Origin of report

Party	ROMANIA
Contact officer for report	
Name and title of contact officer:	Mrs. Adriana Baz, Director- Directorate for Nature Conservation, Biodiversity, Biosecurity
Mailing address:	Bd. Libertatii, no. 12, sector 5, Bucharest ROMANIA
Telephone:	+ 021 316 05 31
Fax:	+ 021 316 05 31
E-mail:	baz@mappm.ro
Submission	
Signature of officer responsible for submitting report:	Adriana BAZ
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Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report:

This is the report of the status of implementation of the Cartagena Protocol on Biosafety in Romania, which ratified the Protocol by the Law 59/2003.
The Protocol entered into force on 28 September 2003.
This is the first national report and it was carried out in August – September 2005.

The MEWM has submitted the draft to the following Authorities in the preparation of the report, in order to ensure a participatory and transparent approach to its development and the accuracy of the information requested:

Ministry of Agriculture, Forests and Rural Development (MAFRD)
Ministry of Health (MH)
National Sanitary Veterinary and Food Safety Authority (NSVFSA)
National Authority for Consumer's Protection (NACP)
National Authority for Customs (NAC)

Obligations for provision of information to the Biosafety Clearing-House

1. Several articles of the Protocol require that information be provided to the Biosafety Clearing-House (see the list below). For your Government, if there are cases where relevant information exists but has not been provided to the BCH, describe any obstacles or impediments encountered regarding provision of that information (note: To answer this question, please check the BCH to determine the current status of your country's information submissions relative to the list of required information below. If you do not have access to the BCH, contact the Secretariat for a summary):
The following relevant information which exists at the date and has not been provided yet to the BCH is listed below: **(a)** The secondary and related legislation regarding GMOs is available, in Romanian language, on the site of the Ministry of Environment and Water Management, at the address www. mmediu .ro at Departamentul de mediu/Legislatie OMG si Notificari and on the site of NSVFSA: www.ansv.ro at Legislatie/Legislatie specifica (Law No. 412/2004 on food safety) **i)** Final decisions: 5 import permits and 5 written consents, issued this year. **q)** The Summary of risk assessment studies and other relevant information included in the dossier submitted by the Notifiers to the competent authority for granting the above mentioned import permits on the basis of Law No 214/19.04.2002 for the approval of the Governmental Ordinance No 49/2000 on Obtaining, Testing, Use and Commercialization of Genetically Modified Organisms resulting from Modern Biotechnology, as or in products. This is due to the lack of English version of the studies. The studies have been published on the MEWM's site: www.mmediu.ro (ex. www. mappm.ro)

Information required to be provided to the Biosafety Clearing-House:

(a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20.3(a))

(b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11.5);

(c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);

(d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and emergency contacts (Article 17.2 and 17.3(e));

(e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);

(f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));

(g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);

(h) Illegal transboundary movements of LMOs (Article 25.3);

(i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10.3 and 20.3(d));

(j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);

(k) Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11.1);

(l) Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11.4) or in accordance with Annex III (Article 11.6) (requirement of Article 20.3(d))

(m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)

(n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);

(o) LMOs granted exemption status by each Party (Article 13.1)

(p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1); and

(q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).

Article 2 – General provisions

2. Has your country introduced the necessary legal, administrative and other measures for implementation of the Protocol? (Article 2.1)	
a) full domestic regulatory framework in place (please give details below)	
b) some measures introduced (please give details below)	X
c) no measures yet taken	

3. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered:

Romanian Governmental Programme includes at the environmental protection chapter, objectives and strategies related to biosafety field.

Romanian legislation related to biosafety sector is currently being reviewed in order to fully harmonize with the relevant EC legislation.

The implementation of the biosafety system in Romania is the task of the authorities dealing with genetically modified organisms:
- Ministry of Environment and Waters Management (MEWM) as the competent authority;
- Ministry of Agriculture, Forests and Rural Development (MAFRD), **Ministry of Health (MH)**, **National Sanitary Veterinary and Food Safety Authority (NSVFSA)**, **National Authority for Consumers Protection (NACP)**, scientific authority represented by **Biosafety Commission**, **National Custom Authority (NCA) -** authorities engaged in **decision making process** concerning import, deliberate release into environment of GMOs and placing them on the market, also with responsibilities as follows:
MAFRD: official registration of transgenic varieties, monitoring and control of GMOs;
MH: controls of the safety of the products for humans consumption containing GMOs;
NSVFSA: GMOs control in food and feed, GMOs traceability control;
ACP: surveillance and control of labelling and traceability of food products;
NCA: custom control of documents accompanying GMOs, import/export registers.

Relevant laws and regulations:

- ***Law No 214/19.04.2002*** *for the Approval of the Governmental Ordinance No 49/2000 on obtaining, testing, use and commercialization of Genetically Modified Organisms resulting from Modern Biotechnology, as or in products,* transposing both Contained Use of GMMs Directive (98/81/EC amending 90/219/EC) and Deliberate Release of GMOs Directive (2001/18/EC, reapealing 90/220/EC).

The provisions of the Law are consistent with the provisions of the Protocol.

The Law applies to the activities related to obtaining, testing, use and commercialization of the organisms that are genetically modified by means of modern biotechnology, and are subjected to a special regime regarding the regulation, authorization and administration:
a. The activities related to the contained use of genetically modified microorganisms;
b. The deliberate release into the environment and placing on the market of the genetically modified organisms, as or in products, so that these activities should be carried out in perfect safety for human health and for the environment protection.

c. Import/export of the genetically modified organisms as or in products.

Under this Law, Romania has approved secondary legislation:
- **Order 684/2002** regarding the composition of Biosafety Commission and the approval of its statute;
- **Order 462/2003** regarding the records of economic agents cultivating genetically modified plants;
- **Order 606/2005** regarding the approval of the format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market, for transposing the Decision 701/2003 of the European Commission.

- **Law No 59/11.03.2003** for ratification of the Cartagena Protocol on Biosafety.

At the moment there are no regulations or guidelines for implementing the Protocol. Regulation 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms will be transposed by the end of the year.
For a better implementation of the provisions of the Law no. 59/2003, Romania is carrying out the UNEP-GEF Project "Development of the National Biosafety Framework for Romania", Ministry of Environment and Water Management being the National Executing Agency for this Project.

Most of the obligation of the Protocol are included in Law 214/2002, see ***Other information.***

- **Law No**. **412/2004** on food safety

- Currently we are amending our framework Law for environmental protection: **Law No 137/1995**, adding general provisions regarding the regime of GMOs obtained through modern biotechnologies and clearly defining responsibilities for involved authorities.

Related regulations:

- **GD No 106/2002,** *Annex III: labelling of GMO food*, with its modifications and completions approved and modified by GD No1719/2004 regarding the food labelling.
- **Law No 266/2002** regarding production, processing, control and quality certification, seeds and breeding material commercialisation, as well as registration of plants varieties.

Romania is preparing the drafts for transposing:
- Regulation no. 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms
- Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed
- Regulation 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.
- Council Decision 811/2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- Council Decision 812/2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms, as or in products.
- Council Decision 813/2002 establishing, pursuant to Directive 2001/18/EC of the European

Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market.

Articles 7 to 10 and 12: The advance informed agreement procedure

See question 1 regarding provision of information to the Biosafety Clearing-House.

4. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2)	
a) yes	
b) no	
c) not applicable – not a Party of export	X
5. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) no	
c) not applicable – not a Party of export	X
6. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	X
b) no	
c) not applicable – no decisions taken during the reporting period	
7. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Romania has not been a Party of export of LMOs.	
8. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
In the present GMOs imports are regulated by the national law on GMOs, ***Law No 214/19.04.2002*** *for the Approval of the Governmental Ordinance No 49/2000 on Obtaining, Testing, Use and Commercialization of Genetically Modified Organisms resulting from Modern Biotechnology, as or in products.* The procedure of the advance informed agreement is provided by the law. 5 permits for import of GMOs have been issued in 2005. The exporter (USA, non Party at the Protocol), complied with all the requirements stipulated in Law 214/2002. No obstacles or impediments encountered.	

1/ The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing

See question 1 regarding provision of information to the Biosafety Clearing-House.

9. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	X
b) no	
c) not applicable (please give details below)	
10. Has your country indicated its needs for financial and technical assistance and capacity building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9)	
a) yes (please give details below)	
b) no	
c) not relevant	X
11. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
12. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:	
MEWM did not receive notifications regarding the export of LMOs intended for direct use for food or feed, or for processing, during the reporting period.	
13. If your country has been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:	
MEWM did not receive notifications regarding the import of LMOs intended for direct use for food or feed, or for processing, during the reporting period	

Article 13 – Simplified procedure

See question 1 regarding provision of information to the Biosafety Clearing-House.

14. If your country has used the simplified procedure during the reporting period, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:
Is not the case for Romania

Article 14 – Bilateral, regional and multilateral agreements and arrangements

See question 1 regarding provision of information to the Biosafety Clearing-House.

15. If your country has entered into bilateral, regional or multilateral agreements or arrangements, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:
Romania signed a cooperation Protocol with Hungary focusing on data transmission and information exchange.

Articles 15 and 16 – Risk assessment and risk management

16. If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2)	
a) yes	X
b) no (please clarify below)	
c) not a Party of import	
17. If yes, did you require the exporter to carry out the risk assessment?	
a) yes – in all cases	X
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import	
18. If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3)	
a) yes – in all cases	X
b) yes – in some cases (please specify the number and give further details below)	
c) no	
19. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)	
a) yes	X
b) no	
20. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes	X
b) no	
21. Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	X

b) yes – in some cases (please give further details below)	
c) no (please give further details below)	
d) not applicable (please give further details below)	
22. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	
b) no (please give further details below)	X
23. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:	
A specific risk assessment is mandatory as a part of the notification dossier and is carried out according to the requirements of the Law 214/2002 which is transposing the provisions of the European Union Directive *2001/18/EC on the deliberate release into the environment of genetically modified organisms.* Its aim is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment. The risk assessment report is presented by the notifier, in concordance with Annexes 12 and 12[1] of the Law 214/2002, which are complying with provisions of Annex III of the Protocol. In the decision- making process, MEWM consults the Biosafety Commission, as scientific body in risk evaluation.	

Article 17 – Unintentional transboundary movements and emergency measures

See question 1 regarding provision of information to the Biosafety Clearing-House.

24. During the reporting period, if there were any occurrences under your jurisdiction that led, or could have led, to an unintentional transboundary movement of a living modified organism that had, or could have had, significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States, did you immediately consult the affected or potentially affected States for the purposes specified in Article 17.4?	
a) yes – all relevant States immediately	
b) partially (please clarify below)	
c) no (please clarify below)	X
25. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:	
Not applicable.	

Article 18 – Handling, transport, packaging and identification

26. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)	
a) yes (please give details below)	X
b) no	
c) not applicable (please clarify below)	
27. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))	
a) yes	X
b) no	
28. Has your country taken measures to require that documentation accompanying living modified organisms that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned? (Article 18.2(b))	
a) yes	X
b) no	
29. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter? (Article 18.2(c))	
a) yes	X
b) no	
30. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:	
Regarding the international transport, Romania ratified the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), through the Law no. 31/1994, also the European Accord on International Carriage by Rail of dangerous goods (RID), in the Convention concerning International Carriage by Rail (COTIF) through the Decree no. 100/1983 and the Protocol for modifying COTIF, through the Law 53/2002. Also, Romania ratified all the International Conventions regarding the transport by the sea. The Romanian Law No.214/2002 contains provisions regarding the handling, transport, packaging and identification. The import permits issued by the competent authority under this law are establishing the	

obligativity for the notifiers to ensure the appropriate packaging, labelling (this product contains GMOs) and deatailed provisions regarding safe handling and transport

Romania is in the process of transposing the following EU regulations:
- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms (by the end of this year).
-Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed
- Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

MEWM and National Authority for Customs are in course of elaborating a Protocol regarding the control of the transboundary movements of GMOs, according to the requirements of the Regulation 1946/2003 , of the Art. 18 of the Protocol and the Decisions of the Conference of the Parties to the Protocol.

Article 19 – Competent national authorities and national focal points

See question 1 regarding provision of information to the Biosafety Clearing-House.

Romanian Ministry of Environment and Waters Management is the national competent authority responsible for implementation of the Cartagena Protocol on Biosafety. MEWM nominated:

- Mrs. Adriana Baz, Head of Nature Conservation, Biodiversity, Biosecurity Department, Ministry of Evironment and Waters Management, as Cartagena Protocol on Biosafety, as National Focal Point;
- Mrs. Ana Maria Comanoiu, superior counsellor at Nature Conservation, Biodiversity, Biosecurity Department as Cartagena Protocol on Biosafety, as National secondary Focal Point

All information about competent national authority and national focal points has been provided to the Biosafety Clearing-House.

Article 20 – Information-sharing and the Biosafety Clearing-House

See question 1 regarding provision of information to the Biosafety Clearing-House.

31. In addition to the response to question 1, please describe any further details regarding your country's experiences and progress in implementing Article 20, including any obstacles or impediments encountered:
MEWM is responsible for the implementation of the Cartagena Protocol on Biosafety and for submitting information to the Biosafety Clearing-House. The MEWM appointed the focal point responsible for keeping the BCH up-to-date and for managing communication between the Secretariat and authorities, the public, validating and registering information to the BCH central portal through the Management Center.

In the framework of the UNEP/GEF project "Development of the National Biosafety Framework for Romania", a web site www.biosafety.ro is under construction Romania is applying for executing the UNEP-GEF "BCH Capacity Building Project" In this context, the site www.biosafety.ro shall be used as national biosafety server

Article 21 – Confidential information

32. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) no	
33. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	X
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import	
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
In conformity with the Law 214/2002, the notifier may indicate to the competent authority the information that should be treated as confidential, the necessary justifications being given as well. Decisions on which information will be kept confidential are taken by the MEWM after consultation with the notifier. Art.I, pc. 50 of the Law 214/2002 specifies the information that could not be treated as confidentially. No difficulties encountered.	
35. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:	
Not applicable	

Article 22 – Capacity-building

36. If a developed country Party, during this reporting period has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition?	
a) yes (please give details below)	
b) no	
c) not applicable – not a developed country Party	X
37. If yes, how has such cooperation taken place:	
38. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
39. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	

40. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	

41. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered:

Romania, as country with economy in transition had benefited from cooperation within the following projects:

The UNEP-GEF project on the Development of National Biosafety Framework for Romania, has the main **scope/objective**: the development of the National Biosafety framework according to Cartagena Protocol provisions, the establishment of: biosafety policy; biosafety regulation; administrativ system; handling request for permits; follow-up activities; public awareness and participation in the decision making process regarding transboundary movement of GMOs.

Activities: for promotion and facilitation of public awareness, education and participation: organizing workshops, meetings and debates on regulating GMOs in Romania; web site design: Biosafety and GMOs in Romania: www.biosafety.ro; brochures editing: Cartagena Protocol on Biosafety for broad understanding; editing workshop reports: evaluating research capacities for modern biotechnologies in Romania.

Workshops:

- Cartagena Protocol on Biosafety – introductory terms;
- Synthesis on inventory studies: identifying gaps, needs and priorities, part A, aspects relating to Romanian research in modern biotechnology;
- Synthesis on inventory studies: identifying gaps, needs and priorities, part B, aspects relating to administrative and legislative issues;
- GMO-Monitoring and Enforcement Systems and Options for Romania; Public awareness and participation in the field of biosafety.

Article 23 – Public awareness and participation

42. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	X
b) yes – limited extent	
c) no	

43. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	X
c) no	
44. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	X
b) yes – limited extent	
c) no	
45. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)	
a) yes – fully	X
b) yes – limited extent	
c) no	
46. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	
b) yes – limited extent	X
c) no	
47. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:	
Romanian legislation on GMOs promotes public awareness and participation as an integral part of its regulatory framework. The MEWM, as competent authority, upon a receipt of a notification, consults the public in the decision making process regarding the deliberate release into environment and on the market of GMOs, following the provisions of the Law 214/2002. According to this Law, the notifications submitted to the MEWM as well as the risk assesment studies and other relevant documents are posted for public information on the site of the Ministry no later than 10 days after receiving the notification. Also, a press release is sent and the comments of the public are expected to be received in 30 days and shall be taken into account in the decision making process. The UNEP-GEF Project "Development of the National Biosafety Framework for Romania", include a component regarding public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms. A seminar on "public awareness and participation in biosafety domain", was held in June this year. Romania is also Party to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, ratified by the Law No. 86/2000.	

Article 24 – Non-Parties

See question 1 regarding provision of information to the Biosafety Clearing-House**.**

48. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:
Import from the USA No difficulties encountered

Article 25 – Illegal transboundary movements

See question 1 regarding provision of information to the Biosafety Clearing-House.

49. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X
b) no	
50. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:	
The measures are provided in Law 214/2002. Also, the import permits are establishing the obligation, for the importers, to comply with the legal provisions related to the transboundary movements of GMOs. The proposed GO for transposing the regulation 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms will include specific, complementary provisions on transboundary movements of living modified organisms, as well as the penalties applicable to the infringements of the legal requirements.	

Article 26 – Socio-economic considerations

51. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	X
c) no	
d) not a Party of import	
52. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	X
53. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:	
In case of import of GMOs for deliberate release into environment, public information and participation in the decision-making process was ensured, for taking into consideration the opinion and interests of the local communities, related to the cultivation of the transgenic plants. The consents for the deliberate release into environment of the GMOs (cultivation of the higher genetically modified plants) are introducing the obligation, for the notifying companies, to establish the locations according to the rules of coexistence and to ensure the appropriate distances to the natural protected areas. Also the cultivation in the natural protected areas with high biological diversity is prohibited by the existing Romanian legislation on biodiversity.	

Article 28 – Financial mechanism and resources

54. Please indicate if, during the reporting period, your government made financial resources available to other Parties or received financial resources from other Parties or financial institutions, for the purposes of implementation of the Protocol.	
a) yes – made financial resources available to other Parties	
b) yes – received financial resources from other Parties or financial institutions	X
c) both	
d) neither	

55. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered:

Romania received financial resources from the following projects:

- The UNEP-GEF project "Development of the National Biosafety Framework for Romania", April 2004 –Sept 2005.
- Remaining activities are supported from state budget.

Other information

56. Please use this box to provide any other information related to articles of the Protocol, questions in the reporting format, or other issues related to national implementation of the Protocol:

See attached tables related to question no.3 (Annex to the Report: ANALYSE ON THE IMPLEMENTATION OF CARTAGENA PROTOCOL, accomplished in the Project UNEP/GEF "Development of the National Biosafety Framework for Romania")

Comments on reporting format

The wording of these questions is based on the Articles of the Protocol. Please provide information on any difficulties that you have encountered in interpreting the wording of these questions:

-

ANALYSE ON THE IMPLEMENTATION OF CARTAGENA PROTOCOL

Checklist of obligations under the Cartagena Protocol

Obligations found in the Cartagena Protocol on Biosafety have been organized in the following categories:

I. Administrative tasks

II. Legal Requirements and/or Undertakings

III. Procedural Requirements: Advance Informed Agreement

IV. Procedural requirements: LMOs for direct use as food, feed or for processing (art. 11)

In the attached tables, these obligations, according to the **Law no 59/2003 for ratifying the Cartagena Protocol**, are compared with the provisions of the Romanian **Law no 214/2002 for the Approval of the Governmental Ordinance No 49/2000 on obtaining, testing, use and commercialization of Genetically Modified Organisms resulting from Modern Biotechnology, as or in products.**

I. ADMINISTRATIVE TASKS
II.

	TASKS	ART.	RESULTS	
	Initial actions		**According to the Law No. 59/2003 for ratifying the Cartagena Protocol**	**Comments related to the provisions of the Law No 214/2002 (the corresponding articles and provisions)**
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1), (2)	**Cartagena Protocol on Biosafety, National Focal Point** **MINISTRY OF ENVIRONMENT AND WATER MANAGEMENT (MEWM)** **Directorate for Nature Protection,**	**Art. 48 of the Law:** (1) The MEWM is the national competent authority and accomplishes the **national focal point responsibilities**, in accordance with the provisions of the international legal documents Romania is party.

	TASKS	ART.	RESULTS	
			Biodiversity and Biosafety 12, Bd. Libertatii, Sector 5, Bucharest, Romania 1. Mrs. Adriana Baz Head of Directorate for Nature Protection, Biodiversity and Biosafety Phone: +40 21 316 05 31 Fax: +40 21 316 05 31 E-mail: baz@mappm.ro 2. Mrs. Ana Maria Comanoiu Counselor, Directorate for Nature Protection, Biodiversity and Biosafety Phone: +40 21 316 33 82 Fax: +40 21 316 02 82 E-mail: comanoiu@mappm.ro	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(as) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1), (2)	**Competent National Authorities; Regulatory functions:** All functions pursuant to the Cartagena Protocol on Biosafety **MOSVIRONMENT AND WATER MANAGEMENT (MEWM)** **Directorate for Biodiversity Conservation and Biosecurity** 12, Bd. Libertatii, Sector 5, Bucharest, Romania	**MEWM** is the competent authority responsible for performing the administrative functions under the Law no. 214. MEWM- the National Competent Authority for regulating GMOs and for issuing permits for import and authorizations for GMOs deliberate release into environment and placing on the market and for controlling the regulated activities; it cooperates with the Public Central Authorities

	TASKS	ART.	RESULTS	
				for the fields: Agriculture, Food, Health, and the National Authority for Consumer's Protection;
3.	Provide the Biosafety Clearing-House with a point of contact	20	**Biosafety Clearing-House Focal Point** **MINISTRY OF ENVIRONMENT AND WATER MANAGEMENT** **Directorate for Nature Protection, Biodiversity and Biosafety** 1. Mrs. Adriana Baz Head of Directorate for Nature Protection, Biodiversity and Biosafety Phone: +40 21 316 05 31 Fax: +40 21 316 05 31 E-mail: baz@mappm.ro 2. Mrs. Ana Maria Comanoiu Counselor, Directorate for Nature Protection, Biodiversity and Biosafety Phone: +40 21 316 33 82 Fax: +40 21 316 02 82 E-mail: comanoiu@mappm.ro	No such provisio n under the Law 214/2002 Will be introduced through a Governmental Ordinance for transposing the EU Regulation no 1946/2003.
4	Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	**MINISTRY OF ENVIRONMENT AND WATER MANAGEMENT (MEWM)** **Directorate for Biodiversity and Biosecurity** 12, Bd. Libertatii, Sector 5, Bucharest, Romania 1. Mrs. Adriana Baz Head of Directorate for Nature Protection,	No such provision under the Law No 214/2002. Will be introduced through a Governmental Ordinance for transposing the EU Regulation no 1946/2003.

	TASKS	ART.	RESULTS	
			Biodiversity and Biosafety Phone: +40 21 316 05 31 Fax: +40 21 316 05 31 E-mail: baz@mappm.ro 2. Mrs. Ana Maria Comanoiu Counselor, Directorate for Nature Protection, Biodiversity and Biosafety Phone: +40 21 316 33 82 Fax: +40 21 316 02 82 E-mail: comanoiu@mappm.ro	
5.	Provide to the Biosafety Clearing-House: - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and - any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	Have been posted on BCH the national laws and the following data bases: Table no 1- International Conventions and multilateral agreements, other international instruments that impact on the use of modern biotechnology Table no 2- Other International Conventions and multilateral and bilateral agreements in the field of the biodiversity, natural resources conservation and environmental protection Table no 3. Biodiversity Conventions and Agreements	No such provision under the Law No 214/2002 Will be introduced through a Governmental Ordinance for transposing the EU Regulation no 1946/2003.
6.	Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	Is not the case	According to the Law No 214/2002, the import can take place only after: - Submitting a Notification for import;

	TASKS	ART.	RESULTS	
				- Obtaining the permit for import, issued by the Competent Authority (MEWM) "Art. 35. - (1) Importers are compelled to notify in written the MEWM before making any import with living genetically modified organisms or products resulted from them".
7.	Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	Is not the case	No such provision under the Law No 214/2002
8.	Notify the BCH if domestic regulations shall apply with respect to specific imports.	14(4)	The Law 214/2002 is posted on BCH	In Romania imports are regulated by the Law no 214/2002
	Provide to the Biosafety Clearing-House: - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; - Final decisions concerning the import or release of LMOs; and - Article 33 reports.	20(3)(c)-(e)	Not yet, because no English version available	The summaries of the risk assessment have been published on the MEWM 's web site www.mmediu.ro (ex www.mappm.ro) **40. Article 37 (of GO 49/2000) will have the following content:** "Art. 37. - (1) The Decision of the MEWM regarding the approval of an import referring to the activities regulated through the present ordinance will be based on the data referring to the risks assessment, in accordance with art. 39, an evaluation based on a scientific and a precautionary approach considering the negative effects on the conservation and sustainable

	TASKS	ART.	RESULTS	
				use of the biological diversity, the risks on the human health as well as, by the case, the social and economic criteria. Risk assessments are elaborated in accordance with Art.40 and Annex 12^1 of the Law No 214/2002 Annex No. 12^1- Principles of fulfilling the risks assessment study on the environment

	TASKS	ART.	RESULTS	
10.	Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	Is not the case.	**20. Article 19 will have the following contents:** 19(1)- The Competent Authority has to: a) Consults the other states' national competent authorities on the problems regarding an accident's occurring, on the action plans in case of emergency, included; b) Inform immediately the international competent bodies about any accident in the sense of the present ordinance, by providing details on the accident's circumstances, the identity and amount of the relevant GM microorganisms/organisms, the appropriate measures taken and their efficiency, as well as an analysis of the accident including the recommendations to limiting its effects in order to avoid such similar accidents in the future.
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	Implementation of obligations under the Protocol is monitored in the project UNEP-GEF.	All the activities regarding GMOs are monitored by the EU, according to the provisions in the Position Paper
12.	Notify the Biosafety Clearing-House of any relevant changes to the information			

	TASKS	ART.	RESULTS	
	provided under part I above.			

II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	**The Law No 214/2002 has as objective the conservation and sustainable use of the biological diversity, taking into account risks to human health.** It covers LMOs, as well as genetically modified microorganisms. The Law introduces **a preventive approach**, asking for prior risk assessment and risk management, as follows: **25. Article 24 will have the following contents:** "Art. 24. - (1) Any legal person, before introducing in the environment a genetically modified organism or a combination of such organisms, should submit a notification to the MEWM. (2) The notification foreseen at paragraph (1) should include: a) A technical dossier with the information specified in annex nr. 8, necessary to fulfilling the environmental risk assessment, especially: b) The risks assessment study according to annex nr. 12^1, together with any bibliographical references and indications regarding the methods used; c) Information on the outcome of the introductions of these genetically modified organisms or of the same genetically modified organisms' combination on Romania's territory and/or outside it. (3) The notifier can refer to the data or outcomes of the notifications previously submitted by other notifiers, on the condition that the information, data and outcomes are non-confidential or that the notifier has their agreement. **26. Article 25 will have the following contents:** "Art. 25. - (1) After receiving the notification, the MEWM, on the basis of the information included in the notification and the documents mentioned at art. 24:

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			a) Informs and consults the public on the received notification; b) Consults the Commission for Biosafety; c) Demands the assents of the central public authorities with responsibilities in: agriculture, food, human health and consumers' protection. **37. At article 35, paragraphs (1), (2) and (4) will have the following contents:** "Art. 35. - (1) Importers are compelled to notify in written the MEWM before making any import with living genetically modified organisms or products thereof. **42. Article 39 will have the following contents:** "Art. 39. – The risks' assessment will be done after a scientific and transparent procedure, taking into account the provisions of annex nr. 12 and the proper risks' evaluation techniques and will aim at identifying and evaluating the potentially negative effects of the genetically modified organism and/or the product resulted from it on the biological diversity, the people's health, considering the social and economic realities."
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2)	According to the Art 2(1) of the Protocol, each party shall take necessary legal, administrative and other measures to implement its obligations under Protocol. The party of export or the exporter is required to notify the Party of import of the transboundary movement and to provide the necessary information According to the **Annex I of the Protocol**. **The content of this Annex is identical with the Annex 11 of the Law 214**, "Information needed to be presented to the national competent authorities in the notifications on the obtaining of the advance informed agreement to carry out the import/export activities with genetically modified organisms" **37. At article 35, paragraphs (1), (2) and (4) will have the following contents:**

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
		11(2)	"Art. 35. - (1) Importers are obliged to notify in written the MEWM before making any import with living genetically modified organisms or products resulted from them. (2) The MEWM will set the notifying procedures in accordance with the provisions of paragraph (1), and will put them at the disposal of the interested parties. *(3) The notification will include information in annex nr. 11* (4) The notifying persons are responsible for the truthfulness of the information provided to the MEWM by notification or any other way, at its request." The Annex 11 is identical with Annex I of the Protocol on Advance Informed Agreement. The provisions of the Art. 11(2) and Annex II of the Protocol, referring to the LMOs intended for food, feed or processing, have a correspondent in Law 214/2002, as follows: **31. Article 29 will have the following contents:** "Art. 29. - (1) Before introducing on the market for the first time of a genetically modified organism or a combination of **genetically modified organisms as a product or in a product**, one has to submit to the MEWM a notification to include: a) The information asked for in annexes nr. 8 and 9, by including the data and outcomes registered during the research-development activities carried out in accordance with the provisions of section 1 of this chapter; b) The risks on environment evaluation study to include the information specified in annex nr. 121; c) The conditions for the introduction on the market of the product, including the specific conditions of use and handling, as well as a proposal for labeling and wrapping that should include at least the demands asked in annex nr. 9.

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			The label has to specify clearly if the genetically modified organism is present. The label with the inscription «This product contains genetically modified organisms» is compulsory. In 10 years will be set the procedures to allowing the application of the labels capable to specify that «This product does not contain genetically modified organisms »; d) A monitoring plan, in accordance with annex nr. 12^2; e) A summary of the notification. (2) If on the basis of the outcomes of any environment introduction notified and approved in accordance with the present ordinance's dispositions or on independent bases, scientifically explained, a notifying person believes that the introduction on the market of a product does not represent a risk for the human health and for the environment, he can propose in the notification not to comply with one or several demands foreseen in annex nr. 9, part B. (3) The notifying person will include in the notification information on the data or outcomes of the introductions in the environment of the same genetically modified organisms or of combinations of genetically modified organisms, previously notified and developed either on Romania's territory or elsewhere. (4) The notifying person can also refer to the date or outcomes of the notifications previously submitted by other notifying persons, if the last ones have given their written assent. (5) Each new product that even if contains or is made of the same genetically modified organisms or combinations of them is meant for a different utilization will be notified separately. (6) The introduction on the market will be only done after getting the authorization issued by the MEWM and with observance of the conditions set in it.
3.	Ensure that any domestic regulatory	9(3)	The Romanian Law no 214/2002 transposes the provisions of the Directive 2001/18/EC,

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
	framework used in place of the AIA procedures is consistent with the Protocol.		which transposes the provisions of the Protocol. The AIA procedure is accomplished by the Notification procedure in the Law 214/2002, according to the Art. 29 of the GO 49/2000, amended by the Law 214/2002: **1. Article 29 will have the following contents:…** See Art. 29, presented above. **40. Article 37 will have the following contents:** "Art. 37. - (1) The Decision of the MEWM regarding the approval of an import referring to the activities regulated through the present ordinance will be based on the data referring to the risks evaluation, in accordance with art. 39, an evaluation based on a scientific and cautious approach considering the negative effects on the sustainable preservation and use of the biological diversity, the risks on the human health as well as, by the case, the social and economic criteria. (2) The MEWM will inform the notifying person in the term foreseen by art. 36, paragraph (1), if: a) The import can take place without a written agreement and in what conditions; b) The import can take place only after the MEWM will give its written assent.
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	Idem
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1), (2)	Idem
6.	Establish and maintain appropriate	16(1)	Idem

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
	mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.		
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	Idem Controls in Custom, based on the co-operation with the national Authority for Customs Co-operation with the MEWM, for fito-sanitary control in the customs
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	This information should appear in the Notification
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	**18. Article 17 will have the following contents:** "Art. 17. - (1) The MEWM, before starting a contained use of GMOs, will check if: a) An emergency plan is drafted for the contained use conditions, where the inefficiency of the isolation conditions might lead to serious anger with immediate or delayed effect on the people's health and/or environment outside the installation's location; etc. … c) The information on such emergency plans, including the proper security measures to be enforced is presented in explicit terms. The information should be updated at proper intervals and should be made public. (2) The MEWM will put at the disposal of the relevant competent authorities in other states the information referred to in paragraph (1), in accordance with the relevant international regulations."

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			19. Article 18 will have the following contents: "Art. 18. - (1) In case of an accident the user should inform immediately the MEWM and provide the following information: a) The accident's circumstances; b) The identity and the amounts of the respective genetically modified microorganisms/organisms; c) Any other data necessary to evaluate the effects of the accident on the population environment's health; d) The measures taken. (2) In the situations foreseen at paragraph (1), the MEWM has to: a) Inform in order to make a more complete evaluation on the accident and, by the case, to make recommendations to avoid similar accidents in the future and cancel the effects that could result from them. b) To make sure that all the necessary measures were taken and, by the case, to immediately inform the competent authorities in the states that could be affected by such accidents." **20. Article 19 will have the following contents:** "Art. 19. - (1) The MEWM has to: a) Consult the other states' national competent authorities on the problems regarding an accident's occurring, on the intervention plans in case of emergency, included; b) Inform immediately the international competent bodies about any accident in the sense of the present ordinance, by providing details on the accident's circumstances, the identity and amount of the relevant genetically modified microorganisms/organisms, the answering measures taken and their efficiency, as well as an analysis of the accident including the

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			recommendations to limiting its effects in order to avoid such similar accidents in the future. (2) The MEWM will enforce the procedure for the information exchange, in accordance with paragraph (1), by setting up and keeping a register of the accidents where will be written the analysis of the accidents' causes and the measures taken to avoid in the future similar accidents." **Art. 42** (1) As regards the illegal traffic, the competent authorities will ask the state of export origin to repatriate it on its account, in accordance with the international law norms and the international legal regulations. (2) The cases of illegal traffic will be notified to the international authorized bodies, in accordance with the procedures set by the international legal regulations in this field.
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	These measures are included in the following: **31. Article 29 will have the following contents:** "Art. 29. - (1) Before introducing on the market for the first time of a genetically modified organism or a combination of genetically modified organisms as a product or in a product, one has to submit to the MEWM a notification to include: a) The information asked for in annexes nr. 8 and 9, buy including the data and outcomes registered during the research-development activities carried out in accordance with the provisions of section 1 of this chapter; b) The risks on environment evaluation study to include the information specified in annex nr. 121; c) The conditions for the introduction on the market of the product, including the specific conditions of use and handling, as well as a proposal for labeling and wrapping that should include at least the demands asked in annex nr. 9. The label has to specify clearly if the genetically modified organism is

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			present. The label with the inscription «This product contains genetically modified organisms» is compulsory. In 10 years will be set the procedures to allowing the application of the labels capable to specify that «This product does not contain genetically modified organisms »; "Sub-annex No. 8A- INFORMATION necessary in the notifications on the deliberate introduction in the environment and on the market of the genetically modified organisms, others than superior plants Annex no. 9 - " ADDITIONAL INFORMATION necessary in case of notifications for the introduction on the market of the genetically modified organisms in accordance Annex nr. 11- INFORMATION needed to be presented to the national competent authorities in the notifications on the obtaining of the advance informed agreement to carry out the import/export activities with genetically modified organisms, in accordance with dispositions of art. 35, paragraph (3)" **Art. 41** (1) The importer, before carrying out the import, will make sure that the exporter of genetically modified organisms and/or products resulted from them is doing the export: a) In conditions of wrapping, identification, labeling and transport that are not less exigent than those enforced on the export state's territory; and b) In conditions regulate through the present ordinance. (2) The importer has to make sure that the documents accompanying the transport comply with the national legislation's demands and the international legal regulations referring to the transport over border of the living genetically modified organisms and the products resulted from them.
11.	Take measures to require that documentation accompanying LMO-FFPs - clearly identifies that they "may	18(2)(a)	**31. Article 29 will have the following contents:** "Art. 29. - (1) Before introducing on the market for the first time of a

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
	contain" LMOs and are not intended for intentional introduction into the environment; and - Provides a contact point for further information.		genetically modified organism or a combination of genetically modified organisms as a product or in a product, one has to submit to the MEWM a notification to include: a) The information asked for in annexes nr. 8 and 9… c) The conditions for the introduction on the market of the product, including the specific conditions of use and handling, as well as a proposal for labeling and wrapping that should include at least the demands asked in annex nr. 9. The label has to specify clearly if the genetically modified organism is present. The label with the inscription "This product contains genetically modified organisms» is compulsory."
12.	Take measures to require that documentation accompanying Limos destined for contained use: - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	These provisions will be transposed by implementing the decisions of the Conference of the Parties in Kuala-Lumpur, Malaysia and participation in the Working Group established to address these aspects Our answer for the Secretariat of the Protocol, in 30 June 2004: According to art. 35 of the national Law 214/2002, which transposes the EU legislation and is consistent with the objective of the Cartagena Protocol on Biosafety, importers of living modified organisms (LMOs) intended for direct use as food or feed, or for processing, are obliged to notify in written the MEWM, as national competent authority, **before making any import with LMOs or products thereof**. Until now, no notification has been received by the MEWM for **the imports of LMOs intended for direct use as food or feed, or for processing (commodities),** but only for import of superior transgenic plants, for their deliberate release into the environment. **Romanian point of view for the future**: - To be established the obligativity for the exporters of LMOs for direct use as food or feed, or for processing, under their jurisdiction: - To specify, in the documentation accompanying transboundary movements known to intentionally **contain LMOs**, that the shipment contain **or may contain LMOs that are intended for direct use as food or feed, or for processing and is not intended for intentional introduction into the**

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			environment; the accompanying documentation has to be consistent with an international standardized documentation system, **or** the shipment to be accompanied by **a document from an accredited LMOs laboratory that specifies the presence or the content of the LMO** (accordingly to the requirements of the legislation in force in the importing country; - To specify the identity of the living modified organism (an unique identification number- OECD code, placed under the Biosafety Clearing House, **or a special custom code, for each commodity**); **- To present details regarding the origin country of export**, the last exporter, the importer and the contact point for case of emergency; -Approval for the import, from the national competent authority in the country of import; Each non-party to the Protocol has to comply with the legislation in force in the importing country, part to the Protocol; - To be developed and assigned an unique identifier for **each approved transgenic material** which is subject to a transboundary movement and a register for unique identifier codes, under the BCH;

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
3.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: - Clearly identifies them as LMOs - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, as appropriate, the name and address of the importer and exporter; and - Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	Idem as to points 11 and 12. The Annex 11"Information needed to be presented to the national competent authorities in the notifications on the obtaining of the advance informed agreement to carry out the import/export activities with genetically modified organisms, in accordance with dispositions of art. 35, paragraph (3)" asks: ..... (o) Declaration that the above-mentioned information is accurate. Art. 41(2) The importer has to make sure that the documents accompanying the transport comply with the national legislation's demands and the international legal regulations referring to the transport over border of the living genetically modified organisms and the products resulted from them
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1), (6)	**50. After article 49, article 49^1 is introduced with the following contents:** "Art. 49^1. - (1) In the notifications submitted to the MEWM, the notifying person could show the information that should be treated as confidential, by

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			presenting the necessary justifications.
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	**49(2)** The MEWM will decide, after consultations with the notifying person, what is the confidential information and will inform the notifying person about its decision **49(3)** The next information can be considered confidential: a) The general characteristics of the genetically modified microorganisms/organisms, the notifying person's name and address, the purpose and place the activity is developing; b) The class the utilization is included in isolation conditions and the isolation measures; c) The conclusions of the risks' evaluation research on the environment and human health; d) The monitoring methods and plans, as well as the response ones in case of accident.
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3), (5)	**49(4)** The MEWM will not unveil to some third parties any information set as confidential and will protect the copyright related to the information received. **49(5)** If, no mater the reasons, the notifying person withdraws its notification, the MEWM should observe the confidentiality of the information received."
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	Idem
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	**49. Article 49 will have the following contents:** "Art. 49. - (1) The authorization procedure of the activities of deliberate introduction on the market of the genetically modified organisms is public. The MEWM ensure the publicizing of activities for which authorization is asked.

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
			(2) In 10 days from receiving a notification, the MEWM should inform the public related to this, by specifying the ways the information could be obtained. (3) The observations of the public are received within 30 days from informing it and will be taken into consideration by the MEWM when making the decision of authorizing the activity proposed. Depending on the information received, public debates could be staged on any aspects regarding the field regulated by the present ordinance." Public awareness is facilitated by seminars, workshops, including activities developed in the UNEP-GEF project 'Development of the National Biosafety Framework"
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	Idem
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	Idem
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	Activities developed in the UNEP-GEF project 'Development of the National Biosafety Framework"
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	**Art. 42** (1) As regards the illegal traffic, the competent authorities will ask the state of export origin to repatriate it on its account, in accordance with the international law norms and the international legal regulations. (2) The cases of illegal traffic will be notified to the international authorized bodies, in accordance with the procedures set by the international legal regulations in this field.
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary	25(2)	Idem

	TASKS	ART.	ROMANIAN SITUATION (according to the relevant Articles in the Law 214/2002)
	movement through repatriation or destruction, as appropriate, upon request by an affected Party.		

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT[i]

	TASKS AND ARTICLE (S) IN THE PROTOCOL	PROVISIONS OF THE LAW No 214/2002
1.	1.Provide written acknowledgement of receipt of notification to notifier within 90 days, including: - Date of receipt of notification, **9(2)(a)** - Whether notification meets requirements of Annex, 9**(2)(b)** -That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; **10(2)(a), 9(2)(c)** **10(2)(b)** **OR** - Whether the import may proceed after 90 days without further written consent. 2.Communicate in writing to the notifier, within 270 days of receipt of notification: - Approval of the import, with or without conditions; - Prohibition of the import; - A request for additional relevant information in accordance with domestic regulatory	**37. Article 35, paragraphs (1), (2) and (4) will have the following contents:** "Art. 35. - (1) Importers are compelled to notify in written the MEWM before making any import with living genetically modified organisms or products resulted from them. (2) The MEWM will set the notifying procedures in accordance with the provisions of paragraph (1), and will put them at the disposal of the interested parties. (3) The notification will include information included in annex nr. 11. (4) The notifying persons are responsible for the truthfulness of the information provided to the MEWM by notification or any other way, at its request." **39. Article 36 will have the following contents:** "Art. 36. - (1) The MEWM confirms the notifying person in written that it has received the notification, within 90 days from its receiving. (2) Confirmation contains the following: a) The date of receiving the notification; b) If the notification contains all the information necessary to making a decision; c) Other specifications, by the case. (3) Non-fulfillment of the confirmation procedure of notification receiving by the MEWM does not mean and will not be interpreted as a tacit agreement of it o making the import." **40. Article 37 will have the following contents:**

	TASKS AND ARTICLE (S) IN THE PROTOCOL	PROVISIONS OF THE LAW No 214/2002
	framework or Annex I; **10(3)(a)-(d)** Or Extension of the 270 day period by a defined period of time; **AND** - Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time **10(4)**	"Art. 37. - (1) The Decision of the MEWM regarding the approval of an import referring to the activities regulated through the present ordinance will be based on the data referring to the risks evaluation, in accordance with art. 39, an evaluation based on a scientific and cautious approach considering the negative effects on the sustainable preservation and use of the biological diversity, the risks on the human health as well as, by the case, the social and economic criteria. (2) The MEWM will inform the notifying person in the term foreseen by art. 36, paragraph (1), if: a) The import can take place without a written agreement and in what conditions; b) The import can take place only after the MEWM will give its written assent. (3) The MEWM will communicate in written the notifying person its decision regarding the import-to-be-done, in the legal term from the conformation of receiving the notification, by showing: a) Its agreement for the import, with or without conditions, by specifying how to enforce this agreement for the subsequent imports of that genetically modified organism or that product formed/resulted from genetically modified organisms; or b) The import ban; or c) The necessity of some additional relevant information in accordance with provisions of annexes nr. 11 and 12; or d) The necessity of prolonging the period necessary to evaluate the additional information received from the notifying person or from other sources, in order to take a documented decision. (4) The notes of the MEWM, in accordance with paragraph (3) will include the reasons that have determined the decision made, except for the case the assent for the import is given unconditionally." Art. 25

	TASKS AND ARTICLE (S) IN THE PROTOCOL	PROVISIONS OF THE LAW No 214/2002
		(3) When calculating the 90 day-period foreseen at paragraph (2) will not be included the period when the MEWM: a) Is waiting for other information it could ask the notifying person, according to paragraph (2) let. C); b) Is waiting the assent of the Commission for Biological Security; c) Is making a public inquiry, is consulting other organizations and/or the public. (4) The notifying person could start the activity proposed only after getting the authorization issued by the MEWM and observing the conditions set by the authorization. (5) If the MEWM deems it has been accumulated enough experience by introducing in the environment certain genetically modified organisms and given the criteria set in accordance with annex nr. 10, it could decide the enforcement of the simplified procedures for the introduction in the environment of such organisms. (6) The authorization for the deliberate introduction in the environment of a genetically modified plant, issued by the MEWM is compulsory to registering the varieties for examination at the State Institute for Varieties Testing and Register."

IV. PROCEDURAL REQUIREMENTS:

LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	TASKS, ACCORDING TO THE PROTOCOL	ARTICLE	*SITUATION IN ROMANIA*
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	Not yet
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have	11(1)	Not yet.

	access to the Biosafety Clearing-House.		
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	Not yet
4.	In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMO-FFPs: - Either as approved under the domestic regulatory framework consistent with the Protocol; **OR** - in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4), (6)	The decision on import of LMO-FFPs is taken under the Romanian regulatory framework, consistent with the Protocol, as was presented.