#### INTERIM NATIONAL REPORT ON IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Party	HUNGARY
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#### Origin of report

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:

In Hungary, the Ministry of Environment is responsible for the implementation of the Cartagena Protocol on Biosafety.

The Ministry of Environment is also responsible for the preparation of the National Report on implementation of the Cartagena Protocol on Biosafety. The Ministry of Environment involved other gene technological authorities in the preparation of the report.

#### 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):

Hungary has created a website serving as Hungarian Biosafety Clearing House. The Hungarian Biosafety Clearing House is available on the following address: http://biodiv.kvvm.hu

On the above mentioned website Hungary provides information on the history of the Cartagena Protocol and the text of the Protocol in Hungarian and English. The website also provides the texts of relating Hungarian and EC laws, regulations and decisions, information on the competent national authority, national focal points and the contact points, a link to the Hungarian Biosafety Website (www.biosafety.hu) which contains the information on the authorized experimental LMO releases in Hungary. The Hungarian BCH gives also answer on several frequently asked questions and gives accessibility of some useful links.

Information on genetically modified organisms and products thereof which are authorized at community level is available on the website of the Joint Research Centre of the European Union.

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);

(1) 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)	X
b) some measures introduced (please give details below)	
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:

Hungary joined the European Community on 1 May 2004. Hungarian legislation has already been harmonized with the relevant EC legislation (for detailed information see the report of the European Community).

Text of the Hungarian legislation is available on the following website in Hungarian language: (www.biosafety.hu).

We provide here a summary of the relevant laws and regulations:

#### Acts on the Gene Technological Activity in Hungary

#### 1) Hungarian Law on Gene Technological Activities (Act No. XXVII of 1998)

After more than one year of preparation a framework-law had been worked out in 1996-1997 in Hungary. The law was passed by the Hungarian Parliament in March 1998. It came into force in January 1999. The law has been modified in 2002 because Directive 2001/18/EC entered into force and there was a need on the harmonisation the Hungarian legislation with the EC Directive.

The Act shall apply to the genetic modification of natural organisms, to the contained use, to the deliberate release into the environment, to the placing on the market, to the import, the export and the transportation of genetically modified organisms and products thereof. Main elements of the law are the establishment of the authorization system as well the institution system for the authorization process.

The Competent authorities are under the control of the competent ministries (there are several authorities according to the type of the activity. The competent authority make the decision on the authorization, issues the permit, in certain, defined cases restricts or bans the GMO-activity, revokes the permit, fines). Authorizing responsibility is shared by the Ministry of Agriculture and Regional Development and the Ministry of Health. The Ministry of Environment and Water also has an important role as a special (veto) authority in giving an expert-opinion on the activities to be authorized.

According to the law, an independent biotechnology committee prepares the decisions and gives opinion on; consisting of 17 representatives of the Hungarian Academy of Sciences, of the competent ministries and of non-governmental organizations.

The law set up a database up for the registration of the relevant information relating to authorized modifications, contained uses, deliberate releases into the environment, placing on the market of genetically modified organisms and GMO laboratories. The law contains detailed rules inter alia on permit fees and validity, on labelling, on transportation requirements, on the waste-management, on the liability for the damages caused by biotechnology activities, on the

supervision of the gene technological activity, and on education and training.

#### 2) Act on the Publication of the Cartagena Protocol on Biosafety signed in 24 May 2000 in Nairobi (Act No. CIX of 2004)

This Act publishes the full text of the Cartagena Protocol on Biosafety in Hungarian and English, signed by Hungary on 24 May 2000.

#### Decrees on the Gene Technological Activity in Hungary

# 1) Decree 142/2004. (IX. 30.) of the Ministry of Agriculture and Rural Development and the Ministry of Economy on Certain Rules of the Gene Technological Activity in the Field of Agriculture and Industry

This decree regulates the conditions of gene technological modification including personal and material terms. It determines the tasks of the notifier who carries out contained use as well the liability of the user. This decree also regulates the release and placing on the market of genetically modified products and the national acknowledgement of plant and animal varieties. The decree contains detailed rules on the labeling, transportation and the list of the laboratories entitled for determining the gene technological origin. Annex 1 to the Decree includes the methods and principles of the environmental risk analysis in accordance with the relevant EC legislation. Annex 2 to this Decree provides guideline on the carrying out of the post market monitoring plan of genetically modified organisms and products thereof.

### 2) Decree 138/2004. (IX. 23.) of the Ministry of Agriculture and Rural Development on the Authorization Fees for the Authorization of the Gene Technological Activity This decree specifies the authorization fees of the gene technological activity.

## 3) Government Decree Nr. 132/2004. (IV. 29.) on the Authorization Procedure of the Gene Technological Activity, and on the Liaison with the European Commission

This decree specifies the authorization process of the gene technological activity, and designates the contact institution – the Ministry of Environment and Water - for the liaison with the European Commission. This decree regulates the conditions of the authorization of contained use of genetically modified micro organisms; it determines classes according to the risk level of the contained use. The legislation contains detailed rules on the intended introduction of genetically modified organisms into the environment, including the placing on the market of genetically modified organisms, and the release of genetically modified organisms into the environment other than placing on the market as well on the authorization process for genetically modified food and feed in line with the relevant EC rules. This decree also regulates the traceability and gives the right to gene technological authority to limit or ban the release of a genetically modified product if it may have adverse effect on the human health or the environment.

## 4) Government Decree 148/2003. (IX. 22.) on the Determination of Gene Technological Penalties

This decree specifies penalties on an effective, proportionate and dissuasive manner. The amount of the penalty depends on the seriousness of the miscarriage as well the consequences to the environment and human health. Further more, it depends on whether it happened at first time or it happened again, or happened by accident.

The gene technological penalty fee can extend from 300 000 HUF to 1 million HUF at the first

occasion, from 1 million HUF to 20 million HUF if repeated.

### 5) Decree 128/2003. (XII. 19.) of the Ministry of Agriculture and Rural Development on the Scientific Advisory Committee

The Act on Gene Technological Activity establishes a scientific advisory body in order to promote the decision of the authorities on the authorization of genetically modified organisms. The secretariat of Scientific Advisory Committee resides the National Institute for Agricultural Quality Control. The Decree determines detailed rules on the operation of the Committee such as rules on the voting, quorum and deputyship as well the case of vote equality.

#### 6) Joint Decree 111/2003 (XI. 5.) of the Ministry of Agriculture and Rural Development, the Ministry of Economy, the Ministry of Health and Family Matters and the Ministry of Environment and Water on Activities which shall be Considered and not Considered as Gene Technological Activity and on the Authorities which are Entitled to Supervise the Gene Technological Activity

This decree determines the activities which shall be considered as gene technological modification and processes considered not to be gene technological modification. The Decree specifies the authorities entitled for supervising the gene technological activity. The supervisors are different authorities in different fields of the gene technological activity.

# 7) Decree 82/2003. (VII. 16.) of the Ministry of Agriculture and Rural Development on the Order of the Record Keeping and Information, and on the Documentation which shall be Attached to the Notification

This decree determines the necessary documentation which shall be enclosed to the application for the authorization of gene technological activity. It regulates the registration process, where the registry office shall keep a record of the number and date of the authorization decision, the description of the genetically modified organisms, the name and address of the user, the name and OECD code of the modified property and the aim and place of the gene technological activity. Information in connection with trade secrets, patents and those data the user asks to keep secret shall be handled confidential.

# 8) Decree 20/2000 (VIII. 25) of the Ministry of Environment on the Designation of the Special Authority which shall contribute to the procedures laid down in (1)-(4) of Article 4 of the Act on Gene Technological Activities

The decree designs the Inspectorate on Environment and Nature Protection as special authority which shall contribute to the procedures laid down in (1)-(4) of Article 4 of the Act on Gene Technological Activities

## 9) Parliamentary Resolution 94/2003 (IX. 23.) on the Ratification of the Cartagena Protocol on Biosafety

The Parliament ratifies the Cartagena Protocol on Biosafety in its resolution and asks the Government to take necessary steps for its publication.

#### 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 exporte jurisdiction of your country? (Article 8.2)	ers $\underline{1}$ / under the
a) yes	x
b) no	
c) not applicable – not a Party of export	
5. If you were a Party of export during this reporting period, did you request any F review a decision it had made under Article 10 on the grounds specified in Article 1	• •
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 fra by Article 9.2(c).	meworks as allowed
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	x
7. If your country has been a Party of export of LMOs intended for release into the reporting period, please describe your experiences and progress in implementing 12, including any obstacles or impediments encountered:	
Not applicable because Hungary has not been a Party of export during the rep	porting period.
8. If your country has taken decisions on import of LMOs intended for release into during the reporting period, please describe your experiences and progress in implem 10 and 12, including any obstacles or impediments encountered:	
See Report of the Commission on Implementation of the Cartagena Protocol European Community.	on Biosafety by the

 $<sup>\</sup>underline{1}/$  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 applie the domestic use of a living modified organism that may be subject to transboundary is use as food or feed, or for processing? (Article 11.2)	<b>^</b>
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 cap respect of living modified organisms intended for direct use as food or feed, or for pro 11.9)	
a) yes (please give details below)	
b) no	х
c) not relevant	
11. Did your country take decisions regarding import under domestic regulatory fram by Article 11.4?	eworks as allowed
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	x
<ul><li>12. If your country has been a Party of export of LMOs intended for direct use for for processing, during the reporting period, please describe your experiences and progres Article 11, including any obstacles or impediments encountered:</li><li>Not applicable. Hungary has not been a Party of export of LMOs intended for or feed, or for processing, during the reporting period.</li></ul>	s in implementing
<ul><li>13. If your country has been a Party of import of LMOs intended for direct use for for processing, during the reporting period, please describe your experiences and progres. Article 11, including any obstacles or impediments encountered:</li><li>Hungary has not been a Party of import of LMOs intended for direct use for for former and the former of the former and the former of the former and the forme</li></ul>	s in implementing od or feed, or for
processing, during the reporting period. (See Report of the Commission on Im	plementation of

processing, during the reporting period. (See Report of the Commission the Cartagena Protocol on Biosafety by the European Community).

#### 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:

Hungary has not used the simplified procedure for imports of LMOs.

#### 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:

Not applicable. Hungary has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14.

#### Articles 15 and 16 – Risk assessment and risk management

16. If you were a Party of import during this reporting period, were risk a decisions taken under Article 10? (Article 15.2)	
a) yes	
b) no (please clarify below)	
c) not a Party of import	X
17. If yes, did you require the exporter to carry out the risk assessment?	
a) yes – in all cases	
b) yes $-$ in some cases (please specify the number and give further details b	below)
c) no	
d) not a Party of import	X
18. If you took a decision under Article 10 during the reporting period, di bear the cost of the risk assessment? (Article 15.3)	id you require the notifier to
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details b	h =1 = )
b) yes in some cases (please speeny the number and give further details t	below)
c) no	below)
	s, measures and strategies to
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis</li> </ul>	s, measures and strategies to
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> </ul>	s, measures and strategies to sions of the Protocol? (Article
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> </ul>	s, measures and strategies to sions of the Protocol? (Article
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> <li>b) no</li> <li>20. Has your country adopted appropriate measures to prevent unintention</li> </ul>	s, measures and strategies to sions of the Protocol? (Article
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1) <ul> <li>a) yes</li> <li>b) no</li> </ul> </li> <li>20. Has your country adopted appropriate measures to prevent unintention of living modified organisms? (Article 16.3)</li> </ul>	s, measures and strategies to sions of the Protocol? (Article x onal transboundary movements
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> <li>b) no</li> <li>20. Has your country adopted appropriate measures to prevent unintention of living modified organisms? (Article 16.3)</li> <li>a) yes</li> </ul>	s, measures and strategies to sions of the Protocol? (Article x nal transboundary movements x nism, whether imported or
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> <li>b) no</li> <li>20. Has your country adopted appropriate measures to prevent unintention of living modified organisms? (Article 16.3)</li> <li>a) yes</li> <li>b) no</li> <li>21. Does your country endeavour to ensure that any living modified organ locally developed, undergoes an appropriate period of observation commendation of the period of the</li></ul>	s, measures and strategies to sions of the Protocol? (Article x nal transboundary movements x nism, whether imported or
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> <li>b) no</li> <li>20. Has your country adopted appropriate measures to prevent unintention of living modified organisms? (Article 16.3)</li> <li>a) yes</li> <li>b) no</li> <li>21. Does your country endeavour to ensure that any living modified organ locally developed, undergoes an appropriate period of observation comme generation time before it is put to its intended use? (Article 16.4)</li> </ul>	s, measures and strategies to sions of the Protocol? (Article x onal transboundary movements x nism, whether imported or ensurate with its life-cycle or
<ul> <li>c) no</li> <li>19. Has your country established and maintained appropriate mechanisms regulate, manage and control risks identified in the risk assessment provis 16.1)</li> <li>a) yes</li> <li>b) no</li> <li>20. Has your country adopted appropriate measures to prevent unintention of living modified organisms? (Article 16.3)</li> <li>a) yes</li> <li>b) no</li> <li>21. Does your country endeavour to ensure that any living modified organ locally developed, undergoes an appropriate period of observation comme generation time before it is put to its intended use? (Article 16.4)</li> <li>a) yes – in all cases</li> </ul>	s, measures and strategies to sions of the Protocol? (Article x onal transboundary movements x nism, whether imported or ensurate with its life-cycle or

2	2 Has	vour co	untry	cooperated	with	others	for the	nurr	nees s	pecified in	Article 1	6 5 ?
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a) yes (please give further details below)

b) no (please give further details below)

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:

х

х

Hungary has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs, whether imported into or developed within the EC, according to the existing EC legislation. The aim of the environmental risk assessment 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 (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).

Hungary established a Scientific Advisory Body which evaluates the risk may be posed by an LMO in order to promote the scientific based decision of the authorities on the authorization of genetically modified organisms.

EC Member States cooperate for the purposes laid down in Articles 15 and 16 of the Cartagena Protocol on Biosafety.

#### 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	
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b) partially (please clarify below)

c) no (please clarify below)

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)	Х
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	Х
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:

The EC has developed a comprehensive legal framework on GMOs, which also addresses the issues of handling, transport, packaging and identification requirement covered by Article 18. Of the recently adopted legal acts, the following are of direct relevance to the implementation of Article 18:

- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms;
- Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed; and
- Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and

labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

These regulations are directly applicable in all Member States, in Hungary as well. For further information see Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community.

#### Article 19 – Competent national authorities and national focal points

See question 1 regarding provision of information 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:

Hungary has designated *Mr Ferenc Sárosi* (Ministry of Environment and Water, Department of International Treaties on Nature Conservation. Address: Költő utca 21, H-1121 Budapest, Hungary. Phone: +361-391-1705, Fax: +361-275-4505, e-mail: sarosi@mail.kvvm.hu) as its national focal point for the BCH.

Hungary is recently uploading more detailed information on its Biosafety Clearing-House and regularly updates the data on the above mentioned homepage.

#### 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	Х
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

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:

Hungary, as a <u>Member <u>sS</u>tate of <u>the</u> European Union considers common European Union criteria concerning confidential information. (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).</u>

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No implementation difficulties or impediments have been 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)	х
b)	no	
c)	not applicable – not a developed country Party	

37. If yes, how has such cooperation taken place:

The JRC of the European Community organized a Training Course on Analysis of Food Samples for GMOs in October/November 2003; in Gödöllő, Hungary, where also Hungarian scientists contributed in the course.

The objective of the training course was to assist the staff of control laboratories to become accustomed with molecular detection techniques, and to help them to adapt their facilities and work programmes to include analyses to comply with worldwide regulatory acts in the field of biotechnology. The course is intended to teach molecular detection techniques to laboratory personnel that have a good level of analytical knowledge, but that have no or little expertise in this specific domain. The areas covered include:

a) DNA extraction from raw and processed materials;

b) Screening of foodstuffs for the presence of GMOs by simple Polymerase Chain Reaction and by nested Polymerase Chain reaction;

c) Quantification of GMOs in ingredients by real-time Polymerase Chain Reaction;

d) Quantification of GMOs in ingredients by the Enzyme-linked Immunosorbent Assay.

The course was open especially to the EU Accession Countries in the context of the enlargement of the EU, including East European economies in transition.

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)		
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	х	
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)	
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	Х

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)		
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	х	
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:		
Hungary has no further comments.		

#### 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 encor information on living modified organisms identified in accordance with the Protocol th 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 decision-making process regarding living modified organisms and make the results of available to the public? (Article 23.2)	
a) yes – fully	
b) yes – limited extent	X
c) no	
46. Has your country informed its public about the means of public access to the Biose House? (Article 23.3)	afety Clearing-
a) yes – fully	
b) yes – limited extent	x
c) no	
47. Please provide further details about your responses to the above questions, as well your country's experiences and progress in implementing Article 23, including any ob impediments encountered:	
Hungaryms considers common European Union criteria concerning confidentia (See Report of the Commission on Implementation of the Cartagena Protocol o the European Community). Public information on activities regarding genetically modified organisms are p	n Biosafety by

Hungary is also Party to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters signed on 3<sup>rd</sup> July 2001 and

published on 4<sup>th</sup> December 2001.

#### 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:

There have not been transboundary movements of living modified organisms between Hungary and a non-Party.

#### 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)

Х

a) yes

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:

Hungary has domestic legislation in force in order to prevent and penalize illegal transboundary movements of genetically modified organisms.

According to the provisions of the Hungarian Law on Gene Technological Activities (Act No. XXVII of 1998) the genetic modification of natural organisms, the contained use, release, placing on the market, import and export of genetically modified organisms and products derived therefrom shall be supervised by authorities designed in a separate decree at the scene of the biotechnology activity.

The biotechnology authority shall, ex officio or upon the recommendation of the special authorities participating in the permitting procedure or in the supervision, revoke the permit from the producer, user, releasing organization, distributor, importer or exporter ordering the immediate termination of the activity, or impose a biotechnology fine, if the genetic modification of the natural organisms, the contained use, release, commercialization, import and export of genetically modified organisms and products derived therefrom do not comply the provisions specified in this Act, in separate laws or in the permit, especially if the biotechnology activity poses a risk to the environment and the human health.

Government Decree 148/2003. (IX. 22.) on the Determination of Gene Technological Penalties specifies penalties on an effective, proportionate and dissuasive manner. The amount of the penalty depends on the seriousness of the miscarriage as well the consequences to the environment and human health.

#### 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		
c) no		
d) not a Party of import	X	
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 datails about your responses to the above questions, as well as description of		

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:

#### 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	Х	
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:		

Hungary received financial resources from the UNEP-GEF for the development of the national Biosafety Clearing House (Hungarian Biosafety Website, see question 1 above).

#### 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:

Hungary has no further comments.

#### 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:

Hungary did not have difficulties in interpreting the wording of the questions.