Republic of Macedonia
Ministry of Environment
and Physical Planning

[redacted]

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Republic of Macedonia
Ministry of Environment and
physical planning

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World Trade Center
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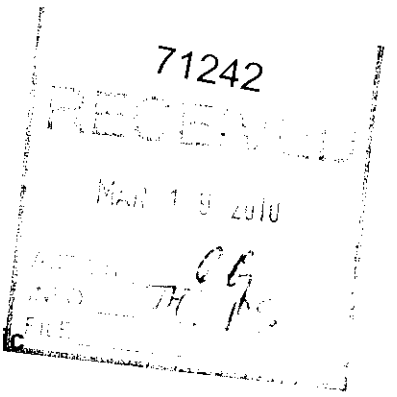
Attn: Mr. Djoghlaf Ahmed, Executive Secretary



Subject : Submission of First Regular National Report on the implementation of the Cartagena Protocol on biosafety, Republic of Macedonia

Dear Sir,

Pursuant to Decision BS –IV/ 14 of MOP 4, we are pleased to inform you that the Ministry of Environment and Physical Planning as competent state body in the Republic of Macedonia, responsible for implementation of the Cartagena Protocol on biosafety has finalizied the First Regular National Report.

Please, find it enclosed hereto.

We wish to take this opportunity to congratulate the Tenth Anniversary of the Adoption of the Cartagena Protocol on biosafety which coincides with the International Year of Biological Diversity.

We would like to thank you for the cooperation and support you have provided to our country, and we hope that it will continue successfully in future too.

Sincerely yours,

Filip Ivanov
Director,
Administration of Environment

Completed reports and any comments should be sent to:

The Executive Secretary
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Origin of report

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Submission	
Signature of officer responsible for submitting report:	Filip Ivanov Director Administration of Environment Ministry of Environment and Physical Planning
Date of submission:	24February 2010
Time period covered by this report:	2005-2009

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 Environment and Physical Planning is the competent state body in Republic of Macedonia, responsible for the implementation of the Cartagena Protocol on Biosafety, as well as for the preparation and submission of the National report on the implementation of the Cartagena Protocol to the Executive Secretary of the Convention for Biodiversity.

In order to provide transparent and participatory approach for the preparation of this Report, as well as to provide for accuracy of the requested information, the Ministry of environment and physical planning, Administration of environment submitted the first draft Report, which was distributed electronically to the following directly involved ministries, bodies and/or scientific institutions:

1. ***Ministry of agriculture, forestry and water economy***
   - ***Veterinary Directorate***
   - ***Phytosanitary Directorate***
   - ***Directorate for seeds and planting material***
2. ***Ministry of health, Food Directorate***
3. ***Ministry of economy, Sector for internal market, Department for consumers' protection***
4. ***Ministry of finance, Customs Administration***
5. ***Faculty of agricultural sciences and food, GMO laboratory***
6. ***Macedonian Academy of Arts and Sciences, Research centre for genetic engineering and biotechnology***
7. ***Consumers Organization of Macedonia***
8. ***Institute for Public Health, Sector for hygiene and environmental protection***

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):

Information was provided to the Biosafety Clearing House.

- National focal point (Articles 19.1 and 19.3 of the Cartagena Protocol on Biosafety
- Contact details about the national competent bodies (Articles 19.2 and 19.3 of CPB) – renewed information with additional national competent bodies in accordance with the national Law on GMO (Official Gazette of RM No.35/08) – undergoing;
- Draft National framework on biosafety – supplement, i.e. publishing the wording of the Law on GMO (Official Gazette of RM, No. 35/08) – undergoing

2. Please provide an overview of information that is required to be provided to the Bio-safety 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	
(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 – national focal points (Article 19.1 and 19.3)	X – contact details for competent authorities (Article 19.2 and 19.3)	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 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
(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
(n) LMOs granted exemption status by each Party (Article 13.1)			X
(o) 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
(p) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information 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)	
b) some measures introduced (please give details below)	X
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:	
Republic of Macedonia signed the Cartagena Protocol on Biosafety on 26.07.2000, and ratified the Protocol on 14.06.2005. The primary goal of Republic of Macedonia is to harmonize the national legislation in all areas, including the GMOs, with the EU legislation. This process was initiated on 1 December 2001, i.e. by signing the Stabilization and Association Agreement between Republic of Macedonia and EU in April 2001, and the entry into force in April 2004. The process was especially intensified in December 2005 when Macedonia was granted the status of candidate country for EU accession.	

Macedonian legislation on GMO is based on the transposition and implementation of the European legislation, namely:

Directive 98/81/EC dated October 1998, changing the Directive 90/219/EEC on contained use of genetically modified organisms and Directive 2001/18/EC dated 12 March 2001, for deliberate release of GMO into the environment and revoking the Directive of the Council 90/220/EEC. Some provisions of the Cartagena Protocol on Biosafety have been transposed in the Law on genetically modified organisms – Law on GMO (Official Gazette No. 35/2008).

This Law regulates the management of genetically modified organisms and combinations of genetically modified organisms and products containing genetically modified organisms, including genetically modified organisms as products, measures to prevent and reduce the possible negative impact on the human health and environment, as consequence of the contained use of genetically modified organisms, deliberate release into the environment of genetically modified organisms or placing products on the market which contain genetically modified organisms and/or are comprised of or originate from a combination of genetically modified organisms including genetically modified organisms as products, as well as cross-border movement of genetically modified organisms and products containing genetically modified organisms and/or consisting of or originating from combination of genetically modified organisms including genetically modified organisms as product.

The Food Directorate at the Ministry of Health is the competent body to manage the GMO, which are used as food for human beings, i.e. food which contains or is consisted of GMOs or which contains ingredients produced from GMO (Official Gazette of RM 78/08). According to the Rulebook on special requirements for safety of food containing GMOs or food produced from GMOs (Official Gazette of RM 78/08), the Food Directorate shall take the samples of food to examine the GMO presence, with support by the food state inspectors as part of their official controls. The samples should be sent for testing at the laboratory at the Faculty of agricultural sciences and food (University Ss. Cyril and Methodious), as this laboratory was authorised to do the testing by the Ministry of health in 2006. Yet, this procedure is still in its initial phase of implementation, and there is an identified significant need for enhancing the capacities of food state inspectors regarding the implementation of this process. The establishment of the State laboratory for GMO testing is still a current issue and in a planning phase, and there is necessity of additional equipment to enhance the laboratory capacities to do the GMO testing.

To date, the policy of the national framework (legislative, administrative, decision-making, monitoring and control) in Republic of Macedonia has not been fully implemented and/or operational in all its segments. There are remaining areas in the national GMO and biosafety legislation, which have not been fully harmonized and/or covered.

The institutional mechanism and administration bodies for biosafety have not been fully defined, including the competent bodies and their authorisations in accordance with their competencies.

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	
b) not yet, but under development	
c) no	X
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	X
d) not applicable – not a Party of export	
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:	
During the reporting period, Macedonia is not a Party of export of GMOs intended for release into the environment.	
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:	
Not applicable. During the reporting period, RM has not reached decision about import of GMOs intended for release into the environment.	

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	

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

b) not yet, but under development	
c) no	X
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	X
c) not relevant	
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. Republic of Macedonia has not been Party 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:	
During the reporting period, Macedonia is not a party of import of GMOs intended for direct use for food or feed, or for processing.	

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:	

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:	
Republic of Macedonia has not entered into bilateral, regional or multilateral agreements or arrangements in accordance with Article 14(1).	

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	
b) not yet, but under development or partially established (please give further	X

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	
b) not yet, but under development or partially adopted (please give further details below)	X
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	
b) yes – in some cases (please give further details below)	
c) no (please give further details below)	X
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)	
b) no (please give further details below)	X
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:	
In accordance with the Law on GMO, prior to the beginning of the contained use, deliberate release of GMO in the environment, and placing products on the market, that are containing GMOs and/or which are comprised of GMOs, the notifier have to carry out risk assessment in accordance with the aim for use. However, the competent body may always request additional risk assessment from different authorised professional sources. The content and the scope of the risk assessment for deliberate release of GMOs into environment, the assessment methodology and the requirements that need to be met by the legal entity that makes the risk assessment, are prescribed by a decree on the part of the minister of environment. According to the existing law, there is no fully established and operational adequate measure for risk management, regulation and control/monitoring. With regard to the risk assessment and risk management, we need to improve our technical and human capacities, and that would be quite difficult unless we receive additional external financial support. The same refers with regard to the adopted measures to prevent the unintentional transboundary movements of GMOs (Article 16.3) within the country. In order to prevent such movement, our representatives and customs officers at the border crossings need to be trained on identification of such cargo transport.	

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:
Not applicable. During the reporting period, there were no occurrences in Republic of Macedonia that led or could have led to an unintentional transboundary movement of GMOs, which had or could have had significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risk to human health. Yet, transboundary movement of GMOs is regulated by the Law on GMO (Official Gazette of RM, No. 35/08, Article 51-58).

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)	
b) not yet, but under development	
c) no	X
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	
b) not yet, but under development	
c) no	X

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	
b) not yet, but under development	
c) no	X

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	
b) not yet, but under development	
c) no	X

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:
Republic of Macedonia has not developed separate regulation regarding the stated documentation.

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:
Pilot phase of the Macedonian Biosafety Clearing House (nBCH) as a simple website in Macedonian and English language was established within the UNEP-GEF Project for development of national biosafety framework. The upgrade of the initial website of the National Macedonian biosafety web portal as information system is necessary so that Republic of Macedonia can fulfil the obligations and liabilities assumed with the ratification of the CPB (Official Gazette of Republic of Macedonia, no.40/05), which is actually the purpose of the UNEP/GEF Project for strengthening the capacities and efficient participation at BCH (since November 2008- ongoing). *Memorandum of understanding for implementation of UNEP/GEF Project for strengthening the capacities and efficient participation in CBH under No. GFL/2328-2716-4771-2102.* The Macedonian national biosafety web portal (http://www.biosafety.gov.mk) shall serve as a focal point for all information on biosafety at national level, including data which is not requested in accordance with CPB, GMOs and necessary information for promotion of the Biosafety system in the country. In order to contribute from the BCH as a whole, the profile of the BCH needs to be raised and also to put accent on the awareness raising in Macedonia. Therefore, several training have been organized within the project: - First national workshop on *BCH as mechanism for implementation of CPB*, held on 17-

18.11.2008 in Skopje, aimed for the members of the working group within the project.

- Second national workshop on *BCH as mechanism for implementation of CPB*, held on 23-24.03.2009 in Skopje, aimed for the representatives from the competent state bodies.
- Third national workshop on *BCH as mechanism for implementation of CPB*, held on 22-23.06.2009 in Skopje, aimed for the inspection services and the customs administration.

MK portal on biosafety will be launched in February 2010, and will enable the public to gain access to information and explanations about issues related to bio-safety both in Macedonian and English language.

Two brochures have been drafted within the Project:

- Wording of the Cartagena Protocol on Biosafety in Macedonian – aimed as a tool for the competent state bodies in the implementation of the Protocol.
- BCH as mechanism for implementation of CPB.

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	
b) not yet, but under development	
c) no	X
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. During this reporting period, Republic of Macedonia is not a Party of import and has not received respective requirements.	
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. Republic of Macedonia is not a Party of export during this 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	
b) 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)	
b) no	X
b) not applicable – not a developing country Party	
44. If yes to question 43, how has such cooperation taken place:	
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)	
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	X
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)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	
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:	

Republic of Macedonia implemented the UNEP/GEF Project "Development of national biosafety framework" in the period from 7 February to 7 March 2005. The Ministry of environment and physical planning was nominated to be the National Executive Agency. The National Coordination Committee was also established, which is responsible to give guidelines for preparation of the National biosafety framework.

Although some basic trainings were provided during several organized workshops within the first UNEP/GEF Project "Development of national biosafety framework", Republic of Macedonia as country with economy in transition still has great needs for capacity building, mainly in the following areas:

- **Legal framework**

In Republic of Macedonia, the legal framework is not fully developed, operational and implemented. In the following period, it will be necessary to adopt and implement several subsidiary acts arising out of the Law on GMOs.

- **Administrative framework**

Institutional mechanisms and bodies for biosafety administration have not been clearly defined, including the competent state bodies and their responsibilities according to spheres in which they apply the competencies.

- **Technical, scientific infrastructures**

Currently, Republic of Macedonia disposes of only one laboratory for testing and examination of GMOs in food. In 2006, the Laboratory for biochemistry and molecular biology at the Faculty for agricultural sciences and food was granted the authorization from the Ministry of Health, Food Directorate for testing and control of GMOs in the food. The laboratory has initiated the accreditation process regarding the introduction of a quality system (ISO 17025).

Question 45

Macedonian delegation attended the sub-regional workshop for Central and Eastern Europe (CEE) countries that develop regulatory and administrative systems for the national frameworks for biosafety. The workshop was held on 9-12 December 2003 in Antalija, Turkey (this is the beginning of the

reporting period). The workshop was organized by UNEP-GEF Project for "Development of national biosafety framework". The workshop focused on the development of regulatory regime and administrative systems for National frameworks for biosafety.

Question 46

Besides the workshop held in Antalija, Turkey (see question 45), the Macedonian delegation participated at the regional workshop for the countries from Central and Eastern Europe, Caucasus and Central Asia (CEECCA) about: Risk assessment and management, as well as raising the awareness and public participation, held in Vilnus, Lithuania, on 27-30 May 2003. The workshop contributed with new initiatives for development of the National biosafety framework in Republic of Macedonia.

In November 2007, Republic of Macedonia applied for the UNEP-GEF project "Capacity building for effective participation in the Biosafety Clearing House for CPB".

For the purpose of successful implementation of the provisions from the Protocol, Republic of Macedonia submitted letter of interest for participation in the UNEP-GEF project "Implementation of national biosafety framework".

Legal, socio-economic expertise:

The needs of highest priority for Republic of Macedonia is in this particular segment refering to the analysis of the connections among other international agreements and requests in accordance with the Protocol, as well as trainings for the policy-makers and regulators. The prioritised needs for drafting legislation/legal analysis, have been only partially accomplished.

Risk assessment and other scientific and technical expertise:

In this particular field, Republic of Macedonia has many needs of highest priority, which have not been fulfilled. (Introduction of mechanism for reviewing the risk assessment, including the bodies to examine the risk assessment (Scientific committee on GMO), which is still not fully operational).

Risk management

Disclosure, management and prevention of unintentional GMO movement, emergency measures for unintentional GMO movement and framework for risk management, strategies and mechanisms, are still needs of priority which are to be further fulfilled.

Awareness raising, education and public participation

Within the UNEP-GEF project "Capacity building for effective participation in the Biosafety Clearing House for the CPB", several modules of trainings have been implemented, mainly with regard to the awareness raising regarding the Protocol and biosafety. In general, public participation is included in the national legislation. However there is need to improve and facilitate public participation in future, especially with regard to the decision-making process.

Exchange of information and data management (including the Biosafety Clearing House)

The needs for strengthening the capacities of Republic of Macedonia remain to be non-fulfilled in the following segments: data collection, management and storage, interoperability of national databases with BCH. During the implementation of the UNEP-GEF project "Development of national biosafety framework", several activities were taken on national level regarding the data collection, information management and storage. Following the completion of the project, i.e. after March 2005 these activities were not taken on continuous bases.

In the period from January 2005 until today, there is not a single activity on national level regarding the exchange of information and data management, including the updating of the records on the national internet site. The main reason is the lack of human and financial resources, as well as intensified work on

the drafting of the Law on GMOs.

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	
b) yes – limited extent	X
c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	
b) yes – limited extent	X
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	
b) yes – limited extent	
c) no	X
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	
b) yes – limited extent	X
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	X
b) yes – limited extent	
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:	
National website on bio-safety (http://www.biosafety.gov.mk). Internet site about the competent bodies for GMO in RM: - Ministry of environment and physical planning: http://www.moepp.gov.mk - Ministry of health: http://www.foodsafety.gov.mk - Ministry of agriculture, forestry and water economy: http://www.foodsafety.gov.mk	

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:	

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	
b) no	X
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:	
For disrespect of the Law on genetically modified organisms (Official Gazette of RM No.35/08), which transposes the Directive 2001/18/EC, the penalties established by the Law shall be applied.	

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	
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:	

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:	

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.

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

GUIDELINES FOR USE OF THE REPORTING FORMAT

The following format for preparation of the first regular national report on implementation of the Cartagena Protocol on Biosafety called for under Article 33 of the Protocol is a series of questions based on those elements of the Protocol that establish obligations for Contracting Parties. Responses to these questions will help Parties to review the extent to which they are successfully implementing the provisions of the Protocol and will assist the Conference of the Parties serving as the meeting of the Parties to the Protocol to assess the overall status of implementation of the Convention.

The deadline for submission of the first regular national report is no less than 12 months prior to the fourth meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol. It is intended to cover activities undertaken between entry into force of the Protocol for the reporting Party and the date of reporting.

For subsequent national reports, the format is expected to evolve, as questions that are no longer relevant after the first national report may be deleted, questions that are relevant to ongoing progress in implementation will be retained, and additional questions will be formulated pursuant to future decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

The wording of questions follows the wording of the relevant articles of the Protocol as closely as possible. The use of terms in the questions follows the meanings accorded to them under Article 3 of the Protocol.

The format tries to minimize the reporting burden on Parties, while eliciting the important information regarding implementation of the provisions of the Protocol. Many questions require only a tick in one or more boxes. 1/ Other questions seek a qualitative description of experiences and progress, including obstacles and impediments to the implementation of particular provisions. 2/ Although there is no set limit on length of text, in order to assist with the review and synthesis of the information in the reports, respondents are asked to ensure that answers are as relevant and as succinct as possible.

The information provided by Parties will not be used to rank performance or to otherwise compare implementation between individual Parties.

The Executive Secretary welcomes any comments on the adequacy of the questions, and difficulties in completing the questions, and any further recommendations on how these reporting guidelines could be improved. Space is provided for such comments at the end of the report.

It is recommended that Parties involve all relevant stakeholders in the preparation of the report, in order to ensure a participatory and transparent approach to its development and the accuracy of the information requested. A box is provided in which to identify those groups who have been involved.

Parties are requested to submit an original signed copy by post and an electronic copy on diskette or by electronic mail. An electronic version of this document will be sent to all national focal points and this will also be available from the Convention's website at: http://www.biodiv.org

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1/ If you feel that, in order to properly reflect the circumstances, it is necessary to tick more than one box, please do so. In this case, you are encouraged to provide further information in the text answers that follow to enable any analysis of results to appropriately reflect the spirit of your answers.

2/ Please feel free to append to the report further information on any of the questions.