directive 2001/18/CE on the deliberate release into environment of GMO:

a) What about risk assessment, management and the concept of precaution?

Any legal person willing to *release* in the environment genetically modified organism must submit a notification to the Ministry of Environment and Water (Art. 24, Law no. 214 of 2002). The notification must include the following documents: a technical file according to Annex 8; risk assessment according to Annex 12.2, including the methods applied; information on the deliberate release of the same organisms in Romania or abroad.

In case of such a deliberate release, which may have effects on human health or on the environment the applicant must review the measures, and to inform the Ministry. The applicant for authorization must take the necessary measures for the protection of human health and of the environment. However, the applicant may request from the Ministry the *simplified procedure of notification*.

Upon receipt of the notification, the Ministry issues the authorisation within 90 days. For issuing the authorisation the *Ministry informs the public on the notification*, consults the Commission for Biological Security, and requires the necessary approvals from the central authorities for agriculture, food and human health and consumer protection.

The *simplified procedure* for the deliberate release may be granted in cases when the Ministry considers that the applicant has sufficient experience in the deliberate release of a genetically modified organism, according to the criteria fixed in Annex 10, and decide to apply the simplified procedure for the deliberate release in the environment of the GMOs concerned.

In order to obtain the authorisation, the applicant must make an evaluation of the contained use according to the procedures stated in Annex 3, section A and B. There are 4 categories of risks in which the evaluation of use could be included. The users need to keep records of the contained use and put there at the disposal of the Ministry of Environment and Water.

According to Art. 17 of Law no. 214 of 2002 the Ministry of Environment and Water shall verify whether there has been elaborated an emergency plan for the contained use of the GMOs where the inefficiency of the contained use may give raise to serious danger with immediate effects or later effects on human health, or on the environment. Such emergency plans will be not required if the applicant can provide the Ministry with a *similar emergency plan issued in the European Union*. In case of an accident the user has to inform the Ministry with the following information: the circumstances of the accident, identification and the quantity of the organisms in case, any other information necessary, and the measures taken (Art. 18). The Ministry has to consult with the national authorities of other states about the causes of the accident, including the plans of intervention in case of emergency, immediately inform the international organisations about the measures taken and their efficiency and provide them with an assessment of the accident, recommendation on the mitigation of the effects and for their avoidance in the future.

According to Article 39 *risk assessment* is carried out according to a scientific and transparent procedure, as required in Annex 12. Risk assessment aims the identification and evaluation of potential negative effects of the GMOs or the product resulted from them on the *biological diversity*, human health, taken into consideration *socio-economic arguments* as well. However, the importer should assure that the conditions of packaging, product specification, labelling and transport in the country of origin are not less stringent than in Romania (Art. 41). In case of illegal import, the competent authorities may require the state of origin to assure the re-import of the GMOs at its expense. Such cases will be notified to the competent international authorities as well (Art. 42).

> *b) Which is the impact of the complex, multi-level EC law procedure for the release of GMO in domestic administrative systems and organizations? In particular, which are the procedures of authorization? Are the scientific bodies involved in such a process and what is their influence on the competent authority's decisions?*

According to the framework law, authorizations for the deliberate release in the environment, placing on the market GMOs, for their contained use may be issued only for legal persons (Art. 41). The same applies for the import licenses related to GMOs (Art. 41).
According to Art. 44 those persons who undertake activities related to GMOs are obliged to take measures for the elimination of waste resulting from their activities.
The authorisation is compulsory for registration of the new plant variety for examination by the State Institute for Testing and Registration of Variety of Plants (Art. 25).
Before the placing of GMOs as such or as product on the market the party concerned must send to the Ministry of Environment a notification including: information according to Annex 8 and 9, information on the effects of the GMOs on the basis of the scientific research, the environmental risk assessment study according to Annex 12.1, the conditions for placing the product on the market, including the specific conditions of handling and use of the products; a proposal for labelling and packaging, according to Annex 9; a monitoring plan according to Annex 12.2, and the resume of the notification. The label on the product must mention that a genetically modified organism is present in the product. The statement" this product contains GMO" is compulsory. *Within 10 years shall be set up the procedures which will allow the use of GMO free product labelling in Romania* (Art.29).

A separate notification needs to be made for imports of genetically modified organisms as such or as products (Art. 35). The decision of the Ministry on the import notification shall be based on the data concerning the risk assessment according to Art. 39, on the basis of

scientific evidence and *precaution.* The authorisation shall take into consideration the negative effects on the conservation of biodiversity, on human heath and if necessary, the *social and economic criteria*. The Ministry of Environment and Water can make the import license subject to conditions.

The length of authorizations shall be established on case by case basis, for a period no longer than 5 years. The renewal of the authorisation is allowed for another period of 5 years.
Law no. 241 of 2002 explicitly states the exclusion from the National List of Species of those genetically modified plants, which do not comply with the provisions of the Law, and the withdrawal from the market of such products as by 31 December, 2002. The Annexes of the Law no. 214 of 2002 transpose into the Romanian legislation the following directives:
Annex 1 implements Annex IA of Directive 98/81/CE
Annex 2 implements Annex A of Directive 98/81/CE
Annex 3 implements Annex III of Directive 98/81/CE
Annex 4 implements Annex IV of Directive 98/81/CE
Annex 8 implements Annex II of Directive 94/15/CEE/1994 (contains the information required for the notification)
Annex 9 implements Annex II of Directive 90/220/CEE/ and Directive 97/35/CE
Annex 10 implements Decision 93/584/CEE
Annex 11 implements Annex i. of the Cartagena Convention
Annex 12 implements Annex ii of the Cartagena Convention
Annex 12.1 establishes the principles on the environmental impact assessment
Annex 13 implements the provisions of Directive 90/219/CEE and 90/220/ CEE on taxes for the issuance of import licence and authorisation of GMOs.

c) What about self-monitoring and supervision by administrative bodies and public entities (NGOs, etc.)? How the safeguard clause is applied?

Ministerial Order no. 838 of 2005 issued by the Ministry of Environment and Water transposes into the Romanian legislation Decision 2002/811/CE and Directive 2001/18/CE Annex vii on the deliberate release in the environment of genetically modified organisms, which amends Directive 90/220/CEE. The Order approves the Guidelines for the application of Annex 12.2 "on *Monitoring Plan*" to the Emergency Ordinance no. 49 of 2000.
Law no. 214 of 2002 provides the obligation of the notifying parties to implement a self-monitoring plan which allows the identification of any direct, indirect, immediate, later or not foreseen effects of the GMOs for human health and the environment, as such or in form of products, after they were put on the market. According to Art. 1 of Law 214 of 2002 the notifying party has to submit to the authority together with the authorization notification a *monitoring plan* as integral part of the notification, according to the model plan provided in the Order.
The authorisation must in all cases clearly specify the monitoring requirements, according to Annex 12.2, including the obligation of the applicant to elaborate and submit reports to the European Commission and the Member States upon Romanian's accession to the EU. Under the heading, Objective of the Monitoring Plan, Section A, it is stated that the risk assessment is aimed to identify on a case by case basis the *potential adverse effects of the genetically modified organisms, regardless whether these are direct, indirect, immediate or later* effects on human health and on the environment, after they were placed on the market. It is clearly stated in the Ministerial Order that the assessment should take account also of the long-term *potential effects* of the GMOs, associated with their *interaction with other organisms, or with the environment*. The assessment of such potential adverse effects should be made according

to the currently applied methodology, which should be founded on scientific evidence, independently verifiable. The objective of monitoring is to confirm that all the hypothesis concerning the occurrence and impact of potential adverse effects of the GMO or of its use are correct and according to the report on the ecological risk assessment, as well as to identify the occurrence of those *potential adverse effects which were not foreseen in the environmental impact assessmen*t. The authorisation establishes the length of *self-monitoring*, and the conditions of the monitoring. The Ministry of Environment and Water shall forward to the European Commission and to the Member States the reports submitted by the notifying parties, and may adapt the monitoring plan in consultation with the authorities of the Member States, upon the first stage of monitoring (after Romania's EU accession). The Order explicitly provides that it should be included in the Monitoring Plan also the supervision of the *unforeseen*, *unexpected potential effects*. However, in this context, the Order mentions that there needs to be taken into account the *cost-efficiency* of the specific monitoring and general supervision. The plan should be drafted according to the most recent scientific knowledge and practices. The general supervision programs and the ecological monitoring programs "*may* be useful as well." In case of *unexpected changes in the environment*, a new assessment of the risks may be necessary, in order to establish whether these have occurred as result of the release of GMOs in the environment or as the result of other factors. Two types of monitoring are mentioned by the Order: the general supervision and the specific monitoring, which is case specific. *The general supervision differs from the specific monitoring because it identifies and registers any adverse effects, being indirect, later, or/and cumulative, unforeseen in the risk assessment*. It is done for a longer period and larger areas, if the case may be. The case by case, specific monitoring serves the confirmation of the correctness of scientific hypothesis of the environmental risk assessment. These focus on the potential effects on human health and environment, mentioned in the risk assessment, *taken into account the location, type of soil, climatic conditions.*
According to Law no. 214 of 2002 the responsibility of elaboration and inclusion of the self-monitoring plan into the notification file for authorisation and its proper implementation lies on the party asking for the notification. "It is not excluded that the central public authority for environment will undertake an additional monitoring in form of case monitoring or of a general supervision". The information resulting from the monitoring reports *will be made public*, according to the legal requirements. The notifying party is obliged to assure the necessary *transparency* of the results of self-monitoring. Therefore, the monitoring plan must include also the modalities of reporting /publication of information that can be done through: information sheets, workshops, exchange of information, documents of the companies, internet sites, commercial and scientific publications.

d) How are transparency and participation dealt with? What about the access to information on GMOs?

Emergency Ordinance no. 195 of 2005 stipulates clearly in Article 5 that the state recognises the right of any person for a healthy and ecologically balanced environment and grants for this purpose: a) their access to information concerning the environment, subject to the requirements of confidentiality, b) their rights to set up organisations for the protection of the environment, c) their right to be consulted in the process of decision making concerning environmental policy and legislation, issuance of regulations, of plans and programs, d) their *right to court actions and administrative actions, directly or through environmental organisations, regardless of damages having occurred or not,* e) their right to compensation for damages suffered.

Emergency Ordinance no. 195 of December 2005 also states in Article 20 paragraph 4 a deadline of 12 months for the establishment of the modalities in which the public can participate in the process of elaboration of the environmental plans and programs. Romania has ratified the Arhus Convention on Public participation by Law 86 of 2000.
Public consultation is compulsory in case of issuance of regulations (Art. 20, paragraph 3 of Law 241 of 2002).
Another significant change introduced by Emergency Ordinance no. 105 of December 22 2005 is that the Ministry of Environment and Water is obliged to consult at least once a year with the representatives of the non-governmental organisations and other representatives of the civil society for the establishment of the environmental strategies (art. 75 lit t).

The authorisation procedure for the deliberate release of genetically modified organism in the environment is a *public procedure*. The dissemination of information on GMO related activities is assured by the Ministry of Environment and Water. Within 10 days upon the receipt of notification the Ministry of Environment and Water has to inform the public and to specify the modalities how the public can get information about the case (Art. 49). Information on pending notifications can be found on the website of the Ministry (www.mmediu.ro).
Comments can be made by the public within 30 days from the date when the information was made public. On the basis of the information received public debates may be organized in relation to any aspects of the activities. The following information cannot be treated as confidential information and exempted from the obligation of transparency: the conclusions of the environmental risk assessment studies, the risk category in which the GMO concerned is included, the method of monitoring, the monitoring plan and the measures in case of accidents (Art. 49, paragraph 1).

Ministerial Order no. 1295 of December 23, 2005 transposes integrally the Council Decision 2002/813/CE on the resume of the notification form for the deliberate release in the environment of the genetically modified organisms for other purpose than placing them on the market, according to Directive 2001/81/CE. The resume is included in the technical file to be submitted to the Ministry of Environment and Water in order to assure the information of the public and the exchange of information concerning the notification with the European Commission and the Member States (upon accession).

e) How is the court review? Is the legal standing of third parties and associations allowed?

According to the Romanian law the decisions on notification, authorisation, restrictions or ban of GMO related activities are administrative acts against which appeals can be made at the administrative courts.
Article 20 paragraph 6 of the Emergency Ordinance no. 195 of 2005 states the right of non governmental organizations to court action, as active party in cases concerning environmental issues. Non-governmental organisations seem to be central driving forces of monitoring and supervision of the implementation GMO legislation in Romania. In this context it should be mentioned that, besides the Greenpeace and other international environmental organisations acting in Romania, Romanian NGOs' role in promoting GMO free areas and GMO agriculture is also strengthening[1]. This procedural right of the NGOs may have an outstanding

[1] National Federation of Organic Farmers FNAE (www. fnae.ro) and the Information Centre on GMOs InfOMG -Romania (www.omg.ngo.ro)

importance in the future in compensating the weak enforcement capacity of the state authorities and raising public awareness.

f) Which is the nature of the penalties fixed according to Art. 33 (criminal, administrative, civil sanctions)?

There are provided three types of sanctions in case of infringement of the legal requirements (Emergency Ordinance 195 of 2005): administrative, civil, and penal sanctions (Art.50).
The nature and the size of damages shall be established by an expert commission appointed by the Ministry of Environment and Water.
Concerning civil damages the only specific provision states that in case of causation of damages in human health, health of animals, biodiversity or the environment the user of genetically modified organism is liable for such damages (art.51). The measures for the remedy of the damages caused by the use of the GMOs are set up in form of a ministerial order, to be issued by the Ministry of Environment and Water. Against such an order the parties interested can submit complaints at the competent administrative court, according to Art. 51. In case the damages are cased by the import and use of GMOs, the international conventions to which Romania is party will be applicable.

Activities conducted by legal persons with genetically modified organisms or products containing GMOs, without asking and obtaining import/export license or and authorisation required by the law constitutes criminal act, with imprisonment from 6 months up to 3 year or/and criminal penalty amounting from 50,000-100,000 RON (Article 98).

4) Authorisation of the placing on the market of GMOs

a) Authorisations for GMOs other than food and feed: what about risk assessment, management and the concept of precaution? Is the benefit resulting from GMO use considered as a factor to be balanced against the expected risk? Does the risk assessment take into account that the GMO may be released under very different climatic and geographical conditions? Is the public involved? Do the authorities issue general authorisations, or do they restrict authorisations to specific climatic and geographical conditions? Are there third party rights of standing to challenge an authorisation?

b) Authorisations for GM Food and Feed under Regulation 1829/03:
a) What is the national practice in relation to the EC authorisation procedure? Are there national risk cultures expressed in the consultation procedure? How are transparency and participation dealt with?

Regulation 1829/2003 on genetically modified feed and food amending Directive 2001/18 has been transposed into the Romanian legislation by Government Decision no. 256 of 22 February 2006.
Art. 4 of the Government Decision provides that the placing on the market of food or food products containing GMO is subject of authorization, according to the community procedure.
According to Art. 4, paragraph 1 the GMOs designated to human consumption as food, or as food product which contains GMOs, and the products obtained out of, or which contain as ingredients GMOs:

a) should not have adverse effects on human health, on animal health and on the environment, should not mislead the consumers,

b) should not be different from food products for which they are substitutes to such extent that the normal consumption of such products would be in the detriment of consumers, from a nutritional point of view.

According to Art. 5, in order to obtain the authorisation, the applicants must submit the following information to the authority:

- information required by Annex II of the Cartagena Protocol,
- detailed description of the production and fabrication method, if the case may be,
- copies of the studies, independent studies if the case may be,
- any other materials available, to demonstrate that the product fulfils the conditions of Art. 4 paragraph 1,
- an analysis that certifies that the characteristics of the food products are not different from the similar conventional products, or a proposal for labelling according to art. 6 lit. paragraph 6,
- either a motivated declaration that the product does not raise *ethical or religious concerns* or a proposal for labelling according to art. 6, lit. b, paragraph 6,
- information on the method of detection, evidence, and specification of the transformation events, and if the case may be, the methods of detection, specification of transformation of the food product,
- samples from the product and counter evidence, where the reference material can be accessed,
- a proposal for monitoring the use of the product, if the case may be, after placing it on the market for human consumption,
- a resume of the file.

In case of GMOs or food products containing or being made of GMOs, the notification must contain in addition: a technical file according to Annex 8 of Law no. 214 of 2002; information on the risk assessment and the conclusions of the risk assessment, a monitoring plan of the effects of the GMOs on the environment, including a proposal on the length of monitoring. The notification has to be sent to the National Authority for the Animal Health and Food Safety, which shall take a decision within 14 days. The Authority shall inform without delay the European Authority for Food Safety about the notification.

Art. 6 establishes the conditions for the distribution of GMO products to final consumers, if the GMO content of such products is more the 0.9%. The following labelling requirements are provided for: a) in case the product contains more ingredients after each ingredient there must be mentioned the GMO concerned, b) in case the ingredient is identified by the name of a category, the expression "contains GMOs or contains (the name) of the ingredient must be mentioned on the list of ingredients, c) in case there is no such list of ingredients, the expression "genetically manipulated" or "produced form the specific genetically modified organism" should be clearly printed on the label. The indication may be put as footnote on the ingredient list, but in such case the fonts used should be of the same size as those used for the list of ingredients. In case the products are offered for sale to the final consumers as food products, which are not pre-packed or as products in small packages, largest surface of which is less than 10 cm square, the information must be exposed permanently and visibly, either on the shelves or immediately near these, or on the package, with fonts sufficiently large in order to allow the identification of the products and must be easily readable.

Detailed provisions on the conditions of distribution and labelling of feed can be found in Art. 7. Placing on the market, the use or processing of GMOs for feed, feed containing GMOs and feed produced of GMOs is subject to authorisation according to the community procedure.

Feed containing GMOs can be placed on the market only if the relevant information on the GMO content is indicated in visible, readable manner, impossible to be deleted from the documents attached and, if the case may be, from the package, or from the receipt or the label attached to the product. In case a product can be used both as food and feed a single notification shall be submitted for authorisation, according to the community procedure (Art. 11).

b) Which is the legal standing in relation to the Commission authorization?

c) Role of the EFSA in providing the European scientific opinion on an application: should there not be a possibility for national scientific agencies, bodies etc. to comment on an application? Should EFSA be obliged to distribute that opinion together with its own opinion?

5) Coexistence:
a) What have MS done in order to protect non-GM agriculture/processing/trade/consumption? Focus on GM free zones, coordination of agricultural practices, liability, implementation of art. 31(3) of Dir. 2001/18
b) Have MS established a scheme ensuring GM free zones? How does the special impact assessment based on Art. 6(3) Habitats Dir. work?

In charge of authorisation and control of GMO agriculture is the Ministry of Agriculture, Forest and Rural Development. The legal framework on assuring traceability of non GMO agriculture from GMO agriculture is provided by the Ministerial Order no. 237 of April 2006. Art. 1 forbids the growing of GMO plants in the immediate vicinity of certified areas and of those being in the process of conversion for ecological farming. The same article requires the setting up of a protection area as a curtain where non GMO plants are grown, usually plants of high size around the GMO plants with the purpose to prevent the transfer of pollens onto the non GMO plants. The framework law on environment protection also contains certain provisions on traceability. Accordingly, Article 54 prohibits any activity of growing and testing GMO plants within the legally protected natural areas and outside these areas. Infringement of these legal provisions constitutes administrative infringement and can be sanctioned with penalties between 10,000 and 15,000 RON in case of infringement by natural persons and 35,000 and 40,000 RON in case of infringements by legal persons. In Romania there are approx. 1000 protected natural areas. Their location is mentioned in the Annex of the Emergency Ordinance and thus accessible to both authorities and the public.
However, chapter 8 of Emergency Ordinance no.195 of December 22, 2005 (the new environmental law) on conservation of biodiversity and of protected natural areas, only states in general terms in Art. 54 that
(1)“ From the date of Romania’s accession to the EU the growing and testing of genetically modified organisms will be according to the *acquis communautaire*”.
(2) From the Date of Romania’s accession to the EU, there shall be forbidden in Romania the cultivation of those genetically modified organisms which are not allowed in the EU”.
(3) The minimum distance from the protected areas within which the cultivation of genetically modified organisms is forbidden, will de established upon consent by the central public authority for the protection of the environment and water, and the central public authority for agriculture, forest and rural development”.
In this context the provisions of Law no. 345 of June 19, 2006 must be also mentioned which amend the framework law on the legal regime of protected natural areas, conservation of natural habitats of wild plants and animals, issued after the legislative changes occurred in

2006 in the field of GMO related activities. Art. 48 of this law stipulates penalties in case of deliberate release of GMOs on the territory of the protected natural areas. The penalties amount from 1,000 to 3,000 RON in case of infringement by natural persons, and from 5,000-10,000 RON in case of infringement by legal persons. However, in this case as well, the same general comments can be made on the effectiveness of these sanctions, as in case of other legal provision on the protection of the environment in Romania, in general. The value of these sanctions seems to be of reduced preventive effect, both in case of natural and legal persons, taken into consideration the irreversible consequences of such releases for the conservation of biodiversity, especially when GMO plants are grown on large areas.
Neither the Emergency Ordinance no. 195 of 2005, nor the 2006 amendments mention of GMOs in the context of the impact assessment procedure related to activities affecting biodiversity.
The Ministerial Order no. 237 of April 2006 on GMO farming states in Art. 5 that the growing of GMO plants is strictly forbidden inside the legally protected natural areas, as well as in the vicinity of these areas, according to the legal provisions. At each county agency for environmental protection there are available county maps indicating the legally protected natural areas.
Genetically modified plants may be grown only subject to authorization issued by the Ministry for Agriculture and Rural Development through its county level agencies (Art. 6). It is forbidden to grow GMO plants on areas of less than 2ha, except for scientific purposes (Art. 6). Within the Ministry there is set up a special Department of GMO for keeping records of the GMO plantations (Art.9). The Ministerial Order provides the setting up at county level of departments for the implementation of policies, for monitoring and statistics of vegetal production, for the authorization of GMOs, and departments for the inspection of the vegetal production, GMO production, animal production and food industry (Art.10). Annex 7 enlists the competences of the county level departments: a) assessment of the applications and issuance of authorization for GMO agriculture; b) assessment and insertion in the county level registries of data concerning the areas used for GMO agriculture, the origin of the seeding material, the type of plants, volume and destination of the production; c) control of the self-reporting obligations of the GMO farmers; d) supervision and transmission of data to the National Registry on GMO Farming; e) monitoring of the proper implementation of the coexistence measures of GMO farming with ecological and conventional farming; f) inspections of the vegetal and animal production, as well as of the food industry; g) inspections at the headquarters of the companies which conduct GMO farming in order to verify their compliance with the GMO legislation; h) participation in the control activity conduced by the county level veterinary and food safety authorities, the National Environmental Guard and the consumer protection authority; i) participation in the public information campaigns of the farmers and the consumers concerning GMO legislation. The inspectors are obliged to inform within 24h the national Environmental Guard, and the National Veterinary and Food Safety Authority about the infringements, so that the necessary legal measures can be taken (Art.10).
The county agencies monitor and keep records of the: assessments of the production and gathering of production, storage and supply of production, quantities supplied, the destination of supplies, the identification data of customers, the stocks. The GMO farmers are obliged to report the situation of stocks and the supplies on a monthly basis (Art. 10). At county level there are kept registers on GMO farming (Art.11). Suppliers of GMO seeds are obliged by the law to request GMO farming authorization from their customers and to keep copies of the authorization together with the identification data of customers and the quantities sold for 5 years, in the supplies registry requested by law (Art. 12).

The deadline for issuing the authorization for GMO farming is relatively short, only 10 days, a period in which there need to be verified the fulfillment of legal requirement by the applicant farmers. The farmers are further compelled to declare at the county department of the Ministry of Agriculture, Forest and Rural Development, upon 30 days from the termination of sowing the area used for GMO farming, the origin of the seeds, type of seeds used (Art. 12). Upon the gathering further reporting is requested by law on the quantity and destination of the vegetal production (Art. 14). These reports need to be countersigned by the *agricultural centre* to which territorial competence the GMO lands belong (art.16). Further reporting obligations are required from the GMO farmers towards the owners of the neighboring agricultural lands and their legal users, as well as to the local authority (the mayor's office) where the agricultural land is situated, about their intention to start GMO farming. The notification must be written (art. 22).
Art. 21 contains the obligation of the framers to take the necessary measures for the contained growing of the GMO plants (to take the necessary measures to prevent the mixing of the GMOs with conventional and ecological products, separate storage, cleaning of the agricultural equipment, of the conditioning equipment and of the transport equipment, according to the legislation concerning the production of seed material. The owners of lands, within the distances of contained growing, as established by specific rules provided by Law 266/2002 and at the limits of distances provided by the authorization for the release of GMOs in the environment and on placing GMOs on the market, may submit complaints against the GMO farmers at the county department of the Ministry for Agriculture and Rural Development from the date of notification received from the GMO farmer, concerning their intention to start GMO farming (Art. 22). The county department is obliged by law to inform upon request the conventional or ecological farmers about the type of agricultural activity conducted in their neighborhood (Art. 23). There is a National Registry of GMOs within the Ministry, managed by the GMO Department. For obtaining an authorization for GMO farming the applicants must submit besides the identification documents a certificate that they are registered in the farmers' registry, a declaration on their responsibility about the size of the agricultural land to be used for GMO farming and a declaration that they will comply with the requirements resulting from the GMO legislation (Art. 7). These application requirements are rather simple, without asking data or proof on the necessary skills for GMO agriculture or the necessary infrastructure and equipment to carry out such activities. However, it is not clear how effectively can the legal conditions of agricultural farming compensate for the simplicity of obtaining the authorization upon obtaining the authorization. The GMO farmers are compelled to keep a registry on the origin of the seeds used for GMO farming and the destination of the production for at least 5 years (Art. 19), and at the supply of the GMO production to their customers they have to specify clearly in the documents concerning the goods and, where possible, on the goods that they are genetically modified, as well as to indicate the code of the GMO (Art.20). The farmers also are obliged, depending on the type of the GMO plants, and according to the conditions stated in the authorization to take the necessary measures for minimum isolation of the GMOs, according to the legislation on the certification of seeds, to create neutral zones and schedule properly the gathering of production, in order to prevent the cross pollution of ecological and conventional plants of the neighborhood areas (Art. 21).
At the moment it seems that the legal sanctions in case of infringement of the prohibition to grow genetically modified organisms inside the protected natural areas are less stringent than in case of growing GMO plants in the vicinity of the protected area. The only explanation for such a paradox legal solution can be the lack of coordination among the specific legal provisions governing protection of biodiversity and GMO agriculture.

Although it seems that the agricultural legislation does its best to assure traceability and protection of biodiversity, the National Agency for Protected Natural Areas and Conservation of Biodiversity has no consultation right in the process of issuance of authorisations and licences. In spite of the significant changes in the legal framework there are clear signs that the enforcement is weak. Recently there have been reported by the Greenpeace two cases on growing GMO plants inside the legally protected natural areas. One case concerns the growing of GMO soy inside the Danube Delta Natural Reserve, and the other the Natural Park Comana.

So far no information is available about any governmental scheme on GMO free zones. However, recently has been designated the first GMO Free Zone in Romania, as initiative of the local public authorities (municipalities) involved, within the framework of an international project, financed by the GRassRoots. The members of this GMO Free Zone are 2 towns and 26 villages in Transylvania.

6) How GMO traceability and labelling issues are dealt with in the Member States' legislation (Reg. 1829/2003, Dir. 2001/18, Reg. 1830/03)? Do national systems of verification exist? How do they work? Which are the penalties introduced by national legislators?

Government Decision no. 173 of February 2006 transposes into the Romania legislation the provisions of Directive 2001/18 as amended by Regulation 1830/2003/CE on the traceability and labelling of genetically modified organisms and traceability and labelling of food containing genetically modified organisms.
The legal requirements on traceability and labelling are the following: in case of placing on the market for the first time products consisting of genetically modified organisms, or which contain such organisms, the undertakings should provide their customers with information concerning the GMOs, and the identification code of the GMO. In each subsequent stage of the marketing, such information must be provided to the customer in writing (Art. 4). Such information must be stored and kept for at least 5 years from the date of the transaction. For the products made of GMOs or containing GMOs the undertakings have to assure that in case of pre-packed products, the package mentions either that " this product contains genetically modified organism" or the name of the genetically modified organism. In case of unpacked products offered to final consumers, the information related to their content should be inserted on a separate sheet which will be exposed near the products. Such requirements do not apply in case of a GMO content less than 0.9% (Art. 5).
In case of placement of GMO product on the market the distributors should submit to the their customers information on each food ingredient obtained out of GMOs, on each feed or feed additive produced from GMOs, and in case of products for which there does not exist a list of ingredient, they must indicate that the product contains GMOs (Art.7).
The authorities in charge of inspection and control are: central public authorities for food, consumer protection, agriculture, health and protection of environment. In case of infringements, the inspecting authority can decide the temporary suspension of the distribution, until the legal requirements are not complied with, or the temporary ban of the activity, in cases when within 6 months from the date of application of the administrative penalties it has been established the infringement of law by the party involved for the second time. Such administrative penalties amount from 500-1,000 RON in case of infringement of the legal provisions on storage, are of 1,000-2,000 RON for the infringement of provisions on traceability, and 500–2,000 RON in case of improper labelling. These penalties seem to be low in value in order to have an effective preventive function, in my opinion. The lower limit

of the penalty in case of not mentioning on the label that the product contains GMOs is around 150 EUR.
This Government Decision is applicable as of June 30, 2006.

7) How are Member States implementing Directive 2004/35/EC on Environmental Liability with specific reference to GMOs?

Directive 2004/35/EC is not yet transposed into the Romanian legislation.

Final remarks on the Romanian legal framework on GMOs:
The Romanian legislation on GMOs is far reaching more liberalistic than most of the Member States' of the EU. The transposition of the *acquis communautaire* into the Romanian legislation has been speeded up only at the very last moment before its EU accession (under the pressure coming from Brussels), and works as substitute for the lacking national regulatory policy and legal framework aimed at prevention and limitation and effective control of GMO related activities. The *acquis communautaire* continues to be considered by the central public authorities rather as an external conditionality related to the EU membership, than a domestic regulatory necessity for the protection of human health and biodiversity. The regulatory policy in place bears the effects of the pro GMOs Romanian policy of the past 15 years, which was led mostly by market values aimed at extensive GMO agriculture in Romania under the influence of strong industrial lobby coming especially from the USA.
The low environmental culture and low public awareness also contributed to such developments in Romania.
The legislative inflation started at the end of 2005 may be misleading when assessing the effectiveness of legal control on GMO related activities in Romania, because the assessment, control and monitoring capacity of both the central and regional authorities continue to be weak, both from technical and financial point of view.
By January 1, 2007 Romania joins the EU, as the largest GMO producer in Europe, with the largest surface used for GMO agriculture, which raises certain concern at European level under the conditions of free movement of goods.
The activation of European monitoring and control mechanisms by January 2007 will certainly improve the effectiveness of the harmonised legislation in Romania. However, most of the ecological damages caused during the past 15 years remain irreparable and significant measures need to be taken for a more effective control of GMO agriculture, which for the time being is out of control, in spite of the exiting legal framework. The increasing number of cases reported by the environmental organisations on illegal growing of GMO plants and illegal trade in GMO seeds are evidence in this regard.