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

Origin of report

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Time period covered by this report:	September 2003 – September 2007

Please provide summary information on the process by which this report has been prepared, including information on the types of stakeholders who have been actively involved in its preparation and on material which was used as a basis for the report:

In Republic of Croatia, the Ministry of Culture, Nature Protection Directorate is the state competent authority responsible for implementation of the Cartagena Protocol on Biosafety.

The Ministry of Culture, Nature Protection Directorate is also responsible for preparation of the National Report on implementation of the Cartagena Protocol to the Executive Secretary of the Convention on Biological Diversity. However, in order to ensure a participatory and transparent approach in preparation of this report as well as the accuracy of the information requested, the Ministry of Culture and its Directorate involved officials from other ministries and authorities and asked them to overview first draft that was dispatched by e-mail and asked them to submit their comments. First draft of this report has been sent to the following officials from the following ministries, authorities and/or scientific institutions:

1. Valentina Zoretić-Rubes (Directorate for Sanitary Inspection, Ministry of Health and Social

Welfare, e-mail: valentine.zoretic-rubes@mzss.hr)

2. Bojan Vidović (Directorate for Sanitary Inspection, Ministry of Health and Social Welfare, e-mail: bojan.vidovic@mzss.hr")
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6. Jelena Žafran-Novak (Croatian National Institute for Public Health, e-mail: j.zafran-novak@hzjz.hr")
7. Meira Bosnić (Ministry of Agriculture, Forestry & Water Management, e-mail : meira.bosnic@mps.hr)
8. Irina Zupan (State Institute for Nature Protection, e-mail: irina.zupan@dzzp.hr)

A first draft of this report was written based on the following elements:

- Existing national legislation in the field of GMOs;
- Existing legislation of the European Union that Republic of Croatia will have to transpose and/or implement directly into its own regulations;
- List of treaties concluded by the Republic of Croatia that are relevant for establishment of the NBF: Convention on Biological Diversity (CBD, Cartagena Protocol on Biosafety (CPB), World Trade Organization (WTO), International Convention for the Protection of New Varieties of Plants (UPOV), International Plant Protection Convention (IPPC), Basel Convention on the Control of Hazardous Wastes and their disposal, Protocol concerning specially Protected Areas and Biological Diversity Mediterranean, Aarhus Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters;
- Outcomes of the Project and final Report of the UNEP-GEF Project on Development of National Biosafety Framework issued in April 2005 (incorporated results of the national survey on the status of biosafety in Croatia);
- The Second and Third National Report on Biodiversity to the CBD issued in February 2007;
- Status of available information on the SCBD BCH website (at the end of August 2007);
- Publicly accessible information on the national biosafety site (http://www.gmo.hr);
- Overview of the national capacity-building needs and priorities required to implement the Biosafety Protocol.

Comments received on the first draft were incorporated into the final submission of this 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):
Republic of Croatia joined the UNEP-GEF Project "Development of the National Biosafety Framework" on 7 February 2003 and finished the Project on 7 January 2005. In November 2004, the web site of the Project became operational. It was designed as a base for the Croatian BCH and is still available at the following link: www.gmo.hr . The Project web page has been also designed with the purpose of offering Project information to the public on a worldwide scale as well as to provide all other topical information on the issues of GMOs and biosafety. Through links, the web page is connected to web pages of other domestic and foreign projects and to institutions concerned with similar problem areas. Latest updates on the BCH have been entered at the time of the finalization of the Project which was in January 2005. Since then, Republic of Croatia did not update its records on the BCH as well as on its own national website in regards to the GMOs, biosafety issues and implementation of the Protocol. Primary reason was a lack of human and financial resources, as well as an intensive work on development of a national legislation and harmonization of Croatian regulations with those of the European Union. It is important to note an additional impediment that Republic of Croatia faced during this reporting period. In 2004, the Government changed and as a consequence many changes happened in the structure of national state authorities. For example, the execution of the UNEP-GEF Project has been assigned from the Ministry of Environmental Protection & Physical Planning to the State Institute for Nature Protection that was part of the Ministry of Culture. In addition, the Nature Protection Directorate which was also a part of the Ministry of Environmental Protection & Physical Planning has been assigned under the Ministry of Culture. All those changes provoked a delay of the Project and influenced other activities related to the updates on the national website as well as records on the CBD BCH website. Current status of the records of the Republic of Croatia on the CBD BCH website is poor and/or outdated. At this moment, only available and/or accurate information on the BCH is on the CPB and BCH NFP. Despite the specification of the competent national authorities and the responsibilities they carry out in accordance with their scope of competence, no information has been prepared and entered to the CBD BCH. In addition, BCH page on the national regulations is outdated. The list of experts has not been updated for a quite long time and will have to be revised to suite better the requirements of the Protocol. Throughout the questionnaire, information to some of the questions is not yet available, meaning that some provisions of the Protocol and their measures have not been incorporated yet to our own legislation. In regards to the updating the records of the Republic of Croatia, it is important to note that that situation has been already dealt with internally. The Ministry of Culture employed a new official, well trained and experienced person with many years of working experience under the Protocol and Biosafety Programme of the CBD. From now on, Ms. Stepic who has been appointed a new Cartagena Protocol on Biosafety and BCH National Focal Point will be responsible for communication with the Secretariat in regards to the implementation of the Protocol as well as responsible for the BCH records of Republic of Croatia. Therefore, in the near future upon issuance of this report, BCH website will be updated regularly with all currently available information on the competent national authorities and existing legislation and later on on any additional legal measures pertaining to GMOs and roster of experts. In regards to our own national website, Republic of Croatia would need an additional funding to extend the national BCH

database and improve and update the national website. As of now, it has not been linked automatically with the BCH Central Portal. Therefore, we are still hoping that the UNEP-GEF Project "Building Capacity for Effective Participation in Biosafety Clearing House of the Cartagena Protocol" will be realized at the end.

When talking about competent national authorities in Republic of Croatia, it is important to note that that issue has been covered both by the Act on GMOs as well as under the Food Act and in some segments might be confusing.

Taking into account both Acts, the situation is the following:

Under the Act on Genetically Modified Organisms ("GMO Act"), Article 3 is on the competent national authorities dealing with GMOs, each within the scope of its competencies.

For the implementation of this Act, performing expert, administrative and inspection activities, in case of GMO and/or products containing and/or consisting of, or originating from GMOs:

1) Contained use in closed system: the competent authority is the central state administration body responsible for science
2) Deliberate release into the environment: the competent authority is the central state administration body responsible for nature protection
3) Placing on the market:
    a) As food: the competent authority is the central state administration body responsible for health
    b) As GMO food and feed for animals: the competent authority is the central state administration body responsible for health
    c) As reproductive material in agriculture, forestry and veterinary medicine: the competent authority is the central state administration body responsible for agriculture, forestry and veterinary medicine
    d) As medicine in veterinary medicine and substances for protection of plants: the competent authority is the central state administration body responsible for agriculture, forestry and veterinary medicine
    e) Inspection supervision of the labelling of GMOs and/or products containing and/or consisting of, or originating from GMOs is under the competence of the State Inspector's Office.

In handling cases referred to in paragraph 1 subparagraphs 1,2 and 3 items b, c and d of this Article, the competent authorities shall obtain prior approval from the central state administration body responsible for health.

For using GMOs and/or products containing and/or consisting of, or originating from GMOs in cosmetics, pharmacy and health services for people: the competent authority is the central state administration body for health.

In addition and under the Food Act, there is an Article 86, Paragraph 7 that covers in more details the Organisation of official controls/inspections on GMO food and feed. (For more details please check Article 2 of this report).

BCH Croatia website has been established under the UNEP-GEF Project and it became operational in November 2004. The URL address is http://www.gmo.hr/.

Croatian web pages on GMO issues contain the following information:

a. Link on the Project

b. Workshops that have been held (December 2003 – December 2004)

c. Information on Legislation:

   i. Croatian legislation (There are several Acts, Regulations, Decisions and Ordinances, but some of them are null and void and have not been replaced with the updated ones.)

   ii. Bilateral, regional and multilateral agreements (There is a list of international treaties that are relevant for establishment of Croatian NBF.)

   iii. EU legislation

   iv. BCH (just the link to the CBD website)

d. News

e. Frequently asked questions

f. Additional links to the following websites of:

   i. International Institutions

   ii. Governmental Institutions

   iii. Research Institutions (Universities, Institutes)

   iv. NGOs

   v. Industry

   vi. News and Scientific Journals

   vii. International Projects and Workshops

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	
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	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
l) Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11.4) or in accordance with annex III (Article 11.6) (requirement of Article 20.3(d))			X
m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)			X
n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);			X

o) LMOs granted exemption status by each Party (Article 13.1)			X
p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13.1);			X
q) Summaries of risk assessments or 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)	
c) no measures yet taken	X

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 Croatia ratified the Cartagena Protocol on Biosafety on 29 August 2002. During this reporting period, i.e. from the year of entry into force of the Protocol until present time, Croatian primary goal was to harmonize national legislation, in every area, with the European Union legislation. This process had started on 1 December 2001 and it has intensified, especially from 2004 when Croatia became an accession country to the EU.

Within the accession process and as a future member state of the European Union, Croatia is obliged to harmonise and implement the requirements of the EU Directives regarding GMOs. Eventually, all applicable EU directives and relevant Council and Commission decisions will be either transposed/implemented into the national legislation or directly applicable in Croatia. Beside the requirements of the European Union legal acts in the biosafety sector and regulations of GMOs, Republic of Croatia is obliged to implement in its legislation provisions of the Cartagena Protocol on Biosafety and other treaties that Republic of Croatia is a signatory, e.g. Aarhus Convention, World Trade Organization (WTO) and its agreements related to GMOs, etc.

In 2003, two key pieces of legislation were enacted regulating this area during a longstanding legal vacuum in the GMO area, a de facto moratorium was applied in the absence of any legal ground. They were the Nature Protection Act (Official Gazette No. 162/2003) and the Food Act (Official Gazette No. 117/2003). However, in the meantime, both Acts have been changed and new ones had been issued holding the same titles. It is important to note that the long-time expected **GMO Act** was published on the 8 June 2005 and it has entered into force eight days later.

Act on Genetically Modified Organisms - GMO Act (Official Gazette No. 70/2005)

This Act regulates the handling of GMOs, products containing and/or consisting of, or originating from

GMOs, contained use of GMOs, deliberate release of GMOs into the environment, placing on the market of GMOs and products containing and/or consisting of, or originating from GMOs, handling, transportation and packaging of GMOs, managing waste resulting from GMOs, liability for damage caused by unauthorised use of GMOs, competent authorities for implementation of this Act, and performing administrative and inspection supervision over the implementation of this Act.

By this Act, releasing GMOs into the environment shall not be permitted in protected areas and in areas of ecological network, areas intended for ecological production of agricultural products and ecological forms of tourism, and areas representing protected zones of impact.

Provisions of GMO Act apply to import, transit, placing on the market, use and production of medicine containing and/or consisting of, or originating from GMOs, only when it is explicitly prescribed.

Provisions of this Act shall not apply to mutagenesis and cell fusion (including protoplast fusion) of the plant cells of organisms that can exchange genetic material through traditional breeding methods, under the condition that these techniques/methods of genetic modification do not include the use of recombinant nucleic acid molecules or genetically modified organisms different from those produced with one or more technique methods.

Under this Act, the Government was supposed to set up the **Council for GMOs** (17 members) for a period of four years. Members have been proposed by the ministers responsible for the protection of nature, protection of environment, science and technology, health and social welfare, agriculture and forestry and economy and labour but at the time of issuance of this report, their selection has not been confirmed in public by the Government.

Duties of this Council are the following: monitoring the state and development in the field of genetic technology application and the use of GMOs, following scientific achievements and giving opinions and incentives in relation to genetic technology application and use of GMOs, delivering its opinion on social, ethical, technical and technological, scientific and other conditions of the use of GMOs, advising the competent government bodies in matters related to the use of GMOs and genetic technology, informing the public about the state and development in the filed of genetic technology application and the use of GMOs and on its viewpoints and opinions.

Further by this Act, it was planned that the Council for GMOs on the proposal of the competent government authorities, establish two Committees for a four-year term.

a) **Scientific Committee for Contained Use of GMOs** (11 members – scientists and experts in the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology, agriculture, forestry and veterinary medicine, safety at work, nature conservancy, environmental protection).
b) **Scientific Committee for the Release of GMOs into the Environment** (9 members – scientists and experts in the field of genetics, ecology, environmental protection, nature conservancy, agriculture, forestry, veterinary medicine, biochemistry and molecular biology, microbiology and medicine.

Planned duties of the Committees were to deliver expert opinion about the use of GMOs in administrative and other procedures, to deliver opinions and proposals in the process of drafting regulations on the use of GMOs, to deliver opinions and give proposals to competent government authorities in the matter of using the GMOs, to carry out such other activities as may be prescribed by present regulations and to submit to the Government annual reports on their activities, which shall be published in a manner accessible to the public.

At the time of the submission of this report, neither the Council nor the two Committees are operational.

In addition to the Act on Genetically Modified Organisms (GMO Act), several **Ordinances** have been issued in relation to GMOs:

1) **Ordinance of the Risk Assessment of the deliberate release of GMOs into the environment** (Issued on 7 December 2006, Official Gazette No. 136/06 with the Annex: Detailed Guidelines on the Methodology for the risk assessment of the deliberate release of GMOs into the environment);
2) **Ordinance on the content and method of implementing the plan of measures for removing the uncontrolled spread of GMOs into the environment** (Issued on 28 December 2006, Official Gazette No. 05/07);
3) **Ordinance on the information format of the content and method of handling notifications concerning the deliberate release of GMOs into the environment** (Issued on 29 May 2007, Official Gazette No. 64/07). There are four Annexes attached to the Ordinance: Application for obtaining the permit for the release of GM higher plants into the environment, Summary Notification Information Format for the release of GM higher plants (GMHPs), Application for obtaining the permit for the release of GMOs into the environment other than higher plants, Summary Notification Information Format for the Release of GMOs other than higher plants in Accordance with Art. 11 of Directive 2001/18/EC).
4) Ordinance on detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs. – This ordinance is in the final stage of the preparation but has not been issued yet.

In addition, a few **other important GMOs regulations** have been published:

1) **Ordinance regulating content of the application for the contained use in closed system** (Official Gazette No. 84/06)
2) **Ordinance regulating safety measures and standards of facilities for contained use of GMOs within a closed system** (Official Gazette No. 84/06)
3) **Ordinance regulating content, scope and methodology of carrying out risk assessment for the contained use of GMOs** (Official Gazette No. 84/06)
4) **Ordinance regulating content of notification for contained use of GMOs classified within the second, third and fourth level of hazard** (Official Gazette No. 84/06).

Food Act (Official Gazette No.46/2007)

This Act regulates the basis for ensuring a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the market. Food Act determines the basic principles and responsibilities, scientific basis, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety. This Act applies to all stages of production, processing and distribution of food and feed, except to primary production for private domestic use or to the domestic preparation, handling and storage of food for private domestic consumption.

Provisions of this Food Act apply to the import, transit, use and production and placing food or animal food (feed) on the market that is a GMO and/or contains and/or consists of or originates from GMOs. It is important to note that, under this Act as well as in the Act on GMOs, precautionary principle is one of the provisions (Art. 7 and Art. 13 respectively).

Generally speaking, this Act is more on the sanitary/hygiene requirements of the food for people and feed for animals, and there are only a few provisions in regards to GMOs in food and feed and on the novel

food (Articles 87, 88 and 89), provision on the placing on the market of novel food, GM food and GM feed (Art. 90), register on notifications issued in reference to Art. 90 (Art. 91), provision on handling risk assessment at the placing on the market of novel food, GM food and feed (Article 92) and on traceability of GM food and feed and labelling of novel food (Art. 93).

Art. 19 (Responsibilities) covers the issue of the competent authority under this Act: "The competent authority (Ministry for Agriculture, Forestry and Water Management), the Ministry responsible for health and the State Inspector's Office shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

In addition, Chapter III covers provisions on the Croatian Food Agency as an agency that shall conduct scientific and professional activities of risk assessment and communication on the results of risk assessment, in the sense of this Act, regarding the safety and hygiene of food and feed. The Agency's mission shall include providing scientific advice and scientific and technical support for the legislation and issues in all fields which have a direct or indirect impact on food and feed safety. The Agency shall provide independent information on all matters within these fields and communicate on risks. The head office of the Agency will be in Osijek.

Chapter VII, Art. 86, Paragraph 7 covers in more details the Organisation of official controls on food and feed. It states that official control will be carried out by the following state authorities:

(a) at the level of primary production and associated operations, by the competent inspection service of the Department of Agricultural Inspection of the competent authority,

(b) at the levels of production and processing:

– on GM food of animal origin, by the veterinary inspection, on GM food of non-animal origin, by the sanitary inspection service, on GM food containing ingredients of animal and non-animal origin, by the veterinary or sanitary inspection in accordance with an implementing regulation made by the head of the competent authority,

– on GM feed, regardless of its origin, by the veterinary inspection,

(c) at the level of retail:

– on GM food, regardless of its origin, by the sanitary inspection,

– on GM feed, regardless of its origin, by the veterinary inspection,

(d) at the import:

– on GM food of animal origin, by the border veterinary inspection,

– on GM food of non-animal origin, by the border sanitary inspection,

– on GM food containing ingredients of animal and non-animal origin, by the border veterinary inspection or the border sanitary inspection in accordance with an implementing regulation made by the head of the competent authority,

– on GM feed, regardless of its origin, by the border veterinary inspection or the veterinary inspection.

Coordination and linkages among national competent authorities are well defined including official laboratory, reference laboratory, Croatian Food Agency, control officials veterinary and sanitary inspectors.

Other directly related GMOs Regulations:

On the 12 March 2003, the Government of the Republic of Croatia passed the **Regulation on the minimum threshold for GMOs** in products below which the products placed on the market shall not have to be labelled as products containing GMOs (Official Gazette No. 34/2004). It has imposed a limit of 0.9% per individual ingredient of a product as the level or random or technologically unavoidable

contamination for the 15 types of GMO allowed in the EU. In addition, plant reproductive material containing GMOs in any amount must be labelled in accordance with a special regulation.

The Ordinance on the conditions to be fulfilled by a laboratory for testing, control and monitoring of GMOs and products containing GMOs (Official Gazette No. 98/2004):
This Ordinance establishes the conditions related to the premises, equipment and employees qualifications, to be fulfilled by laboratories for testing, control and monitoring of GMOs and products containing GMOs. In August 2004, the Minister for Health & Social Welfare (MHSW) had granted authorization for testing, control and monitoring of GMOs and products containing GMOs to the laboratory, which was set up in the Croatian National Institute for Public Health (CNIPH), Zagreb, in September 2003.

Other Acts:

Nature Protection Act (Official Gazette No. 70/2005)

Currently, this Act regulates the system of protection and integrated conservation of nature and its assets. It has been issued in June 2005 and it does not mention issues of GMOs *per se.*
Art. 56 states that Preservation of ecological network shall provide for conservation of habitat types in a favourable state or regeneration of habitats whose favourable state were impaired.
Art. 57, para.4: Sorts of habitat types, habitat map, endangered and rare habitat types as well as safeguard measures for conservation of habitat types shall be specified in the ordinance passed by the Minister.
On 12 December 2005, Republic of Croatia, Ministry of Culture issued its Ordinance reflecting Art. 57, para.4. In its Annex III (part A, B, C, D, E, F, H), one of the safeguard measures in protection each and different type of habitat is not to introduce GMOs into that particular habitat.
Art. 62, 63 and 64 of the current Nature Protection Act are on the Conservation of Genetic Diversity. Those articles cover the following topics: genetic materials, access to genetic sources, equitable benefit sharing and gene banks.

The Water Management Act (Official Gazette No. 107/1995, No. 78/1998 and No. 150/05):

The Act establishes "Croatian Waters" – the legal entity in charge of water management tasks. Water permits are issued under certain conditions for some of the dangerous substances in water. These substances are defined under the Regulation on Dangerous Substances in Water (Official Gazette No. 78/1998). Sometimes different biological agents, which can consist of or are GMOs, are used in the water treatment facilities. The following articles: 70, 72, 76 and 128-134 refer to these subjects. The Department of water management (MAFWM) is responsible for implementation of this Act.

The Ecological Production of Agricultural and Food Products Act (Official Gazette No. 12/2001 and 79/2007):

This Act governs ecological production of agricultural and food products, processing in ecological production, trade in ecological products, unprocessed vegetable and animal products, products fully or partly consisting of such products, marking in ecological production, performance of expert and inspection control and other issues relevant for the implementation of a unique system of ecological production. In Article 15 of this Act, it is specifically stated that the use of GMOs and all products that consist of or are produced from GMOs are "banned" in ecological production. It is also prohibited to use GMOs as reproduction material, secondary ray material, additives and secondary substances or as packaging. This Act issued in 2007 has just minor additions, e.g. changes in Art. 2 (changes in terms and/or explanations used under the Act) and changes of Article 17 (definition of the term "ecoproduct"). The Ministry of Agriculture, Forestry and Water Management is responsible of implementation of this

Act.

The Minor Offences Act (Official Gazette No. 88/2002, No. 122/2002 and No. 105/2004)

This Act first came into force on 1 October 2002. Article 30, directly specifies which type of fine will be issued for offences committed, during import, transport, contained use, placing on the market and release into environment of GMOs. The Ministry of Justice is responsible for implementation of this Act.

Consumer Protection Act (Official Gazette No. 79/2007):

This Act covers general law on consumer protection. In Article 17, content of the product declarations have been described. Amongst other label declarations, a statement by the manufacturer on the existence of any modified features of products including organisms, ingredients, parts & additives should be included, plus the type of modification, if any, should be in line with special regulations. It also states that other by-laws will define specific declaration for specific products. The Ministry of Economy, Labour and Entrepreneurship is in charge of implementation of this Act.

The Amendments Act to he Transport of Dangerous Substances Act (Official Gazette No. 97/1993, 34/1995 and No. 151/2003):

This Act regulates transport of dangerous substance-type of transport & cargo, the duties of personnel involved in the transportation, conditions for packaging & for transportation and governmental bodies responsibilities for inspections in transport.
Regulations on the transportation of dangerous substances:

a) The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) applies to roads.
b) The Ordinance on International Carriage of Dangerous Goods by Railway (RID) applies to railways.
c) The European Agreement concerning the International Carriage of Dangerous Goods by Inland
d) Waterways (AND) apply to rivers and lakes within the country.
e) The International codex of dangerous cargo (IMDG Code) applies to sea transport.
f) The Convention on International civil air transport, Annex 18, applies to air transportation.

The packaging of the products that contain or are made from GMOs is prepared in accordance with this Act. The Ministry of the Sea, Tourism, Transport and Development (MSTTD) is responsible for its implementation.

The Seeds, Plant Material and Registration of Varieties of Agricultural Plants Act (Consolidated text, Official Gazette No. 140/2005):

The Government of the Republic of Croatia at its session held on 21 September 2004 first passed the "Consolidated" text of this Act. It regulates production and trade of agricultural seeds, seedlings, mycelium of edible and medicinal fungi, agricultural seed material, recognition of varieties of agricultural plants and other topics, which are important for establishing a unique system fro agricultural seeds and seedlings. Article 1 states that production, trade and placing on the market of GM agricultural seeds, seedlings, mycelium of edible and medicinal fungi, agricultural seed material, registration of varieties of GM plants are governed under the Act on GMOs.

Some Acts and Ordinances have been translated but not all of them. In the near future, those translated Acts will be all available on the BCH website and others upon availability of translations.

At present, the national biosafety framework policy (regulatory, administrative, decision-making,

monitoring, state control and enforcement) in Republic of Croatia has not been fully completed and/or operational in all the necessary segments. There are still areas in the national legislation for GMOs and biosafety that have not been fully harmonized and/or covered. Various different Ministries are now responsible for various different parts of GMO legislation and there is a serious need for involved ministries to transparently communicate and coordinate their activities including their actions in drafting additional regulations, by-laws, ordinance etc.

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	
d) not applicable – not a Party of export	X
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	
c) not applicable – no decisions taken during the reporting period	X
10. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Not applicable. During this reporting period, Republic of Croatia has not been a Party of export of LMOs	

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

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 this reporting period, Republic of Croatia has not taken any decisions on import of LMOs 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	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	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:	
During this reporting period, Republic of Croatia has not been a Party of export of LMOs intended for direct use for food or feed, or for processing.	
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 this reporting period, Republic of Croatia has not been a Party of import of LMOs 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:	
Not applicable.	

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 Croatia has not entered into any bilateral, regional or multilateral agreement or arrangement as per 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 details below)	X
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	
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:	
Under the Act on GMOs, prior to the commencement of contained use, deliberate release of GMOs into the environment, placing GMOs and products containing and/or consisting of GMOs on the market, the applicant shall prepare a risk assessment for the intended use. However, competent authority can always request an additional risk assessment from different authorized professional source. On the basis of the analysis of GMO features and the intended use, including the environment likely to be exposed to risk, the risk assessment shall contain an evaluation of the possible adverse effect, level of hazard, necessary prevention and other safety measures, including the plan of emergency measures (case of contained use of GMOs). Risk assessment shall establish an estimate of possible negative effects and their possible consequences, level of hazard and needed supervision measures, while taking into account the effect on human health, based on the analysis of GMO's characteristics and its intended release into the environment and ecological system in which the GMO would be released, and biological diversity that could be exposed to risk Plan of measures is obligatory and it contains: method of supervision GMOs in case on uncontrolled spread in the environment, estimate of possible consequences and hazard to biological diversity,	

environment and human health, needed protection measures, measures needed for preventing further spread and for removing the GMO, and remediation of the environment that could be exposed to the uncontrolled spread of GMOs (case of release of GMOs into the environment).

The content and scope of risk assessment for placing GMO or products containing and/or consisting of, or originating from GMOs on the market, the methodology of assessment and requirements that need to be met be the legal person for drawing up the risk assessment, shall be prescribed by ordinance by the head of the central state administration body responsible for health, subject to the approval of the heads of central state administration bodies responsible for agriculture, forestry and veterinary medicine.

Under the current legislation appropriate measure to manage, regulate and control/monitor risks are not completely set up and operational. In the area of risk assessment and risk management we need to improve our technical and human capacities, but that is quite difficult without additional funding from outside. The same refers in regards to adopted measures to prevent unintentional transboundary movements of LMOs (Article 16.3) within the country. In order to prevent such movements, our officials and custom officers at borders need training in identification of such cargo transports.

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:

During this reporting period in Republic of Croatia there were no occurrences that led, or could have led, to an unintentional transboundary movement of a LMO 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. However, transboundary movement of GMOs has been regulated by the Act on GMOs (Art. 12).

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:	
Article 53 of the Act on GMOs covers the issue of handling, transport and packaging of GMOs. By our law, accompanying documentation shall clearly label the GMO that is: intended for direct use for food or for cattle feed or for processing and marked that it is not intended for deliberate release into the environment; intended for contained use, and mark all the conditions and requirement for safe handling, storing, transport and use, place to obtain further information, including name and address of the individual or institution to whom the GMO was entrusted to; intended for deliberate release into the environment, and mark identity and appropriate characteristics and/or traits, all conditions for safe handling, storing, transport and use, as well as the place for obtaining further information. The head of the competent authority shall prescribe by ordinance the conditions for handling and packaging, and for road, railway, air and river transport of the GMO, while taking into account all international regulations and practices.	

Regarding our reply to the question 32, it is important to note that although Republic of Croatia in its legislation covers issues of handling and documentation that accompany LMOs for food, feed or for processing, our country has not developed detailed regulation on such documentation. As a future member state of the European Union, Croatian legal system has to implement following EU regulations: Regulation (EC) 1946/2003 of 15 July 2003 on transboundary movements of GMOs that covers exports of GMOs to third countries and unintentional movements of GMOs; Regulation (EC) 1829/2003 of22 September 2003 on GM food and feed, covering the placing on the market of GMOs intended for food and feed and of food or feed products containing, consisting of or produced from GMOs; Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs; Commission Regulation (EC) No. 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the application for the authorization of new GM food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation; Commission Regulation (EC) No. 65/2004 of 14 Januar 2004 establishing a system for the development and assignment of unique identifiers for GMOs.

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:
For all details, please see questions 1, 2 and 48.

Article 21 – Confidential information

37. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) not yet, but under development	
c) no	
38. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import / no such requests received	X

39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:
Not applicable. During this reporting period, Republic of Croatia was not a Party of import and no such requests have been received.
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. During this reporting period, Republic of Croatia was not a Party of export.

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:	
Not applicable.	
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
c) not applicable – not a developing country Party	
44. If yes to question 43, how has such cooperation taken place:	
Republic of Croatia did not contribute to the biosafety capacity building of another country Party to the Protocol.	
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)	
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:

Although some basic training has been provided on several workshops organized during the first UNEP-GEF Project ("Development of National Biosafety Framework"), Republic of Croatia as a Party with economy in transition still has a great number of biosafety capacity building needs unmet, mainly in the following area:

1) Legislative and regulatory framework:
In the Republic of Croatia, legal framework has not been fully developed and/or operational and implemented. There is a need to harmonize and implement already existing regulations and develop numerous measures, technical guidance, by-laws, ordinance, etc.
Republic of Croatia has a lot of priority needs in regulatory training, i.e. legal, policy and particularly in enforcement and inspection.

2) Administrative framework:
Republic of Croatia has unmet priority needs in the following segments: customs and border control procedures, Decision making system and administrative procedures, and Inter-agency communication and coordination.
By the above-mentioned laws in Republic of Croatia, institutional mechanisms and entities for administering biosafety have been clearly defined, including competent national authorities and their responsibilities according to the scope of their competencies. Mechanism(s) for inter-institutional coordination (e.g. steering committees) are not yet in place and operational.

3) Technical, scientific and telecommunications infrastructures:
In this segment, Republic of Croatia still has the following priority needs: border control and inspection

facilities, database infrastructure and protocols.

LMO testing laboratories and equipment is only a partially met priority need. At this moment, Republic of Croatia has only one laboratory for LMO testing and identification of GMOs in food. We would need an additional funding to equip the laboratory for testing GMOs in grains and seeds. For the time being, we are sending such examples to the laboratory outside the country.

4) Funding and resource management, such as financial assistance (grants or loans):

a) Republic of Croatia participated in the **UNEP-GEF funded project "Development of National Biosafety Framework"** that started on 7 February 2003 and was finished on 7 January 2005. Project achieved numerous objectives: The Ministry of Environmental Protection and Physical Planning has been nominated as the National Executing Agency. (In April 2004, with the change in the Government, the State Institute for Nature Protection that was part of the Ministry of Culture took over that function. Since that period, Nature Protection Directorate that was previously part of the Ministry of Environmental Protection and Physical Planning also became part of the Ministry of Culture (MC) holding the same functions as before, i.e. coordination with the Secretariat and implementation of the CBD and the Cartagena Protocol on Biosafety.) The National Co-ordinating Committee has been established to advise and guide the preparation of a National Biosafety Framework. Survey on existing uses of biotechnology and the arrangements for safe use of biotechnology has been conducted and a database was created detailing relevant outputs of the national surveys. National website has been established and is available at the following link: http://en.gmo.hr/ .

A list of 50 national experts in fields related to biotechnology, biosafety, risk assessment and risk management of LMOs had been finalized. Survey of all existing national legislation or legal instruments related to biotechnology/biosafety was conducted four times and all Acts have been translated. Survey on existing national biosafety frameworks in the countries of the sub-region had been conducted and the list of all bilateral, regional and multilateral agreements that Croatia is member of or has ratified and are relevant for establishment of NBF has been listed at the following link:
http://en.gmo.hr/index.php/zakonska_regulativa/medunarodni_ugovori .

Following six workshops have been organized under this project: "Genetically Modified Plants in Agricultural Production and New Legislation" workshop was held at Stubičke Toplice on 16 December 2003. "Genetic engineering, GMO and Croatian legislation" workshop was organised on 9 January 2004 in Zagreb in collaboration with the Institute of Education of the Republic of Croatia (IERC). "Croatian Biosafety-Related Legislation" workshop, concerning legislation and inspection was held on 13-14 May 2004 in Zagreb. "GMO problem area in Croatia and Europe" workshop was designed for the NGOs concerned with nature conservancy, representatives of the scientific community and journalists. "Treatment of Genetically Modified Organisms" workshop took place in Zagreb on 22 October 2004. The last one, "GMOs - The National Biosafety Frameworks of Croatia" workshop took place in Zagreb on 16 December 2004.). "Glossary" of commonly used terminology has been published as well as a booklet "Development of National Biosafety Framework in Republic of Croatia".

b) In June 2004, Republic of Croatia applied for the **UNEP-GEF Project "Building capacity for effective participation in the Biosafety Clearing House of the Cartagena Protocol".** At the time of writing this report, that project has not started yet.

c) Since Republic of Croatia's biosafety capacity-building needs still remain unmet, in order to successfully implement the provisions of the Protocol, in the teleconference that took place in April 2007, our country expressed implementation of the NBF of the Cartagena Protocol on Biosafety as our country's priority. Therefore, in the near future it is expected that the Republic of Croatia will submit

letter of interest to participate in the **UNEP-GEF Project "Implementation of the National Biosafety Framework".**

5) Mechanisms for follow-up, monitoring and assessment:
National action still should be taken to fulfil priority needs such as in emergency measures for unintentional movements, inspection procedures and control measures as well as in the mechanism for detecting unintentional or illegal LMO movement.

6) Human Resources Development and Training:
Republic of Croatia has priority needs in training and human resource development particularly in the following area: Evaluation of genetic modification; Molecular biology skills (e.g. gene isolation, sequencing etc.); Scientific methods and protocols relevant to risk assessment and management. In the area of detection, testing and quantitative analysis of LMOs, Republic of Croatia met its priority needs to the some extent but that should be further developed and assessed.

7) Legal, social and economic expertise:
Republic of Croatia priority needs in this segment are in analysis of the linkages between other international agreements and Protocol requirements and in training of policy-makers and regulators. Priority needs in legal drafting and analysis are only partially met.

8) Risk assessment and other scientific and technical expertise:
In this area, Republic of Croatia has a lot of priority needs unmet. We need any means including training to address the following needs: Competence to review and audit risk assessments; Establishment of risk assessment review mechanisms, including consideration of risk assessment review bodies (independent scientific advisory committees fully operational); National risk assessment frameworks, principles, procedures and mechanisms; Risk assessment methodologies and Risk assessment scientific expertise.

9) Risk Management
Detection, management and prevention of unintentional transfer of LMOs, Emergency measures for unintentional LMO releases and Risk management frameworks, strategies and mechanisms are priority needs that still need to be fulfilled.

10) Public awareness, education and participation
During the UNEP-GEF Project, variety of measures to promote awareness of biosafety and the Protocol has been achieved. In our legislation public participation has been assured. However, our need would be still to improve and better facilitate public participation in the decision-making.

11) Information exchange and data management (including the Biosafety Clearing-House):
Republic of Croatia capacity needs remain unmet in the following segments: Data collection, management and storage, Interoperability of national databases with the Biosafety Clearing-House and National Node of the BCH. Along with the execution of the UNEP-GEF Project on "Development of the National Biosafety Framework", several actions at the national level have been taken in regards to data collection, management and storage of information but that did not continue after the project finished at the beginning of January 2005.

In the period from January 2005 until now, there has not been any activity at the national level in information exchange and data management, including updating records on the national website as well as on the Biosafety Clearing House. Primary reason was a lack of human and financial resources, as well as an intensive work on development of our new Act, i.e. GMO Act, other regulations/ordinances and their harmonization with the same legislation of the European Union.

12) Scientific, technical and institutional collaboration:
There is an obvious need that Republic of Croatia needs to improve communications among its own state authorities, facilitate faster scientific, technical and institutional collaboration and establish more efficient inter-institutional networks. Republic of Croatia still did not take a full advantage of regional and sub-regional biosafety advisory mechanisms and centres of excellence. Therefore, establishment of mechanisms for regional and international cooperation and sharing of experiences is still needed. Republic of Croatia should be more involved in regional and/or international collaborative mechanisms and initiatives.

13) Technology Transfer:
Republic of Croatia has the following unmet priority needs that would require full attention in the near future: Technologies for handling, transport, packaging and identification of LMOs, Technologies for monitoring and Technologies for risk assessment of LMOs.

14) Identification of LMOs:
In this segment, Republic of Croatia has the following priority needs unmet: Documentation and Inspection systems for LMOs shipments and Methods and systems for identification of LMOs, e.g. unique identification systems. Any help to address those needs would be welcomed.

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	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	
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	
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:
Under the Act on GMOs, information on the use of GMOs and information on procedures under the governance of the competent national authorities shall be public (Art. 11). Competent national authority shall allow the public to have insight in the content of the notification, content of technical documentation, risks assessment and opinion of the particular Committee in the course of procedures for issuing approvals. Procedures for granting a permit for a contained use, deliberate release of GMOs into the environment, placing on the market of GMOs, they all provide public access to the documents and public participation as well as permit delivery of public opinions and comments within 30 days. In the case of issuing permit for placing on the market GMOs, permit will be issued after the completion of the public hearing within 105 days upon receipt of the application. In regards to the register of GMOs, it will be kept by the Ministry and other competent government authorities, each within the scope of its competencies. In the register of GMO closed systems, certificates and authorization granted for a contained use of GMOs, the deliberate release of GMOs into the environment and placing on the market of GMOs or products containing GMOs, shall be recorded. Anybody shall have the right to be given access to the information contained in the register of GMOs and to require and obtain copies of GMO register entries against payment of a fee that shall not exceed actual costs of issuing copies. Information treated as confidential shall not be entered into the register of GMOs.

Article 24 – Non-Parties

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

55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?	
a) yes	
b) no	X

56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:
Not applicable.

Article 25 – Illegal transboundary movements

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

57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X
b) no	
58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?	
a) yes	
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:	
During this reporting period, there was no transboundary movement of LMOs into Republic of Croatia. However, Republic of Croatia as a future member state of the European Union, will have to follow EU legislation in that respect, such as Article 33 of the EC Directive 2001/18 on the deliberate release into the environment of GMOs; Article 18 of Regulation No. 1946/2003 on transboundary movements of GMOs; Article 45 of Regulation No. 1829/2003 on GM food and feed.	

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:	
During this reporting period in Republic of Croatia, we have not taken any decision on import, taking into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to local communities. Socio-economic considerations should be taken into account while assessing the impact of the approval	

on particular communities (e.g. livelihoods of farmers); assessing the economic impacts on organic farmers of the potential loss of "GM-free" status (issue of co-existence); the potential loss of export market for agricultural produce; concerns about the potential impact of a particular GMO on food security; etc.
Since Republic of Croatia does not have means and capacities for assessing such socio-economic consequences and impacts of LMOs, there was no any such analysis in Croatia.

In order to minimize in the future adverse effects from GMOs, issue of co-existence should be considered within the national legislation. In that sense, Republic of Croatia might apply directly European Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure co-existence of GM crops with conventional and organic farming.

In addition, further guidance from the Secretariat on the implementation of Article 26 of the Protocol would be gladly expected.

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:

Republic of Croatia participated in the funded UNEP-GEF Project "Development of National Biosafety Framework".

The letter of interest has been sent in 2004 for our participation in the UNEP-GEF Project "Building Capacity for effective participation in the Biosafety Clearing House of the Cartagena Protocol". We are hoping that this project still might take place.

In the near future, Republic of Croatia will submit the letter of interest to participate in the funded UNEP-GEF Project "Implementation of the National Biosafety Framework".

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:

Reporting format is clear and could be used as a guidance format to improve activities of Parties in implementing numerous provisions of the Cartagena Protocol on Biosafety as well as guidance in adjusting/amending their national legislation.

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 have been encountered in interpreting the wording under this reporting format as well as in the attached questionnaire (Questions derived from the decisions of COP-MOP relating to assessment and

review of the effectiveness of the Protocol).