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

Origin of report

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

This report updates the EC's interim-implementation report submitted in 2005.

The interim report was written based on publicly accessible information on relevant EC legislation and implementation. Additional information, particularly on practical implementation, was sought from relevant Commission services, some EU Member States as well as selected stakeholders engaged in the international grain trade. This draft was then circulated for review to officials occupied with biosafety issues both within the European Commission and amongst EU Member States. Additional comments received were integrated into the final version of the report.

This first regular implementation report updates the interim report. It reflects responses given to a questionnaire circulated to Member States and stakeholders on the implementation of Regulation (EC) 1946/2003 on transboundary movements of genetically modified organisms. A draft of this report was circulated to officials occupied with biosafety issues both within the European Commission and amongst EU Member States to seek further comments and information. Responses received were integrated into the final version 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):

The EC has provided the BCH with comprehensive information in the listed categories and is constantly working to improve the information flow in this area.

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		
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)	X
b) some measures introduced (please give details below)	
c) no measures yet taken	

4. Please provide further details about your response to the above question, as well as description of your country's experiences and progress in implementing Article 2, including any obstacles or impediments encountered:

EC legislation on genetically modified organisms (GMOs) has been in place since the early 1990s. The EC introduced specific legislation on GMOs to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology products. Over the last decade, the EC has created a comprehensive legal framework for ensuring safety in the development, use and transfer of GMOs. The main legal measures include:

- Directive 90/219/EC of 23 April 1990 on the contained use of genetically modified micro-organisms.
- Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.
- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, covering the field testing of GMOs (mainly Part B) and the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products (mainly Part C). The Annex to this report lists further implementing measures relating to Part B and Part C of Directive 2001/18/EC.
- Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms covers exports of GMOs to third countries and unintentional movements of GMOs.
- Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed, covering the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs.
- Regulation (EC) No 1830/2003 of 22 September 2003 concerning the traceability and

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

- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

A list of all legal measures pertaining to genetically modified organisms has been submitted to the Biosafety Clearing-House and is reproduced in the Annex to this report. More information on the content of these legislative acts can be found in "Questions and Answers on the regulation of GMOs in the EU", available at: http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf

In the case of Directive 2001/18/EC and of Regulations (EC) No 1829/2003, 1830/2003 and 1946/2003, Member States have introduced domestic provisions to ensure enforcement and/or transposition of this legislation within their respective territories.

The implementation of the Cartagena Protocol on Biosafety in the EC relies on a wide range of legislative measures applying to the use of GMOs within the European Union, including imports. The main measures are Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EC) No 1829/2003 on GM food and feed and Regulation (EC) No 1946/2003 on the transboundary movements of GMOs (adopted in June 2003).

The main elements of Directive 2001/18/EC are:

- Principles for environmental risk assessment for GMO releases into the environment;
- The obligation to carry out post-market monitoring, including on long-term effects associated with the interaction with other GMOs and the environment;
- The obligation to inform the public;
- A requirement for Member States to ensure labelling and traceability at all stages of the placing on the market;
- An information requirement to allow the identification and detection of GMOs to facilitate post-market inspection and control;
- A limitation on first approvals for the release of GMOs to a maximum of ten years;

A European Commission report to the European Parliament on the implementation of Directive 2001/18/EC is available at: http://europa.eu.int/comm/environment/biotechnology/pdf/com_575_final.pdf with annexes available at: http://europa.eu.int/comm/environment/biotechnology/pdf/sec2004_1063_en.pdf.pdf

A second Report from the European Commission has been forwarded to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC. (COM(2007) 81 final; Annexes to the Report SEC (2007) 274).

The main elements of Regulation (EC) No 1946/2003 are:

- The obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- The obligation to provide information to the public and to our international partners on EU practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs;
- A set of rules for the export of GMOs intended to be used as food, feed or for processing;
- Provisions for identifying GMOs for export.

The main elements of Regulation (EC) No 1829/2003 are:

- A centralised, uniform and transparent procedure for all applications for placing on the market, concerning GMOs themselves or the food and feed products derived from GMOs;
- A requirement that such products: not have adverse effects on human health, animal health or the environment; not mislead the consumer or user; not differ from the food/feed they are intended to replace so that their normal consumption would be nutritionally disadvantageous for human beings; and not harm or mislead the consumer by impairing the distinctive features of the animal products.
- The obligation to enter authorised products into a public register of GM food and feed;
- A limitation on approvals to a maximum of ten years.

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	X
b) no	
6. Were you a Party of export during this reporting period?	
a) yes	X
b) no	
7. Is there a legal requirement for the accuracy of information provided by exporters 1/ under the jurisdiction of your country? (Article 8.2)	
a) yes	X
b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
8. If you were a Party of export during this reporting period, did you request any Party of import to review a decision it had made under Article 10 on the grounds specified in Article 12.2?	
a) yes (please give details below)	
b) not yet, but under development	
c) no	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	X
b) no	
c) not applicable – no decisions taken during the reporting period	

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

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:

Some MS have exported LMOs for research and development purposes, including field trials. Please check reports by EU Member States for further information.

11. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:

The EC applies its domestic legislative framework instead of the Protocol's advance informed agreement procedure. This framework is compatible with the provisions of the Protocol.

The EC's domestic legislative framework is built on a range of legislative measures described above and listed in the annex to this report.

Under Directive 2001/18/EC, a company intending to market a GMO must first obtain a written consent to this end. The authorisation procedure for placing the GMO on the market involves all Member States, as authorised products are granted free movement throughout the territory of the EU. The application (called "notification") is first submitted to the competent national authority of an EU Member State. The notification must include a full evaluation of the impact on human health and the environment. Having received the notification, the national authority must issue an opinion which will take the form of an "assessment report".

This assessment report may be favourable or unfavourable. In the event of a favourable opinion for the placing on the market of the GMO concerned, the Member State, after having received the notification and produced the assessment report, informs the other Member States via the European Commission. The other Member States and the Commission examine the assessment report and may issue their own observations and objections.

If there are no objections by other Member States or by the European Commission, the competent authority that carried out the original assessment authorises the placing on the market of the product and may stipulate conditions for placing on the market. The authorisation has a maximum duration of ten years and may be renewed provided certain conditions are met (for example on the basis of the results of the post-market monitoring programme).

If objections are raised, the procedure provides for a conciliation phase among the Member States and the Commission. The objective of this phase is to resolve the outstanding questions. If at the end of the conciliation phase the objections are maintained, a decision must be taken at Community level. The Commission first asks for the opinion of the European Food Safety Authority (EFSA) on the maintained objections. EFSA is the independent scientific advisory body on food safety and some environmental issues such as the environmental risk assessment of GMOs in the European Community.

The Commission then presents a draft decision to the Regulatory Committee composed of representatives of the Member States for an opinion. If the Committee gives a favourable opinion by qualified majority, the Commission adopts the decision. In case the Regulatory Committee gives a negative opinion or is not able to reach a qualified majority either in favour or against, then the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision. Within 30 days after the adoption of the Decision, the national Competent Authority which has first received the notification grants the written consent. During

the notification process, the public is also informed and has access to the publicly available data on the Internet.

A person or a company who wishes to introduce GMOs into the environment for experimental purposes must first obtain written authorisation from the competent national authority of the Member State within whose territory the experimental release is to take place. It is given on the basis of an evaluation of the risks presented by the GMO – or GMOs – for the environment and human health. Hence, the authorisation procedure is simpler than the one referred to above. It is a purely national procedure as it is only applicable in the Member State where the notification was submitted. However, the other Member States and the European Commission may make observations to be examined by the competent national authority.

To obtain authorisation for placing on the market of food or feed containing or consisting of a GMO, the applicant has also the possibility of filing an application under Regulation (EC) No 1829/2003 on GM food and feed pursuant to the "one door, one key" principle: With a single application he can obtain an authorisation for the deliberate release of a GMO into the environment – in accordance with the criteria established by Directive 2001/18/EC – and the authorisation to use this GMO in food and feed – in accordance with the criteria established by Regulation (EC) No 1829/2003 (for more details the response to question 16).

Updated lists of GMOs authorised under Directive 2001/18/EC and of pending authorisations under this instrument are available at http://ec.europa.eu/environment/biotechnology/index_en.htm.

Updated lists of GMOs authorised under Regulation 1829/2003 and of pending authorisations under this instrument are available at http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm.

A Community register of authorised genetically modified food and feed, also including products that are subject to Commission decisions on withdrawal from the market is available at: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing

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

12. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	X
b) not yet, but under development	
c) no	
d) not applicable (please give details below)	
13. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9)	
a) yes (please give details below)	
b) no	
c) not relevant	X

14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	X
b) no	
c) not applicable – no decisions taken during the reporting period	

15. If your country has been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:

Not applicable. The EC was not a country of export during the reporting period.

16. If your country has been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:

The EC has developed a comprehensive legal framework on GMOs, which also addresses the import of LMOs intended for direct use for food or feed, or for processing. The EC has declared with reference to Article 14.4 Cartagena Protocol that it relies on its existing legislative framework for intentional movements of GMOs within the Community and for imports of GMOs into the EC. Of the recently adopted legal acts, the following are of direct relevance to the implementation of Article 11:

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

The last three Regulations entered into force in 2003. The latter two have been applicable since mid-April 2004. Various other instruments have been adopted in connection with this legislation, including:

- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003; and
- Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.
- Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) 1830/2003

In relation to Article 11, the EC wishes to recall that Regulation (EC) 1829/2003 on genetically modified food and feed applies to applications for the placing on the market of the following products:

- GMOs for food and feed use; and
- Food and feed containing GMOs, consisting of such organisms or produced from GMOs.

The Regulation stipulates that the products to which it applies must not:

- Have adverse effects on human health, animal health, or the environment;
- Mislead the consumer or user;
- Differ from the food/feed they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for human beings or animals;
- In the case of genetically modified food or feed, harm or mislead the consumer by impairing the distinctive features of the animal products.

The Regulation creates a centralised, uniform and transparent procedure for applications for placing on the market GMOs or the food and feed products derived from GMOs. Authorisations are valid throughout the EC unless otherwise prescribed in the authorisation decision. They are granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority (EFSA) and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

Applications are submitted first to the competent authority of a Member State, that transmits this application to EFSA without delay. The application must clearly define the scope of the application, indicate which parts are confidential and must include a monitoring plan, a labelling proposal and a detection method. EFSA carries out the scientific risk assessment covering both the environmental risk and human and animal health safety assessment. The competent authorities of Member States have the possibility of commenting during the risk assessment process. ESFA concludes its opinion, based on its own findings and after consideration of comments received from Member States. Afterwards, EFSA makes its opinion available to the public and the Commission invites comments from the public. EFSA has produced guidance documents for the risk assessment of GMO plants and derived food and feed, which provides detailed information. See http://www.efsa.europa.eu/en/science/gmo/gmo_guidance.html

On the basis of EFSA's opinion, the Commission proposes to the Member States granting or refusing of authorisation. The Commission may diverge from the opinion if it justifies its position. A committee composed of Member States' representatives decides on the Commission's proposal by qualified majority. If the proposal is rejected by qualified majority or if the Regulatory Committee is not able to reach a qualified majority, then it is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision.

Updated lists of GMOs authorised under Regulation 1829/2003 and of pending authorisations under this instrument are available at http://ec.europa.eu/food/food/biotechnology/authorisation/index_en.htm.

A Community register of authorised genetically modified food and feed, also including products that are subject to Commission decisions on withdrawal from the market is available at: http://europa.eu.int/comm/food/food/biotechnology/authorisation/commun_register_en.htm.

Products that consist of GMOs or which contain GMOs and food products derived from GMOs authorised under the above procedure are subject to traceability requirements in application of Regulation (EC) No 1830/2003. The traceability rules make it mandatory on the operators concerned – all persons who place a product on the market or receive a product placed on the market within the EC, except the final consumer – to be able to identify their supplier and the companies to which the products have been supplied.

In the case of a product consisting of or containing GMOs, operators must ensure that the following is transmitted in writing to the operator receiving the product:

- An indication that the product or some of its ingredients contain or consist of GMOs; and
- The unique identifier(s) assigned to those GMOs. In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information relating to the unique identifiers may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

The operators must hold the information for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available.

GMOs and food or feed containing, consisting of or produced from GMOs which have been authorised under the above procedure are also subject to the labelling requirements laid down in Regulation (EC) No 1830/2003 and Regulation (EC) No 1829/2003. Generally, according to Regulation (EC) No 1830/2003 for all pre-packaged products consisting of or containing GMOs, operators are to indicate on a label: "This product contains genetically modified organisms" or "This product contains genetically modified [name of organisms(s)]". In the case of non pre-packaged products offered to the final customer or to mass caterers, these words must appear on, or in connection with, the display of the product. In addition, Regulation (EC) No 1829/2003 lays down specific labelling requirements for GM food and feed.

EC legislation acknowledges that adventitious or technically unavoidable presence of GM material in products placed on the market in the European Union can occur during cultivation, handling, storage and transport.

Therefore, conventional products that contain traces of authorised GMOs are not subject to traceability and labelling requirements if the traces of these GMOs are below a limit of 0.9 per cent, provided the presence of this material is adventitious or technically unavoidable.

During the reporting period, the EC has imported more than 3 million tons of maize that may have contained GMOs and also 100 million tons of soybeans that may have contained GMOs. Since entry into force of the EC's regulations on labelling and traceability in April 2004, shipments that may contain living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP) should be clearly identified as containing LMOs and those LMOs should be identified by the unique identifier in line with the OECD's guidelines on unique identifiers of genetically modified plants. In the case of mixtures of LMO-FFP shipments, the exact list of GMOs present in the shipment may be replaced by the list of GMOs "that have been used to constitute the shipment." Most operators use commercial invoices for purposes of documentation. Based on the EC's limited experience to date, the new labelling and traceability requirements have not posed a significant problem for international trade in this area (See report COM 2006 197). In 2008, the EC will draw up a second report on its experience with the traceability and labelling regulation.

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:	
The EC has not made use of the simplified procedure for imports of LMOs as specified in Article 13.	

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?	
a) yes	
b) no	X

20. If your country has entered into bilateral, regional or multilateral agreements or 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:
The EC has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14(1). The EC has determined as per Article 14(4) and 9 (2) (c) that it relies on its existing legislative framework for intentional movements of GMOs within the Community and for imports of GMOs into the EC. This decision has been communicated to other Parties through the Biosafety Clearing-House.

Articles 15 and 16 – Risk assessment and risk management

21. If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2)	
a) yes	
b) no (please clarify below)	
c) not a Party of import / no decisions taken under Article 10	X- for reason given above to Q 11
22. If yes to question 21, did you require the exporter to carry out the risk assessment?	
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	X- for reason given above to Q 11
23. If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3)	
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	X- for reason given above to Q 11
24. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)	
a) yes – fully established	X
b) not yet, but under development or partially established (please give further details below)	

c) no	
25. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes – fully adopted	X
b) not yet, but under development or partially adopted (please give further details below)	
c) no	
26. Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)	
a) yes – in all cases	X
b) yes – in some cases (please give further details below)	
c) no (please give further details below)	
d) not applicable (please give further details below)	
27. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	X
b) no (please give further details below)	
28. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:	

The EC has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs, whether imported into or developed within the EC. The aim of the environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, both direct and indirect, immediate or delayed, on human health and the environment.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms establishes in Annex II principles for the environmental risk assessment, in Annex VI guidelines for the assessment reports and in Annex VII guidelines for the monitoring plan to be applied in cases where consent has been given to the placing on the market of GMOs. Several supporting documents specify provisions contained in the Directive:

- Commission Decision 2002/623/EC of 24 July 2002 establishes guidance notes on the objective, elements, general principles and methodology of the environmental risk assessment referred to in Annex II to Directive 2001/18/EC.
- Council Decision 2002/811/EC of 3 October 2002 establishes guidance notes supplementing Annex VII to the Directive, describing the objectives and general principles to be followed to design the monitoring plan.
- Council Decision 2002/812/EC of 3 October 2002 establishes the summary information format.
- The EU Scientific Steering Committee published in March 2003 the 'Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed', which was complemented by a set of guidance documents produced by the European Food Safety Authority. See http://www.efsa.europa.eu/en/science/gmo/gmo_guidance.html

In accordance with the precautionary principle, environmental risk assessments must be based on the following principles:

- GMO characteristics and GMO use that have the potential to cause adverse effects are to be compared to characteristics and use of the non-modified organism from which the GMO is derived;
- Risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- Risk assessment should be carried out on a case by case basis;
- New information on the GMO and its effects may need to be readdressed in order to determine whether the risk has changed and whether there is a need for amending the risk management accordingly.

Article 4 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms demands that any person submitting a notification under the authorisation procedures for GMO releases into the environment or placing on the market of GMOs as or in products needs to carry out an environmental risk assessment. Annex III of the Directive specifies the information that may be necessary to carry out the risk assessment.

The environmental risk assessment comprises several steps that need to be addressed:

- Identification of characteristics which may cause adverse effects. These characteristics will vary from case to case and may include direct effects on human health or the environment as well as indirect effects occurring through a causal chain of events, through interactions with other organisms, transfer of genetic material or changes in use or management. As observations of indirect effects are likely to be delayed, immediate effects during the period of the release of the GMO as well as delayed effects that become apparent at a later stage or after termination of the release need to be considered.
- Evaluation of the potential consequences of each adverse effect, if it occurs.
- Evaluation of the likelihood of the occurrence of each identified potential adverse effect.
- Estimation of the risk posed by each identified characteristic of the GMO.
- Application of management strategies for risks from the deliberate release or marketing of GMOs.
- Determination of the overall risk of the GMO.

Annex VII of the Directive provides guidance on the monitoring plan as part of the risk management strategy. More specific guidance notes are provided in Council Decision 2002/811/EC of 3 October 2002. The objective of the monitoring plan is to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the risk assessment are correct, and to identify the occurrence of adverse effects of the GMO or its use which were not identified in the risk assessment.

The design of the monitoring plan should, among others:

- Be detailed on a case by case basis;
- Take into account the characteristics of the GMO, its use and scale of use, and the range of relevant environmental conditions;
- Incorporate general surveillance for unanticipated adverse effects;
- Provide for case-specific monitoring for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed and indirect effects which have been identified in risk assessment.;
- Provide for the use of already established routine surveillance practices where appropriate.

At last, it may be interesting to know that the EC has cooperated with members of the European

Economic Area (Norway, Iceland and Liechtenstein) on the issue of antibiotic resistance markers in risk assessment.

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	

Article 18 – Handling, transport, packaging and identification

31. Has your country taken measures to require that living modified organisms that are subject to transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards? (Article 18.1)	
a) yes (please give details below)	X
b) not yet, but under development	
c) no	
d) not applicable (please clarify below)	
32. Has your country taken measures to require that documentation accompanying living modified organisms for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for information? (Article 18.2(a))	
a) yes	X
b) not yet, but under development	
c) no	
33. Has your country taken measures to require that documentation accompanying living modified organisms that are destined for contained use clearly identifies them as living modified organisms and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned? (Article 18.2(b))	
a) yes	X

b) not yet, but under development	
c) no	

34. Has your country adopted measures to require that documentation accompanying living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter? (Article 18.2(c))	
a) yes	X
b) not yet, but under development	
c) no	

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

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

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

The three Regulations entered into force in 2003. The latter two have been applicable since mid-April 2004. Two implementing Regulations in this area also took effect in April 2004:

- Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003; and
- Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

The EC has also put in place requirements concerning the handling, transport, packaging and identification of GMOs, for any use foreseen in Article 18 of the Protocol.

In relation to Article 18(1), the EC wishes to recall that existing EC legislation contains appropriate rules on the safe transport, handling and packaging of GMOs. These rules are contained in:

- Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (last amended by Commission Directive 2003/28/EC); and
- Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail (last amended by Commission Directive 2003/29/EC).

In relation to Article 18(2)(a), the EC wishes to recall that, under Article 12 of Regulation (EC) No 1946/2003 on transboundary movements of GMOs, exporters are required to state in a document accompanying the GMO, which is to be transmitted to the importer receiving the GMO:

- that it contains or consists of GMOs; and
- the unique identification code(s) assigned to those GMOs if such codes exist.

Article 12 further stipulates that for GMOs intended for direct use as food or feed, or for processing, the above information must be supplemented by a declaration by the exporter:

- stating that the GMOs are intended for direct use as food or feed, or for processing and indicating clearly that they are not intended for deliberate release into the environment; and
- giving details of the contact point for further information.

In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing, the above identification requirements may be replaced by a list of unique identifiers used to constitute the mixture.

Regulation 1829/2003 lays down rules on labelling of all GM food and feed. GM food and feed has to be labelled as GM, except if they contain GM material in a proportion no higher than 0.9% and if this presence is adventitious or technically unavoidable.

Under Regulation (EC) 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market. In particular, the Regulation requires that:

- operators are to have systems and standardised procedures in place to identify to whom and from whom products are made available; and
- in the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, written information on the unique identifier(s) assigned to the GMOs of which the product consists or which are contained in it, may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

In Regulation (EC) No 65/2004 of 14 January 2004, the EC has established a system for the development and assignment of unique identifiers for genetically modified organisms. The Regulation adopts the format developed by the OECD for Unique Identifiers for Transgenic Plants, which in mid-April 2004 became mandatory for the EC's domestic regulatory framework for GMOs. Moreover, the EC has extended use of this format to unique identifiers for genetically modified micro-organisms and animals pending the development and adoption of any other specific format at an international level. The EC considers the use of the unique identifier as a key to access information available on the Biosafety Clearing-House.

In relation to Article 18(2)(b), the EC wishes to recall that EC legislation contains rules on identification of GMOs that are destined for contained use, in line with the Protocol. Regulation No (EC) 1946/2003 on transboundary movements of genetically modified organisms requires exporters of GMOs destined for contained use to state in accompanying documentation

- that it contains or consists of GMOs;
- the unique identification code(s) assigned to those GMOs if such codes exist;

In addition, this information shall be supplemented by a declaration by the exporter which shall specify:

- any requirements for the safe handling, storage, transport and use of the GMOs; and
- the contact point for further information, including the name and address of the individual or institution to whom or which the GMOs are consigned.

In relation to Article 18(2)(c), Regulation No (EC) 1946/2003 requires exporters of GMOs destined for

deliberate release into the environment to ensure that documentation accompanying the GMO states:

- that it contains or consists of GMOs; and
- the unique identification code(s) assigned to those GMOs if such codes exist;

In addition, this information shall be supplemented by a declaration by the exporter which shall specify:

- the identity and relevant traits and characteristics of the GMOs;
- any requirements for the safe handling, storage, transport and use of these GMOs;
- the contact points for further information and, as appropriate, the name and address of the importer and exporter; and
- a declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

The above requirements regarding identification and documentation of GMOs are in line with Article 18 of the Protocol and without prejudice to further specific requirements imposed by EC legislation.

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:
The EC appointed the Joint Research Centre (JRC) of the European Commission as the European Community BCH Focal Point in January 2004. According to BS-I/3, BCH National (and/or regional, institutional) Focal Points liaise with the Secretariat regarding issues of relevance to the development and implementation of the Biosafety Clearing-House, including information clearance before publication to the BCH central portal, liaison with the Secretariat regarding the technical aspects (layout, system, database) of national participation to the Biosafety Clearing-House. In this respect, the JRC has contributed to the work of the Informal Advisory Committee (IAC) of technical experts on the BCH, collaborating with the review of the first year activity of the BCH central portal which was undertaken with a view to defining the medium-to-long term programme of work. The JRC has also organised or hosted various meeting among the BCH national Focal Points in the Member States to review the modalities of collaboration. As a first activity undertaken by the JRC, the interoperability with the central BCH portal with a push mechanism was tested by implementing a prototype using open source development and deployment environments. This prototype has evolved in the implementation of a toolkit that can be used to set up a general interoperable node. At the same time, the development of GMOREGEX, a workflow, information dissemination and exchange application has been completed. This application includes the EC BCH module which will allow automated submission of the information generated during the authorisation process and relevant to the BCH data exchange to the BCH Central Portal. The GMOREGEX/ EC BCH application is currently in the pilot phase with Member States Competent Authorities and can be accessed at the web address http://gmoregisportal.jrc.it/.

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:

The EC applies its domestic legislative framework instead of the Protocol's advance informed agreement procedure. This framework is compatible with the provisions of the Protocol. It contains confidentiality provisions that apply equally to domestic and foreign producers of GMOs.

Article 25 of Directive 2001/18/EC on the deliberate release into the environment of GMOs stipulates that the European Commission and the Member States shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received. The Directive allows the notifier to indicate the information in the notification that should be treated as confidential, provided that verifiable justification is given in such cases. Decisions on which information will be kept confidential are taken by the competent authority of Member States after consultation with the notifier. Exemptions from the confidentiality clause include:

- General description of the GMO or GMOs, name and address of the notifier, purpose of the release, location of release and intended uses;
- Methods and plans for monitoring of the GMO or GMOs and for emergency response;
- Environmental risk assessment.

Article 30 of Regulation (EC) No 1829/2003 on genetically modified food and feed allows applicants to indicate which information submitted under the Regulation they wish to be treated as confidential, based on verifiable justification. The European Commission determines, after consultation with the applicant, which information shall be kept confidential, excluding the following:

- Name and composition of the GMO, food or feed and, where appropriate, indication of the substrate and the micro-organism;
- General description of the GMO and the name and address of the authorisation holder;
- Physico-chemical and biological characteristics of the GMO, food or feed;
- Effects of the GMO, food or feed on human and animal health and on the environment;
- Effects of the GMO, food or feed on the characteristics of animal products and its nutritional properties;
- Methods for detection, including sampling and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food or feed;
- Information on waste treatment and emergency response.

Article 16 of Regulation (EC) No 1946/2003 on transboundary movements of GMOs obliges the European Commission and the Member States not to divulge to third parties any confidential information received or exchanged under this Regulation. It allows the exporter to indicate the information in the

notification that should be treated as confidential, provided that justification is given in such cases. However, the following information is excluded from the confidentiality clause:

- Name and address of the exporter and importer
- General description of the GMO or GMOs
- A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking into account risks to human health
- Any methods and plans for emergency response.

40. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:

Not applicable, not a Party of export during the reporting period. However, as already mentioned above, some MS have exported LMOs for research and development purposes, including field trials. Please check reports by EU Member States for further information.

Article 22 – Capacity-building

41. If a developed country Party, during this reporting period has your country cooperated in the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition?

a) yes (please give details below)	X
b) no	
c) not applicable – not a developed country Party	

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

The EC and its Member States have contributed to capacity-building initiatives in the field of biosafety for the effective implementation of the Protocol in developing country Parties as well as in Parties with economies in transition. The European Commission has co-financed the workshop on capacity building on Article 18 of the Cartagena Protocol held in November 2004 in Bonn, Germany. Moreover, the EC has cooperated in a range of biosafety-related capacity building projects during the reporting period that include:

1. EU Twinning Project PL 01/EN/IB/03 – "Biological Safety System in Poland"

The overall objective of this project was to assist Poland in improving the administrative capacity in the field of biological safety by development of a national biosafety system in line with EU standards which covers the contained use of GMO as well as their deliberate release into the environment and placing on the market. The main project components were: 1) Project Inception Phase, 2) Legal review and assessment of the state of approximation of the Polish legislation to the EC' Acquis Communautaire; 3) Decision-Making; 4) Inspection; 5) Assistance in establishing accredited laboratories; 6) Assistance in establishing an electronic information system; and 7) Assistance in promoting public information and public participation. The EC provided $1.7 million funding from its PHARE programme to support this project over the period from November 2002 to November 2004.

2. Capacity Building Opportunity JRC/WHO Joint Manual on Analysis of Food Samples for the Presence of GMOs

The EC and the World Health Organisation have collaborated since 2000 in the organisation of training courses on detection techniques for GMOs in foods. The aim is to provide analytical biotechnology skills to food control laboratory staff and to promote the use of validated and harmonised methods for detecting, identifying and quantifying GMOs. As part of this joint effort, training courses have been held in the WHO European Region, including Central and Eastern European economies in transition.
A manual has been developed to assist relevant laboratory personnel with a good level of analytical knowledge, but with no or little expertise in this specific domain to become accustomed with molecular detection techniques, and to help them adapt their facilities and work programmes to include analyses which comply with regulatory instruments in the field of biotechnology. The specific objectives of the project are 1) to provide theoretical and practical information on the methodologies and protocols currently used and 2) to assist in the diffusion and dissemination of skills in GMO detection and quantification, taking into account the context of the different working environments and individual needs.

3. EC-JRC Training Courses on the Analysis of Food and Feed Samples for the Presence of GMOs.

Provision of training support has been widely recognised as essential to ensure dissemination of appropriate reference scientific background and for the alignment of means and methods with legislative requirements. Accordingly, since 2000 a series of training courses have been organized to promote the diffusion of a harmonised approach in the detection and quantification of GMOs.

Specific objective of the training courses is to assist the staff of control laboratories to become accustomed with molecular detection techniques, and to help them to adapt their facilities and work programmes to include analyses to comply with worldwide regulatory acts in the field of biotechnology. Specific topics covered included

a) DNA extraction from raw and processed materials;

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

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

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

Staff from more than 100 laboratories has been trained so far. Training courses were organised both in response to general needs and open to participants from EU and non EU countries laboratories as well as focused in response to special needs: support to EU Accession Countries in the context of the enlargement process, including Eastern European economies in transition (Hungary, 3-7/11/2003, Cyprus, 6-10/6/2005, Ispra, 12-16/6/2006); support for the diffusion of harmonised approaches in GMO detection in the Maghreb Region (Tunisia,18-22/9/2006) and in the Black Sea Region Countries (Sofia, 25-29/6/2007).

4. European Network of Genetically Modified Organisms (GMO) Laboratories

The EC's Joint Research Centre has acted as a catalyst for bringing national GMO laboratories together by establishing the European Network of Genetically Modified Organisms (GMO) Laboratories. The Network develops methods for tracing GMOs and provides free electronic access to this information to all interested parties, including from developing countries and economies in transition.

5. EC Research Funding

EC research funds provide opportunities for capacity building-related research. Under the Fifth Framework Programme two international cooperation projects were supported on GM oilseed rape breeding and on Bt cotton management, both with Chinese partner organisations. Under the Sixth Framework Programme, the Integrated Project "Co-Extra" (GM and non-GM supply chains: their CO-EXistence and TRAceability) is looking for integrated methodologies to trace GM materials all along the food chain and to facilitate the coexistence of genetically modified, conventional and organic crops. It will develop practical systems – suitable for use by all stakeholders in the food chain – for sampling, tracing, labelling and documenting GM content of foods and feeds. "Co-Extra" includes participants from Argentina, Brazil and Russia. International cooperation continues to be a priority for Food, Agriculture and Biotechnology research under the Seventh Framework Programme (announced in April 2005) and will provide further opportunities for promoting capacity building.

6. Study on "Guidelines for Green, White, Blue and Red Biotechnologies"

The European Commission (DG Development) in 2005 funded a study on "Guidelines for Green, White, Blue and Red Biotechnologies" with the purpose of proposing practical operational guidelines to assist decision-makers considering EU support for pro-poor biotechnologies in developing countries.

7. Project on Consumer organisations and the Cartagena Protocol on Biosafety

This project runs for a duration of 24 months and aims at sensitising and better informing consumers in developing countries about biosafety issues in general and the Cartagena Protocol in particular. It is expected that the project will increase the prioritisation of biosafety in the developing world for the benefit of biodiversity and consumer health and safety and will enable consumers to better exercise their right to a healthy, sustainable environment, to choose and to be informed, and to be skilful advocates of their own interests in the area of biosafety.

7. Global Conference on GMO Analysis

The Joint Research Centre of the European Commission is organising the first "Global Conference on GMO Analysis" which will be held in Como (IT), 24-27 June 2008. The themes of the Conference include:

- Theme 1: Requirements for the implementation of GMO analysis along the production chain
- Theme 2: Method development and technical aspects
- Theme 3: Harmonization, standardization and Accreditation – the way to Quality Assurance

Details on the call for expression of interests are available at:
http://gmoglobalconference.jrc.it/default.htm

43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition?	
a) yes (please give details below)	
b) no	
c) not applicable – not a developing country Party	X

44. If yes to question 43, how has such cooperation taken place:

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	
e) not applicable – not a developing country Party or a Party with an economy in transition	X
46. If a developing country Party or a Party with an economy in transition, have you benefited from cooperation for technical and scientific training in the use of risk assessment and risk management for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	X
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)	
c) no – capacity-building needs remain unmet (please give details below)	
d) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	X
48. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 22, including any obstacles or impediments encountered:	
No further comments	

Article 23 – Public awareness and participation

49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))	
a) yes – significant extent	X
b) yes – limited extent	

c) no	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
51. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	X
b) yes – limited extent	
c) no	
52. Does your country, in accordance with its respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and make the results of such decisions available to the public? (Article 23.2)	
a) yes – fully	X
b) yes – limited extent	
c) no	
53. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	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:	
EC legislation on GMOs promotes public awareness and participation as an integral part of its regulatory framework. EC legislation on traceability and labelling of GMOs authorised in the EC is specifically aimed at ensuring that accurate information is available to the public. Moreover, the EC is Party to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (signed in 1998 and ratified in 2005). The main legal instrument to align EU Member States legislation with the provisions of the Aarhus Convention on access to information is Directive 2003/4/EC of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC. To further support citizens' rights of access to information, the EC has also adopted Directive 2003/35/EC on public participation, Regulation 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents and Regulation 1642/2003 of 22 July 2003, amending Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. An amendment to the Aarhus Convention making was adopted in May 2005. This amendment makes more specific the obligations placed on Parties with regard to public participation in genetically modified organism (GMO) decision-making processes. Relevant Community law governing GMOs, and in particular Directive 2001/18/EC and Regulation (EC) No 1829/2003, incorporates provisions for public participation in decision-making on GMOs, consistent with the amendment to the Aarhus Convention.	

The Community has decided on 18 December 2006 to ratify this amendment; the ratification has not yet taken place since the Community would like it to happen as far as possible simultaneously with the ratification by its Member States.

Article 9 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms stipulates that Member States shall consult the public and, where appropriate, groups on the proposed deliberate release of GMOs into the environment for any other purpose than for placing on the market. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion. Member States are to make available to the public information on all intentional releases of GMOs into the environment in their territory, and the Commission shall make available to the public the information contained in the system of exchange of information established within the EC.

In cases of GMO notifications for placing on the market of GMOs as or in products, Article 24 of Directive 2001/18/EC stipulates that the Commission makes available to the public the summary dossier that is to accompany notifications for placing on the market of GMOs or a combination of GMOs as or in products. It also provides for the Commission to make available the assessment report issued by the national authority of the Member State which received the notification.

Regulation (EC) No 1829/2003 on genetically modified food and feed establishes a register of genetically modified food and feed authorised under this Regulation, including product specific information. It makes non-confidential data available to the public. Article 5 of the Regulation stipulates that the European Food Safety Authority receiving from national authorities an application for authorisation for placing on the market of GM food shall make a summary of the application available to the public. The public can make comments to the Commission on the authority's opinion. Monitoring plans are to be made available to the public after deletion of any information identified as confidential. Similar provisions exist with regard to the authorisation of GM feed (Article 17). Access to information held by the European Food Safety Authority in relation to procedure under Regulation 1829/2003 should be provided according to Regulation 1049/2001.

Directive 90/219/EEC on the contained use of GM micro-organisms in conjunction with Directive 98/81/EC amending Directive 90/219/EEC states that EU Member States may provide, where appropriate, that the public shall be consulted on any aspect of proposed contained use. It includes a requirement that information on emergency plans and safety measures to be taken in the event of an accident is made publicly available.

With regard to transboundary movements of GMOs, Article 6 of Regulation (EC) No 1946/2003 requires the Commission to make available to the public all non-confidential documents related to notifications of exports of GMOs to third countries. In cases of unintentional transboundary movements of GMOs, Article 14 requires Member States to take the appropriate measures to inform, among others, the public about the movement.

The EC maintains online information systems that provide the public with up-to-date information on the legislative framework for GMOs, applications for GMO authorisations and imports, decisions taken by relevant authorities, the results of environmental risk assessment and measures provided as part of risk management. The EC's main information portal for these purposes is:

- The Biotechnology and GMOs Information Website, which can be accessed at: http://gmoinfo.jrc.it/default.asp.

Further information sites include:

- Biotechnology and GMOs Unit website: http://biotech.jrc.it/
- Community Reference Laboratory for GM Food and Feed: http://gmo-crl.jrc.it/
- Directorate-General Environment's Biotechnology portal: http://europa.eu.int/comm/environment/biotechnology/index_en.htm
- European Food Safety Authority: http://www.efsa.eu.int/index_en.html
- European Community Biodiversity Clearing-House Mechanism: http://biodiversity-chm.eea.eu.int/

The EC is currently supporting a new internet-based information system, 'GMO-Compass', which provides the public with information about the benefits and risks of GMOs. The site is to contain information about risk analysis, risk assessment and management, as well as political, legal and socio-economic aspects. The website can be accessed at: http://www.gmo-compass.org/eng/home/

Information on GMO regulation is also provided through summary documents and information brochures that are available to the public, including 'Questions and Answers on the Regulation of GMOs in the European Union', which is available at http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf

Article 24 – Non-Parties

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

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

56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:
As regards imports of LMOs, the EC applies its domestic legislative framework to all imports of LMOs, whether these originate from parties or non-parties to the Protocol. As regards exports of LMOs, notification requirements of the exporter to the competent authority of the Party of import established by Regulation (EC) No 1946/2003 apply regardless of whether the country of import is a Party or a non-Party to the Protocol. Copies of the respective documents are, *inter* alia, sent to the European Commission (Article 6). Since entry into force of Regulation (EC) No 1946/2003 in November 2003, numerous copies of export notifications for LMOs intended for deliberate release into the environment to non-Parties have been received. In practically all instances, these notifications relate to the export of LMOs for use in small-scale field trials; hardly any to LMOs intended for commercial use.

Article 25 – Illegal transboundary movements

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

57. Has your country adopted appropriate domestic measures to prevent and penalize, as appropriate, transboundary movements of living modified organisms carried out in contravention of its domestic measures? (Article 25.1)	
a) yes	X

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

59. Please provide further details about your response to the above question, as well as description of your country's experiences in implementing Article 25, including any obstacles or impediments encountered:

According to Directive 2001/18/EC, it is the Member States that are obliged to take domestic measures to prevent and penalize illegal transboundary movements of GMOs. European legislation contains explicit obligations on Member States to lay down rules on penalties applicable to infringements of the provisions of European regulations. It further states that these penalties shall be effective, proportionate and dissuasive. Specific requirements on Member States to determine penalties applicable to breaches of European and national GMO regulations can be found in:

- Article 33 of the Directive 2001/18/EC on the deliberate release into the environment of GMOs;
- Article 18 of Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms; and
- Article 45 of Regulation (EC) No 1829/2003 on genetically modified food and feed.

Article 53 of Regulation (EC) No 178/2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety provides for the possibility to adopt appropriate Community emergency measures for food and feed imported from a third country in order to protect human health, animal health and the environment, where the risk, can not be contained satisfactorily by means of measures taken by the Member States concerned. On this legal basis the Commission adopted on 18 April 2005 emergency measures regarding imports of the non-authorised genetically modified organism Bt10 in maize products and adopted on 5 September 2007 emergency measures regarding the non-authorised genetically modified organism 'LL RICE 601' in rice products. On the basis of satisfactory information regarding the absence of Bt10 in imports to the EU, the measures regarding this maize were repealed on 7 March 2007.

GM fish or 'glofish' have been found in some Member States (including Belgium, Czech Republic, Finland, Germany and the United Kingdom). Since these fish were not notified under Part C of Directive 2001/18/EC, their imports into and sale in the EU constituted illegal transboundary movements in the sense of Article 25 of the Protocol. Further information on measures adopted by Member States in this regard can be found their national reports.

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	X
d) not a Party of import	

61. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	
c) no	X

62. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:
Socio-economic considerations have been relevant at Member State level for the question of co-existence. The European Commission has issued a Recommendation on 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming. This non-binding Recommendation aims at ensuring that no form of agriculture be excluded in the EU and that consumers and producers are given a choice with regard to agricultural produce. However, it is the Member States that are to develop measures for coexistence, informed by the guidelines provided by the European Commission. The Commission has issued an implementation report of national co-existence measures in 2006 (COM(2006)104 final) and will report again on this issue in 2008. Article 31 of the Directive 2001/18/EC states that every three years the Commission publishes a summary based on the Member States reports on the measures taken to implement the provisions of the Directive.

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	X
b) yes – received financial resources from other Parties or financial institutions	
c) both	
d) neither	

64. Please provide further details about your response to the above question, as well as description of your country's experiences, including any obstacles or impediments encountered:
No further comments unless DEV/ AIDCO point to concrete financing activities that should be mentioned.

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.