# FIRST REGULAR NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

## Origin of report

| Party:                               | Hungary   |
|--------------------------------------|---|
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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 report updates the interim implementation report of Hungary submitted in 2005.

The Ministry of Environment and Water is responsible for the implementation of the Cartagena Protocol in Hungary, and has therefore prepared this report.

The report was written based on publicly accessible information including the Hungarian legislative framework. On the other hand, additional information was sought from relevant Hungarian Ministries and other state institutions. The draft of this report was circulated for review to all relevant Ministries which are dealing with biosafety issues in Hungary.

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 Biosafety Clearing-House (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 provided the central BCH with comprehensive information in the listed categories and is constantly working to improve the information flow in this area.

Hungary has created two National Biosafety Websites as well (http://biodiv.kvvm.hu and www.biosafety.hu).

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. The text of the Protocol is available in Hungarian and English. The website also includes 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.

However, no experts has been nominated to the "Roster of Experts" on behalf of Hungary yet.

2. Please provide an overview of information that is required to be provided to the Biosafety Clearing-House:

| Type of information   | Information exists and is being provided to the Biosafety Clearing-House | Information exists but is not yet provided to the Biosafety Clearing-House | Information<br>does not exist<br>/not<br>applicable |
|---|--|--|---|
| 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)) | X  |  |   |
| 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);  | X  |  |   |
| c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);   |  |  | X   |
| d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19.1 and 19.3), and   | X  |  |   |

| 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);   |  |  | X   |
| f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));   | X  |  |   |
| g) Occurrence of unintentional transboundary<br>movements that are likely to have significant<br>adverse effects on biological diversity<br>(Article 17.1);   |  |  | X   |
| Type of information   | Information exists and is being provided to the Biosafety Clearing-House | Information exists but is not yet provided to the Biosafety Clearing-House | Information<br>does not exist<br>/not<br>applicable |
| h) Illegal transboundary movements of LMOs (Article 25.3);  |  |  | X   |
| 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));                                       | X  |  |   |
| j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);   | X  |  |   |
| 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);   | X  |  |   |
| 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)) | X  |  |   |
| m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)   |  |  | X   |
| n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);   |  |  | X   |

| o) LMOs granted exemption status by each Party (Article 13.1)   |   | X |
|---|---|---|
| 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);                                |   | X |
| q) Summaries of risk assessments or<br>environmental reviews of LMOs generated by<br>regulatory processes and relevant information<br>regarding products thereof (Article 20.3(c)). | X |   |

## *Article 2 – General provisions*

| 3. 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  |   |

4. 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:

Hungarian legislation on genetically modified organisms (GMOs) has been in place since 1998. The act on gene technological activities takes into account risks posed by genetically modified organisms on human and natural environment. Its purpose is to preserve the balance in nature, to protect human health, to support scientific and economic development as well as to enforce the provisions of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

Hungary acceded the European Community in 2004, its legislation is in harmonization with current EC legislation. The main implementation measures are Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms – which is fully transposed in Hungary, Regulation No 1829/2003 on GM food and feed and Regulation No 1946/2003 on the transboundary movements of GMOs. For more details of the above mentioned comprehensive legal framework please see the European Community's implementation report.

The main legal measures which are in harmonization with the EC legal framework include:

# Hungarian Act on gene technological activities (Act No. XXVII of 1998)

The Act on gene technological activity 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 harmonisation the Directive as well as in 2006 in order to adopt detailed rules regarding the co-existence of genetically modified crops with conventional and organic farming.

The Act shall apply to genetic modification of natural organisms, to contained use, to deliberate release into the environment, to placing on the market, to import, export and transportation of genetically modified organisms and products thereof.

Main elements of the act are the establishment of the authorization system as well the institution system

for the authorization process. Competent authorities are under the control of the competent ministries (there are several authorities according to the type of the activity. The competent authority takes the decision on the authorization, issues the consent, revokes the permit,

and poses fines). Authorizing responsibility is shared by the Ministry of Agriculture and Rural Development and the Ministry of Health. The Ministry of Environment and Water has an important role in the notification process as a special (veto) authority in giving an expert-opinion on the notification in environmental point of view.

According to the law, an independent biotechnology committee gives opinion on the notifications. It consists representatives of the Hungarian Academy of Sciences, of the competent ministries as well as of non-governmental organizations.

The Act sets up a database 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 Act contains detailed rules inter alia on labelling, transportation requirements, waste-management, on liability for the damages caused by biotechnology activities, as well as on education and training.

■ Decree 20/2000 (VIII. 25) of the Ministry of Environment on the designation of the special authority which contributes 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 gives an expert opinion in the authorization process in environmental point of view.

Decree 82/2003. (VII. 16.) of the Ministry of Agriculture and Rural Development on the order
of the registering and supplying data as well as on the documentation which shall be enclosed
in the notification regarding the gene technological activity

This decree determines which documents and information shall be enclosed to the notification for the authorization of the gene technological activity. It involves provisions regarding the data registration process. The institution designated for registering and supplying data shall keep a number of data such as the registration number and date of the issue of the authorization decision, the description of the genetically modified organisms, the name and address of the consent holder, the name and OECD code of the modified property and the aim and place of the gene technological activity. Information in connection with business information, patents and those data the user asks to keep secret shall be handled confidential. Summary of the environmental risk assessment is open for the public.

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

The Hungarian Parliament ratified the Cartagena Protocol on Biosafety in its resolution and called upon the Government to take necessary steps for its publication.

Joint Decree 111/2003 (XI. 5.) of the Ministry of Agriculture and Rural Development, the Ministry of Economy and Transport, the Ministry of Health, Social and Family Matters and the Ministry of Environment and Water on activities which shall be considered and not considered as gene technological activity as well as on authorities which are entitled to supervise the gene technological activity

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

■ Decree 128/2003. (XII. 19.) of the Ministry of Agriculture and Rural Development on the

# organization and the activity of the Gene Technological Advisory Committee

The Act on Gene Technological Activity establishes a scientific advisory body in order to support the decision process on the authorization of genetically modified organisms. The Decree determines detailed rules on the operation of the Committee such as rules on the voting, quorum and deputyship.

## • Government Decree 148/2003. (IX. 22.) on the imposing gene technological penalties

This decree stipulates the amount of penalties on an effective, proportionate and dissuasive manner. The amount of the penalty depends on the seriousness of the non compliance as well as on its impact on the environment and human health. Furthermore, the amount of the penalty depends on whether the non compliance happened at first time or it happened repeatedly, or happened accidentally.

The gene technological penalty fee extends from 300 000 HUF to 1 million HUF at the first occasion, from 1 million HUF to 10 million HUF if repeated.

 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 as well as in English, signed by Hungary on 24 May 2000.

• Government Decree Nr. 132/2004. (IV. 29.) on the authorization procedure of the gene technological activity as well as on the liaison with the European Commission

This decree lays down the authorization process of the gene technological activity and designates the Ministry of Environment and Water which is responsible for the liaison with the European Commission in gene technological issues. The decree includes detailed rules regarding the authorization of contained use of genetically modified microorganisms, the deliberate release of genetically modified organisms into the environment – including 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 as the authorization process of genetically modified food and feed in line with the relevant EC rules.

■ 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 in case of the different gene technological activities.

 Decree 142/2004. (IX. 30.) of the Ministry of Agriculture and Rural Development and the Ministry of Economy and Transport 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 obligations of the notifier who carries out a contained use activity, the deliberate 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 labelling and transportation as well as the list of the accredited national laboratories entitled for determining the gene technological origin. Annex 1 to the Decree includes the methods and principles of the environmental risk assessment in accordance with the relevant EC legislation. Annex 2 to the Decree provides guideline on how to carry out post market monitoring of genetically modified organisms and products thereof.

Full text and a short English summary of the above mentioned legislation is available in Hungarian on the following website: http://biodiv.kvvm.hu.

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

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

| 5.  | 5. Were you a Party of import during this reporting period?   |              |  |
|---|---|--------------|--|
|   | a) yes  | X            |  |
|   | b) no   |              |  |
| 6.  | Were you a Party of export during this reporting period?  |              |  |
|   | a) yes  |              |  |
|   | b) no   | X            |  |
| 7.<br>juri  | Is there a legal requirement for the accuracy of information provided by exporters sdiction of your country? (Article 8.2)  | 1/ under the |  |
|   | a) yes  | X            |  |
|   | b) not yet, but under development   |              |  |
|   | c) no   |              |  |
|   | d) not applicable – not a Party of export   |              |  |
|   | If you were a Party of export during this reporting period, did you request any Pariew a decision it had made under Article 10 on the grounds specified in Article 12.  |              |  |
|   | a) yes (please give details below)  |              |  |
|   | b) not yet, but under development   |              |  |
|   | c) no   |              |  |
|   | d) not applicable – not a Party of export   | X            |  |
| 9. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).  |   |              |  |
|   | a) yes  |              |  |
|   | b) no   |              |  |
|   | c) not applicable – no decisions taken during the reporting period  | X            |  |
| 10. 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:    |   |              |  |
| No  | t applicable – Hungary is not a Party of export.  |              |  |
| 11. 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: |   |              |  |
| The European Community applies its domestic legislative framework instead of the Protocol's advance informed agreement procedure. This framework is compatible with the provisions of the Protocol. The Hungarian legislative framework is in line with EC legislation.     |   |              |  |
| inv   | In case a person or a company intend to place on the market a GMO, the decision is taken at EC level involving all Member States. For more details please see the European Community's implementation report. |              |  |

 $<sup>\</sup>underline{1}$ / The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

If a person or a company intend to release GMOs into the environment for experimental purposes, the decision is taken in accordance with Directive 2001/18/EC on deliberate release of GMOs into the environment at Member State level that is the Ministry of Agriculture and Rural Development in Hungary. Between 2004 and 2007 14 written authorizations has been issued by the national competent authority for import of GM maize, barley and tobacco seeds for experimental release in Hungary. For more details see: http://www.biosafety.hu.

(http://www.biosafety.hu/list.php3?name=natid+comname+sciname+cultivar+trait+gene+status+location s+company+category&like=import)

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.

| 12. Is there a legal requirement for the accuracy of information provided by the application that domestic use of a living modified organism that may be subject to transboundary ruse as food or feed, or for processing? (Article 11.2)     | •                     |  |
|---|-----------------------|--|
| a) yes  | X                     |  |
| b) not yet, but under development   |                       |  |
| c) no   |                       |  |
| d) not applicable (please give details below)   |                       |  |
| 13. 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                     |  |
| 14. Did your country take decisions regarding import under domestic regulatory fram by Article 11.4?  | eworks as allowed     |  |
| a) yes  | X                     |  |
| b) no   |                       |  |
| c) not applicable – no decisions taken during the reporting period  |                       |  |
| 15. 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 progress Article 11, including any obstacles or impediments encountered: |                       |  |
| Not applicable. Hungary was not a country of export during the reporting period.  |                       |  |
| 16. 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 progress Article 11, including any obstacles or impediments encountered: |                       |  |
| The European Community has a comprehensive legal framework which addresses int  | er alia the import of |  |

LMOs intended for direct use for food or feed, or for processing. This area is regulated by EC Regulations which are directly applicable in all Member States – in Hungary as well. For more details see

the EC implementation report.

# Article 13 – Simplified procedure

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

| 17. Have you applied the simplified procedure during the reporting period?   |                   |
|--|-------------------|
| a) yes   |                   |
| b) no  | X                 |
| 18. If your country has used the simplified procedure during the reporting period, or i unable to do so for some reason, please describe your experiences in implementing Ar any obstacles or impediments encountered: | -                 |
| Hungary has not made use of the simplified procedure for imports of LMOs as specifi  | ed in Article 13. |

Article 14 – Bilateral, regional and multilateral agreements and arrangements See question 1 regarding provision of information to the Biosafety Clearing-House.

| 19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?  |                     |
|--|---------------------|
| a) yes   |                     |
| b) no  | X                   |
| 20. If your country has entered into bilateral, regional or multilateral agreements or ar you have been unable to do so for some reason, describe your experiences in impleme during the reporting period, including any obstacles or impediments encountered: |                     |
| Hungary has not entered into any bilateral, regional or multilateral agreements or a Article 14(1).  | arrangements as per |

# Articles 15 and 16 – Risk assessment and risk management

| 21. 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  |   |
| b) no (please clarify below)  |   |
| c) not a Party of import / no decisions taken under Article 10  | X- for reason given above to Q 11       |
| 22. If yes to question 21, 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 below)   |   |
| c) no   |   |
| d) not a Party of import / no decisions taken under Article 10  | X- for reason<br>given above to<br>Q 11 |
| 23. 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   |   |
|---|---|
| b) yes – in some cases (please specify the number and give further details below)   |   |
| c) no   |   |
| d) not a Party of import / no decisions taken under Article 10  | X- for reason<br>given above to<br>Q 11 |
| 24. Has your country established and maintained appropriate mechanisms, measures a regulate, manage and control risks identified in the risk assessment provisions of the F 16.1)   |   |
| a) yes – fully established  | X                                       |
| b) not yet, but under development or partially established (please give further details below)  |   |
| c) no   |   |
| 25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3)   | ndary movements                         |
| a) yes – fully adopted  | X                                       |
| b) not yet, but under development or partially adopted (please give further details below)  |   |
| c) no   |   |
| 26. Does your country endeavour to ensure that any living modified organism, whether locally developed, undergoes an appropriate period of observation commensurate with 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)   |   |
| 27. Has your country cooperated with others for the purposes specified in Article 16.5  | 5?                                      |
| a) yes (please give further details below)  |   |
| b) no (please give further details below)   |   |
| 28. Please provide further details about your responses to the above questions, as well your country's experiences and progress in implementing Articles 15 and 16, includin impediments encountered:   |   |
| The competent Hungarian authorities carry out risk assessments on the basis of legislation. For an overview of the EC procedure for risk assessment and risk manage EC's implementing report.   |   |

Article 17 – Unintentional transboundary movements and emergency measures

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

| 29. 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) yes – partially consulted, or consultations were delayed (please clarify below)  |   |  |
| c) no – did not consult immediately (please clarify below)  |   |  |
| d) not applicable (no such occurrences)   | X |  |
| 30. Please provide further details about your response to the above question, as well a your country's experiences in implementing Article 17, including any obstacles or impencountered:   | • |  |
| Not applicable  |   |  |
| Article 18 – Handling, transport, packaging and identification  |   |  |
| 31. 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) not yet, but under development   |   |  |
| c) no   |   |  |
| d) not applicable (please clarify below)  |   |  |
| 32. 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) not yet, but under development   |   |  |
| c) no   |   |  |
| 33. 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) not yet, but under development   |   |  |
| c) no   |   |  |
|   |   |  |

34. 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) not yet, but under development |   |
| c) no                             |   |

35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:

Hungary is a Member State of the European Community, its legislation is in line with the legal framework of the EC. For more details please see the EC implementation report.

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.

36. 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:

In Hungary, the Ministry of Environment and Water has been designated as focal point for the Biosafety Clearing-House (BCH) (Contact: Ms Kitti Lippai, Ministry of Environment and Water, Biodiversity Division, EU Legal and Coordination Department. Address: H-1011 Budapest, Fő u. 44-50., Hungary. Phone: +361-395-6857, Fax: +361-275-4505, e-mail: lippai@mail.kvvm.hu).

#### *Article 21 – Confidential information*

| 37. 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) not yet, but under development   |   |
| c) no   |   |
| 38. 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 / no such requests received   | X |
|   | 39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered: |   |
|   | Not applicable  |   |
| 40. 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, not a Party of export during the reporting period.

#### *Article 22 – Capacity-building*

41. 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)                | X |
|---|---|
| b) no   |   |
| c) not applicable – not a developed country Party |   |

42. If yes to question 41, how has such cooperation taken place:

The Joint Research Centre of the European Community organized a Training Course on Analysis of Food Samples for GMOs in October/November 2003; in Gödöllő, Hungary. Also Hungarian scientists contributed to 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 Countries with economies in transition.

43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition?

| a) yes (please give details below) |  |
|------------------------------------|--|
| b) no                              |  |

| c) not applicable – not a developing country Party   | X |
|--|---|
| 44. If yes to question 43, how has such cooperation taken place:   |   |
| Not applicable   |   |
| 45. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training in the proper and safe management of 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)   |   |
| 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  | X |
| 46. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training in the use of risk assessment and risk 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  | X |
| 47. If a developing country Party or a Party with an economy in transition, have you be cooperation for technical and scientific training for enhancement of technological and 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  | X |
| 48. Please provide further details about your responses to the above questions, as well your country's experiences and progress in implementing Article 22, including any ob impediments encountered:                        |   |
| No further comments  |   |

Article 23 – Public awareness and participation

49. 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   |                   |  |
| 50. If yes, do you cooperate with other States and international bodies?  |                   |  |
| a) yes – significant extent   | X                 |  |
| b) yes – limited extent   |                   |  |
| c) no   |                   |  |
| 51. Does your country endeavour to ensure that public awareness and education encominformation on living modified organisms identified in accordance with the Protocol thimported? (Article 23.1(b))  |                   |  |
| a) yes – fully  | X                 |  |
| b) yes – limited extent   |                   |  |
| c) no   |                   |  |
| 52. 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   |                   |  |
| 53. Has your country informed its public about the means of public access to the Biosa House? (Article 23.3)  | fety Clearing-    |  |
| a) yes – fully  | X                 |  |
| b) yes – limited extent   |                   |  |
| c) no   |                   |  |
| 54. Please provide further details about your responses to the above questions, as well   | as description of |  |

54. 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:

Public awareness and participation is an integral part of the regulatory framework on GMOs of the EC and Hungary. For more details see the EC implementation report.

Public information on activities regarding genetically modified organisms (including information on all intentional releases of GMOs into the environment) on the Hungarian Biosafety Websites (see question 1 above). Drafts and final authorization decisions are published in the Official Journal as well as on the website of the Ministry of Agriculture and Rural Development.

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 3rd July 2001 and published on 4th December 2001.

Article 24 – Non-Parties

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

| 55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?   |   |
|--|---|
| a) yes   |   |
| b) no  | X |
| 56. 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: |   |
| Not applicable.  |   |

*Article 25 – Illegal transboundary movements* 

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

| 57. 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  |   |
| 58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?  |   |
| a) yes   | X |
| b) no  |   |

59. 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 Act 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 imposing 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. Furthermore, the amount of the penalty depends on whether the non compliance happened at first time or it happened repeatedly, or happened accidentally.

The gene technological penalty fee extends from 300 000 HUF to 1 million HUF at the first occasion, from 1 million HUF to 10 million HUF if repeated.

The Commission adopted on 18 April 2005 emergency measures regarding imports of the non-authorised genetically modified organism Bt10 in maize products which was implemented in Hungary with Decree 31/2006. (IV. 29.) of the Ministry of Agriculture and Rural Development, the Ministry of Economy and Transport and the Ministry of Finance. The emergency measure has been overruled on 7 March 2007 by Commission Decision No. 2007/157/EC. The national regulation on its implementation is currently under preparation in Hungary.

There have been one illegal transboundary movement of living modified organisms ('LLRICE601' rice variety which is not authorized in the EU) into Hungary during the reporting period. The regional Institutes under the National Public Health and Medical Officer's Service collected 35 samples from USA-origin long grain rice lots and sent them to the GMO laboratory of the National Institute for Food Safety and Nutrition for analysis. Those samples were negative for LLRICE 601. The Animal Health and Food Control Stations took 10 rice samples from the same type lots and sent them to the National Food Investigation Institute for analysis. One of them contained 'LLRICE601' rice variety. The lot was destroyed and reported through the Rapid Alert System for Food and Feed (RASFF).

# Article 26 – Socio-economic considerations

60. 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

| a) yes – significant extent |   |
|-----------------------------|---|
| b) yes – limited extent     |   |
| c) no                       | X |
| d) not a Party of import    |   |

61. 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 |

62. 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:

Socio-economic considerations were also taken into account when the Hungarian Parliament amended the Act on Gene Technological Activity in 2006 and adopted detailed rules on co-existence of genetically modified crops with conventional and organic farming. By developing national measures for co-existence, Hungary has taken into account the Recommendation 2003/556/EC of the European Commission of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. Our national legislation addresses inter alia the issue of the potential economic loss and impact of the admixture of GM and non-GM crops, and the most appropriate management measures that can be taken to minimise admixture.

However, there has not been commercial GMO cultivation in Hungary during the reporting period.

## Article 28 – Financial mechanism and resources

| 63. 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   |   |

64. 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 Hungarian Biosafety Website (www.biosafety.hu).

## Other information

65. 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:

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:

No difficulties encountered