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

Origin of report

Party:	Czech Republic
Contact officer for report	
Name and title of contact officer:	Milos Nemec, Ph.D.
Mailing address:	Ministry of the Environment of the Czech Republic Vrsovicka 65 10010 Prague 10 Czech Republic
Telephone:	+420 267 122 026
Fax:	+420 267 310 013
E-mail:	milos_nemec@env.cz
Submission	
Signature of officer responsible for submitting report:	Pavel Forint Head of Department of Environmental Risks Ministry of the Environment of the Czech Republic Vrsovicka 65 10010 Prague 10 Czech Republic
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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:

The Ministry of the Environment (hereinafter the „Ministry") acts as the central administrative body of the Czech Republic concerning the assessment of genetically modified organisms (GMOs) impact on the components of the environment and the biodiversity. The department – secretariat of the Czech Commission for the Use of GMO and Products - that acts as the workplace of the national contact person for CPB and Biosafety Clearing-House (BCH) was commissioned to prepare the First Regular National Report of the Czech Republic on the Implementation of the Cartagena Protocol on Biosafety (CPB). Information and experience of the staff of the Ministry of Agriculture, Ministry of Health, the Czech Environmental Inspection (hereinafter the „Inspection") and the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products (expert advisory body of the Ministry) were further used when preparing 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 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):

Department of Environmental Risks at the Ministry of the Environment of the Czech Republic participates in the activities of the National Focal Point of the Biosafety Clearing-House in the Czech Republic (BCH-CZ) being responsible for subject matter together with CENIA, Czech Environmental Information Agency establishing technical and methodological background for the activities of BCH-CZ. Current co-operation of the both elements has not yet been sufficiently effective and so creates a delay in publication of the prescribed data in BCH-CZ.

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 does not exist /not 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- Provided by the European Commission		
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 emergency contacts (Article 17.2 and 17.3(e));	X		
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 movements that are likely to have significant adverse effects on biological diversity (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 does not exist /not 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- Decisions are made at the EU level		
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- Decisions are made at the EU level		
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- Provided by the European Commission		
n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);	X- Provided by the European Commission		
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 environmental reviews of LMOs generated by regulatory processes and relevant information		X	

regarding products thereof (Article 20.3(c)).			

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:

Domestic regulatory framework concerning the biosafety contains two elements – national legislation and European Community legislation, which is obligatory for the Czech Republic as the Member State of the European Union.

The Act No. 78/2004 Coll., **on the use of genetically modified organisms and genetic products, including the marked amendments performed by the Act No. 346/2005 Coll.** *(in short Act 78/2004)* is the basic national legal instrument of the Czech Republic concerning the biosafety.
This act is in compliance with the enforceable European Community law.

Contents of the Act 78/2004:

PART I Introductory Provisions
§ 1 The object of the Act
§ 2 Basic definitions
§ 3 The use of genetically modified organisms and genetic products
PART II General Provisions
§ 4 Authorisation for use of genetically modified organisms and genetic products
§ 5 Administrative procedure for granting consent for the contained use, for the introduction into the environment, and for registration into the List for placing on the market
§ 6 Public consultation
§ 7 Risk assessment of the use of genetically modified organisms and genetic products
§ 8 New information
§ 9 Protection of some information
§ 10 Making information available to the public
§ 11 Labelling
§ 12 Amendment and repeal of consent and registration into the List for placing on the market
§ 13 Termination of authorisation for the use of genetically modified organisms and genetic products
§ 14 Professional consultant
PART III Contained Use and Introduction into the Environment
Chapter I Contained Use
§ 15 § 16
Chapter II Introduction into the Environment

§ 17 § 18
Chapter III Common Provisions for Contained Use and Introduction into the Environment
§ 19 Obligations of persons authorised for contained use and of persons authorised for introduction into the environment § 20 The emergency response plan
§ 21 Measures taken in case of an accident
§ 22 The Register of permitted genetically modified organisms and the Register of users
PART IV The Placing on the Market
§ 23 § 24
PART V Import, Export and Transit of Genetically Modified Organisms and Genetic Products
§ 25 Import and export of genetically modified organisms and genetic products
§ 26 Transit of genetically modified organisms and genetic products
PART VI Performance of State Administration
§ 27 Administrative bodies in the are of the use of genetically modified organisms and genetic products
§ 28 The Ministry
§ 29 The Ministry of Health
§ 30 The Ministry of Agriculture
§ 31 The Inspection
§ 32 The custome authorities
§ 33 Other administrative bodies
PART VII Remedial Measures and Penalties
§ 34 Remedial measures
§ 35 Penalties
§ 36 Relation to the Code of Administrative Procedure
PART VIII Transitional and Concluding Provisions
§ 38 § 39
§ 40 Entry into force
Annex 1 *Technical procedures, as results of which a genetically modified organisms may arise, and technical procedure, which do not lead to the arising of genetically modified organism*
Annex 2 *Safety criteria for genetically modified organisms*
Annex 3 *Risk categories for contained use*
Annex 4 *Requirements of the Code of Practice for a workplace where genetically modified organisms are used*

Czech Republic as the Member State of the European Union **acts to the law of the European Community (EC)** that is described in detail in the parallel EC report.

The basic EC legal instruments concerning the biosafety are as follows:

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, Official Journal L 106, p. 1-38.
(in short Directive 2001/18/EC)
Directive 2001/18/EC is transposed by the Act 78/2004.

Regulations – directly applicable legislation:

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, Official Journal L 287, p. 1-10.

(in short Regulation (EC) No 1946/2003)

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, Official Journal L 268, p. 1-23.
(in short Regulation (EC) No 1829/2003)

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, Official Journal L 268, p. 24-28.
(in short Regulation (EC) No 1830/2003)

The parallel EC Report contains the complete list of EC legal instruments concerning the biosafety.

It is necessary to consider any part of domestic regulatory framework in the context of relevant part of EC law. This fact is especially to keep in mind when explaining some basic conceptions and the consecutive answers in this First Regular National Report of the Czech Republic on the Implementation of the Cartagena Protocol on Biosafety (hereinafter „Report").

Definitions

1) Cartagena Protocol

"Export" means intentional transboundary movement from one Party to another Party;

"Import" means intentional transboundary movement into one Party from another Party;

"Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

2) Regulation (EC) 1946/2003

„Export" means :
(a) the permanent or temporary leaving of the customs territory of the Community of GMOs meeting the conditions of Article 23(2) of the Treaty
(b) the re-export of GMOs not meeting the conditions referred to in (a) which are placed under a customs procedure other than transit procedure

„Import" means the placing under a customs procedure, other than transit procedure, of GMOs introduced into the customs territory of a Party or non-Party outside the Community from a Party within the Community

„Transboundary movement" means the intentional or unitentional movement of a GMO between one Party or non-Party and another Party or non-Party, excluding intentional movements between Parties within the Community

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

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

5. Were you a Party of import during this reporting period?	
a) yes	
b) no	X
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	X
7. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2)	
a) yes	X
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
8. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) 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	X
c) not applicable – no decisions taken during the reporting period	
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:	
Not applicable. The Czech Republic has not been a country of export during the reporting period.	
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:	
According to EC legislation (Directive 2001/18/EC and Regulation (EC) 1829/2003) all decisions concerning imports for placing on the market, including release into the	

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

environment, are made at the EU level. Only decisions on deliberate releases of GMOs for other purpose than for placing on the market (i.e. for field trials) are made at the national level.

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 applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	X
b) 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 frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X

15. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:
Not applicable. The Czech Republic has not been 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 food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:
The Czech Republic has not been a country of import of GMOs intended for food or feed, or for processing according to Article 3 of the Regulation (EC) 1946/2003 during the reporting period.

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 if you have been unable to do so for some reason, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:	
Czech Republic has not used the simplified procedure during the reporting period.	

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 arrangements, or if you have been unable to do so for some reason, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:	
Czech Republic 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

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
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
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

24. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)	
a) yes – 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 transboundary movements of living modified organisms? (Article 16.3)	
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 imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	X
b) yes – in some cases (please give further details below)	
c) no (please give further details below)	
d) not applicable (please give further details below)	
27. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	X
b) no (please give further details below)	
28. 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:	

The EC 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.
The review on EC legislation concerning „risk assessment" and „risk management" and the intent thereof are included in the Report of EC.

Risk assessment provisions are the integral part of the Act 78/2004 (see § 7).

Specialised control laboratories play an important role in risk management (supervision and control) at the use of GMO in the Czech Republic.

The Ministry of the Environment as the competent authority on the use of GMOs and on Biosafety in the Czech Republic along with the Czech Environmental Inspection decided to use experienced laboratories with advanced background as control laboratories for GMO issue. Based on a tender organised by the Ministry, laboratories of the three institutions were chosen as control

laboratories for the implementation purposes.

These are laboratories of :

(1) Institute of Chemical Technology, Faculty of food and biochemical technology, Department of Biochemistry and Biotechnology,

(2) Research Institute of Crop Production, Department of Molecular Biology, Laboratory for GMO identification and DNA fingerprinting, both laboratories are involved in introduction of GLP to sampling of GMO,

(3) National Institute of Public Health, Department of Toxicology, Laboratory for Molecular Biological Methods.

Since 2001 the laboratories have:

- *carried out the tests for the Czech Environmental Inspection of imported crops (soybeans, maize) and of samples of material from field trials (maize),*
- *prepared the methodology for sampling of soybeans and maize kernels*
- *prepared the implementation of relevant standards*
- *participated in the projects of the Ministry of the Environment for the monitoring of possible environmental impacts of GM crops,*
- *established a bank of reference materials and samples of GM material approved in the Czech Republic (import and field trials)*
- participated in European Network of GMO Laboratories (ENGL) and attended training courses in Joint Research Centre EC in Ispra, Italy.

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 as description of your country's experiences in implementing Article 17, including any obstacles or impediments encountered:

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:	
The Czech Republic acts to EC legislation (Regulation (EC) 1946/2003, Article 12)	

Article 19 – Competent national authorities and national focal points

See quest The Czech Republic acts to EC legislation (Regulation (EC) 1946/2003, Article 12)ion 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:
Biosafety Clearing-House (BCH-CZ) was established in the Czech Republic in 2004. The Department of Environmental Risks at the Ministry of the Environment of the Czech Republic serves as National Focal Point of BCH, (and it is also a contact point for the Cartagena Protocol. The aim of creators of BCH-CZ was to create a simple and robust information system, which should gradually fulfil requests of the Cartagena Protocol when emphasising pragmatism and conciseness without extensive general comments available in other sources. The creation and development of BCH-CZ was accompanied with some organisational and personnel problems causing that BCH-CZ has still not reached the desired form and function. We believe that mentioned problems should be solved by improvement of the co-operation between the Department of Environmental Risks of the Ministry of the Environment and CENIA, Czech Environmental Information Agency establishing technical and methodological background for the activities of BCH-CZ. UNEP – GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing-House should also contribute to better performance of BCH-CZ.

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:	

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:
The Czech Republic has not been a country 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)	
b) no	
c) not applicable – not a developed country Party	X
42. If yes to question 41, how has such cooperation taken place:	
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)	X
b) no	
c) not applicable – not a developing country Party	
44. If yes to question 43, how has such cooperation taken place:	
The Czech Republic has actively participated in the co-operation within the region of Central and Eastern European (CEE) countries. Even before the reporting period (April 24 – 25, 2003) the „Sub-Regional Meeting on Biosafety Framework“ was held in Prague by the Ministry of the Environment, which was attended by the representatives of the UNEP Biosafety Unit, European Commission, Slovak Republic, Hungary, Croatia, Slovenia and the Czech Republic. In November 2006 the Joint Inception Workshop of the Czech Republic and Slovak Republic was held in Prague, whose program was oriented toward exchanging experience from solving the projects UNEP/GEF „Support for the Implementation of the Draft National Biosafety Framework“ and „Building Capacity for Effective Participation in the Biosafety Clearing-House“ between both countries.	
45. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the proper and safe management of biotechnology to the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	

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	
46. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
47. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training for enhancement of technological and institutional capacities in biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	X
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
48. 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:	

Question 45:

Czech Republic's delegation attended the **Sub-Regional Workshop for Central and Eastern European (CEE) countries on Developing a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBF)**, which was held in Antalya, Turkey, from 9 to 12 December 2003.

The workshop was organised under the UNEP-GEF Project on "Development of National Biosafety Frameworks".

The workshop focused on how to develop a regulatory regime and administrative systems for National Biosafety Frameworks.

The workshop dealt with the different options and obligations that countries face while setting up their NBF. The main issues covered by the workshop were designed on the regulatory regime and administrative systems, sharing of experience among different countries and discussions on the various alternatives.

The workshop has provided many new incentives for the building of the National Biosafety Framework in the Czech Republic.

Question 46:

Analogous to the workshop in Antalya (see question 45) the Czech Republic's delegation attended the **Subregional Workshop for the Countries of Central and Eastern Europe, the Caucasus and Central Asia (CEECCA): Risk Assessment and Management, and Public Awareness and Participation,** which was held in Vilnius, Lithuania, from 27 to 30 May 2003 (it is before the beginning of the reporting period).

The workshop was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of Lithuania.

The workshop contributed by new incentives to the building of the National Biosafety Framework of the Czech Republic.

Question 47:

During the reporting period the project **PHARE CZ01-06-03_Technical Equipment for the Monitoring of Genetically Modified Organisms (GMOs)** was realised in the Czech Republic. The technical implementation of this project rested upon the Ministry of the Environment of the Czech Republic, Environmental Risks Department.

The main purpose of the project was to strengthen the capacity of the national system of GMO laboratories control within the competence of the Ministry of the Environment (MoE) as the Competent Authority for the use of GMO and thus contribute effectively to the acquis implementation in the field of GMO and biosafety.

The project contributed in the fundamental way to achieving three main targets as follows:

- **to complete the equipment for three chosen control workplaces including modern apparatuses and technologies,** which provide for the detection of the presence of GMO released into the environment and circulation, capture of non-permitted GMO, e.g. in imports, and monitoring of the contingent risks connected with the use of GMO at the level comparable to EU.
- **to interconnect well equipped control laboratory workplaces at the basis of national l network**, which will serve for GMO detection and monitoring for the needs of the statee administration
- **to contribute to harmonisation of diagnostic procedures with EU**

Question 48:

During the first half of the reporting period – although, at the high level of the development of molecular biology and modern biotechnologies including procedures of GMO preparation and with well organised basis of the future biosafety framework – the Czech Republic enjoyed a privilege intended for **the countries of transition economy**. In that time the Czech Republic was eligible for solving UNEP/GEF projects, and used the eligibility for gaining the support of the participation in projects. The participation in UNEP/GEF projects intensified the perception of the role of Cartagena Protocol and conception of National Biosafety Framework and contributed to the co-operation of the individual sections (the environment, agriculture, public health).

The Czech Republic has participated in solving the problems as follows:

UNEP/GEF Project „Development of the National Biosafety Framework for the Czech Republic", since July 1, 2002 until March 31, 2004

The results of the project are summarized in the final report (Ministry of the Environment, Prague, March 2004), which is divided into 5 main chapters:

1. *National biosafety policy, its priorities, relations to sectoral policies and strategies. Information on status of ratification of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety by the Czech Republic.*
2. *Regulatory regime, principal acts related to biosafety and main decrees in force, institutions responsible for their implementation.*
3. *System to handle notifications or requests for authorisation of certain activities, competent authorities.*
4. *Systems for enforcement and monitoring of impacts on the environment and human health, responsible institutions.*
5. *System and measures to enhance public education, awareness and participation, relation to national strategie documents, competent authorities. Basic information on the Biosafety Clearing-House, related websites.*

In the course of the Project duration several workshops were organized for different groups of stakeholders.

UNEP/GEF Project "Support for the Implementation of the Draft National Biosafety Framework for the Czech Republic, it should take place from August 2006 to July 2010

New project which is linked to the previous UNEP/GEF Project „Development of the National Biosafety Framework for the Czech Republic", focuses on concrete actions and measures in five areas:
- *biological safety policy,*
- *legislation, administration and handling of applications for permission to use GMO,*
- *system to handle notification,*
- *monitoring and supervision/control of measures taken to ensure biological safety*
- *disclosure of information and ensuring public participation.*

Among project objects are: the enforcement of biosafety principles into the main strategic documents of the Czech Republic, participation in the particular international and regional negotiations, amendments to regulatory regime and the support of activities of the Czech Commission for the Use of GMO and Genetic Products, further improvement of the technical equipment of workplaces including laboratories for detection and control, organising seminars and dissemination of information (website of the Ministry of the Environment, publications, media), etc. The proposed measures include all departments related to the issue of biosafety.

UNEP/GEF Project „Building Capacity for Effective Participation in the Biosafety Clearing-House", planned for the period of 2006 – 2008

This project, which was approved as supplementary to the project "Support for the Implementation of the Draft National Biosafety Framework for the Czech Republic", is realised on the basis of Memorandum of Understanding concluded between UNEP and the Ministry of the Environment. The aim of the project is to help the Czech Republic to achieve the interoperability of BCH-CZ within Biosafety Clearing-House network.

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 encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	X
b) yes – limited extent	
c) no	
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 Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	
b) yes – limited extent	X
c) no	
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:	
According to §10 of the Act 78/2004 the Ministry of the Environment shall enable public access to information through the official board of the Ministry, via Internet, and in another appropriate manner in the municipality or region, on whose territory the immediate contained use or introduction into the environment proceed or are expected considering all circumstances. The other ways of public information are: open meetings of the Czech Commission for the Use of GMO and products, workshops and specialized courses, publications, leaflets, radio and TV programmes etc. Question 52: **Every individual** may forward to the Ministry of the Environmentt in writing his/her opinion within 30 days of making the summary of the contents of the request available to the public. If in case of a request for granting consent for the introduction into the environment or for registration into the List for placing on the market, the Ministry receives negative opinion on introduction of GMO into the environment or on the placing thereof on the market, in which environmental risk assessment results are doubted or an objection to insufficient protection of the health and the environment is made, the Ministry shall arrange for **public consultation** prior to making decision on the submitted request.	

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	X
b) no	
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:	
Transboundary movements of GMO between the Czech Republic and non-Parties (according to Article 3 par. 14 of Regulation (EC) No 1946/2003) in the reporting period include the exchange of GMO (GMM, hybridomas, laboratory animals etc.) under conditions of the contained use for the scientific purposes and the import of **unremarkable amounts** of agricultural commodities from non– Parties (maize, rape and soya) that **maybe contain** GMO impurities.	

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:	

Question 57:

According to Directive 2001/18/EC, it is the Member States that are obliged to take domestic measures to prevent and penalize illegal transboundary movements of GMOs. European legislation contains explicit obligations of Member States to lay down rules on penalties applicable to infringements of the provisions of European regulations.
Corrective measures and penalties are **the integral part of the Act 78/2004**.

If the Inspection discovers that the use of GMO and genetic products occurred or occurs in contrary with this Act or in contrary with the decisions issued pursuant to this Act, it may, depending on the seriousness of the infringed obligation, suspense or even prohibit the further use thereof.
For example, the Inspection may impose a penalty of up to **5,000,000 CZK** on a person that uses genetically modified organisms or genetic products without appropriate authorisation, or that fails to terminate the use in compliance with conditions laid down in the decision.

Question 58:

The presence of aquarium GM „Glofishes“ (Zebrafishes (Brachydanio rerio)) was detected, which became the subjects of the illegal trade. It is likely that the part of these animals was obtained from the area outside of EU, and therefore the principle of **the illegal transboundary movement** was carried into effect under Regulation (EC) 1946/2003. Although the glofishes do not endanger biodiversity in the Czech Republic, they have not been authorised either to be place on the market or for the contained use.

In the Czech Republic was the issue discussed by the expert advisory body of the Ministry, the Czech Commission for the Use of GMOs (CzC GMOs) at its meeting on 19 September 2006. The recommendations and procedure suggested by the CzC GMOs are as follows:

- *the Joint Research Centre EC (JRC) should provide detection methods for fluorescent proteins.*
- *the Czech institutions that are capable of detecting green fluorescent protein (GFP, origin of jellyfish Aequoria victoria) in fish should make some unofficial analysis on samples of "suspiciously coloured" Danios collected on the Czech market, but the unified and verified detection methodology is a prerequisite for regular inspections by the supervision authorities.*
- *the Czech authorities and laboratories are prepared to cooperate with JRC in development of detection methodology. According to the experts, in case the Danios are modified, there could be more transgenes presented according to the origin of the fish.*
- *Aside from the accredited laboratory engaged in GFP identification also the Czech Environmental Inspection participates in the further solving of the case of GM glofishes.*

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

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:

Question 60:

Although the Czech Republic is not a Party of import, the co-existence provisions have been included in the current Czech legislation regulating the cultivation of GM crops:

a) **Act No. 257/1997** on agriculture and its amendment No. 441/2005
(general act on agriculture including binding specifically measures for **coexistence in general**), instruments:

- *notification of fields with GM crops to neighbouring farmers and Ministry of Agriculture (MoA) prior and after sowing*
- *minimal distance between GM crop and non-GM crop of the same species (possibly buffer strip)*
- *keeping information on GM crop and its product handling on the farm*
- *facilitation of checks (marking place of GM crop production on field)*
- *sanction for not complying with the measures (up to the amount of 17 000 EUR)*

b) **Decree No. 89/2006**, on more detailed conditions for production of GM variety (binding crop specific coexistence measures for maize and potatoes following the above mentioned general act on agriculture), instruments:

- *notification of fields with GM crops to neighbouring farmers and MoA prior sowing:*
  - *for maize and potatoes – by 1st March*
- *notification of fields with GM crops to neighbouring farmers after sowing:*
  - *for maize and potatoes – within 15 days*
- *notification of fields with GM crops to MoA after sowing:*
  - *for maize and potatoes – within 30 days*
- *minimal distance between GM crop and non-GM crop of the same species (possibly buffer strip):*
- *keeping information on GM crop and its product handling on the farm*
  - *for the purposes of GMO traceability*
  - *information on purchase of seed, production of GM crop, sales of harvested production*
  - *available in companies*
  - *minimally for the period of 5 years*

c) **Act No. 78/2004** on genetically modified organisms and their products and its amendment No. 346/2005
(not specifically for coexistence but in general for handling with GM organisms incl. commercially grown crops), instruments dealing with coexistence issue:

- *notification of fields with GM crops to the Ministry of the Environment*
- *labelling of GMO products*

Notice: a) and b) in competence of the Ministry of Agriculture,
c) in competence of the Ministry of the Environment.

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	
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:

The Czech republic is:

(a) the standard contributor (i.e. contributions of determined level) to the Trust Fund for the Cartagena Protocol

(b) the ultra-standard contributor to the Global Environment Facility (GEF), whereby the financial resources available to other Parties are jointly created

(c) receiving financial resources for solving the projects:

- UNEP/GEF Project „Development of the National Biosafety Framework for the Czech Republic“ (2002-2004)

- UNEP/GEF Project „Support for the Implementation of the Draft National Biosafety Framework for the Czech Republic“ (2006-2010)

- UNEP/GEF Project „Building Capacity for Effective Participation in the Biosafety Clearing-House” (2006-2008)

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