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

### Origin of report

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Submission	
Signature of officer responsible for submitting report:	
Date of submission:	TO BE COMPLETED
Time period covered by this report:	2005 (interim report) - now

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 Germany's interim-implementation report from 2005. The interim report was written based on publicly accessible information on relevant legislation and implementation.

Additional information, particularly on the practical implementation, was contributed mainly by the Federal Office of Consumer Protection and Food Safety (BVL), which is the Competent National Authority for the Cartagena Protocol and the Point of Contact for the purposes of Art. 17 of the Protocol, and officials in institutions involved in capacity building.

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):

As a member of the EU the European legislation on genetically modified organisms (GMOs), which has been in place since the early 1990s, is either directly applicable in Germany or has been implemented into German law. Therefore the comprehensive information given in the report of the EU also partly covers the situation in Germany.

The relevant national legal framework has been provided to the BCH recently.

With respect of further information requirements of the Protocol it is to be expected that the required information will be provided step by step in the near future.

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);  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		
1) 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	X	X	

regarding products thereof (Article 20.3(c)).		

#### *Article 2 – General provisions*

3. Has your country introduced the necessary legal, administrative and other measure implementation of the Protocol? (Article 2.1)	es for
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:

The EC has created a comprehensive legal framework and introduced specific legislation on GMOs. For further details please refer to the report of the EU.

Germany has fully implemented existing EC-legislation (see EC report) into national law through the German Gentechnikgesetz [Gene Technology Act] and the EG-Gentechnikdurchführungsgesetz [German law regulating the implementation of te European provisions in the field of GMO]. Please refer to Annex 1 for a comprehensive list of the German legal framework provided to the BCH recently. These legal measures are publicly available on the homepage of the German Competent National Authority (BVL) which also hosts the German BCH-homepage (currently under development):

- <a href="http://www.bvl.bund.de/cln\_027/nn\_491818/DE/06">http://www.bvl.bund.de/cln\_027/nn\_491818/DE/06</a> Gentechnik/09 BiosafetyClearingHouse/05 RechtlicheGrundlagen/rechtGrundlagen node.html nnn=true
- http://www.biosafety-bch.de/

In addition to European legislation German law foresees administrative fines and penalties to ensure compliance with relevant provisions. The Articles 38 and 39 of the German Gentechnikgesetz [Gene Technology Act] as well as the §§ 6 and 7 of the German EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] include penal provisions that serve to enforce the aims and provisions of the Cartagena Protocol. These provisions penalize behaviours that can contravene the goals of the Cartagena Protocol, for example the deliberate release of a GMO into the environment or the placing on the market of a GMO without the necessary authorization by the competent authority.

Moreover, § 6, 2<sup>nd</sup> paragraph of the German EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] penalizes the transboundary movement of living modified organisms carried out in contravention of the relevant German and European laws.

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 jurisdiction of your country? (Article 8.2)	1/ under the	
a) yes	X	
b) not yet, but under development		
c) no		
d) not applicable – not a Party of export		
8. If you were a Party of export during this reporting period, did you request any Par review a decision it had made under Article 10 on the grounds specified in Article 12.		
a) yes (please give details below)		
b) not yet, but under development		
c) no	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		
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:		
According to Art. 6 Regulation (EU) No. 1946/2003, which adopts requirements of the Protocol to the EU legal framework, exporters have to notify the transboundary movement of LMO intended for release into the environment to the Competent National Authority and the EU Commission.		

In Germany, during the reporting period consent for import and release into the environment for the purpose of field trials and developments has been presented for 6 such notifications, one exporter notified the export of LMO intended for contained use.

The notifiers did not report on obstacles in these notifications.

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:

To date, Germany has not taken decisions on import of LMOs intended for release into the environment. However, under the EU domestic legal framework, several decisions have been taken. This framework is

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

compatible with the provisions of the Protocol. Please refer to the EU report for further details.

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-H	louse.	
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 cap respect of living modified organisms intended for direct use as food or feed, or for pro 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 frame by Article 11.4?	eworks as allowed	
a) yes	X	
b) no		
c) not applicable – no decisions taken during the reporting period		
15. If your country has been a Party of export of LMOs intended for direct use for 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. Germany has not been a country of export of LMOs intended for direct use for food or feed, or for processing to date.		
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:		
Decisions within the EU legal framework regarding the import of LMOs intended for direct use for food or feed, or for processing, apply within the entire EU, hence in Germany, too. For further details regarding the decisions taken, please refer to the comprehensive information given by the EU in the report of the EC.		
Article 13 – Simplified procedure		
See question 1 regarding provision of information to the Biosafety Clearing-H	louse.	
17. Have you applied the simplified procedure during the reporting period?		
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b) no	X
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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:

Germany 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:	
Please see the information given by the EU which also covers the situation in Germany.	

# 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 in the EU report 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 in the EU report 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 in the EU report to Q 11	
24. Has your country established and maintained appropriate mechanisms, measures a regulate, manage and control risks identified in the risk assessment provisions of the F 16.1)		
a) yes – fully established	X	
b) not yet, but under development or partially established (please give further details below)		
c) no		
25. Has your country adopted appropriate measures to prevent unintentional transbour of living modified organisms? (Article 16.3)	ndary movements	
a) yes – fully adopted	X	
b) not yet, but under development or partially adopted (please give further details below)		
c) no		
26. Does your country endeavour to ensure that any living modified organism, whether locally developed, undergoes an appropriate period of observation commensurate with generation time before it is put to its intended use? (Article 16.4)		
a) yes – in all cases	X	
b) yes – in some cases (please give further details below)		
c) no (please give further details below)		
d) not applicable (please give further details below)		
27. Has your country cooperated with others for the purposes specified in Article 16.5	5?	
a) yes (please give further details below)	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 competent German authorities conduct necessary risk assessements on the basis of the relevant EU legislation, which provides 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.

For an outline of the EU procedure please see the reply of the EU.

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 have led, to an unintentional transboundary movement of a living modified organism thave had, significant adverse effects on the conservation and sustainable use of biolog taking also into account risks to human health in such States, did you immediately compotentially affected States for the purposes specified in Article 17.4?	that had, or could gical diversity,	
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 desc your country's experiences in implementing Article 17, including any obstacles or impedimencountered:		
Not applicable.		
Article 18 – Handling, transport, packaging and identification		
31. Has your country taken measures to require that living modified organisms that ar transboundary movement within the scope of the Protocol are handled, packaged and conditions of safety, taking into account relevant international rules and standards? (A	transported under	
, , ,		
a) yes (please give details below)	X	
	X	
a) yes (please give details below)	X	
a) yes (please give details below)     b) not yet, but under development	X	
a) yes (please give details below) b) not yet, but under development c) no	ing modified 'may contain' living	
a) yes (please give details below) 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 liv organisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environm	ing modified 'may contain' living	
a) yes (please give details below) 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 liv organisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environm contact point for information? (Article 18.2(a))	ring modified 'may contain' living ment, as well as a	
a) yes (please give details below) 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 liv organisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environmentation or information? (Article 18.2(a)) a) yes	ring modified 'may contain' living ment, as well as a	
a) yes (please give details below) 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 liv organisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environmentation of the information? (Article 18.2(a)) a) yes b) not yet, but under development	ring modified 'may contain' living ment, as well as a  X  ring modified d organisms and et point for further	
a) yes (please give details below) 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 liv organisms for direct use as food or feed, or for processing, clearly identifies that they modified organisms and are not intended for intentional introduction into the environmentate point for information? (Article 18.2(a)) a) yes b) not yet, but under development c) no  33. Has your country taken measures to require that documentation accompanying liv organisms that are destined for contained use clearly identifies them as living modifies specifies any requirements for the safe handling, storage, transport and use, the contact information, including the name and address of the individual and institution to whom	ring modified 'may contain' living ment, as well as a  X  ring modified d organisms and et point for further	

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:

Germany has implemented the relevant EU legislation including provisions for handling, transport and packaging in the Gene Technology Act (§ 17b Gentechnikgesetz). This includes details about the labelling of products containing or consisting of LMO.

For further details please see the reply of the EU.

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 National Focal Point according the Art. 19 of the Protocol is the Federal Ministry of Food, Agriculture and Consumer Protection. Since April 2006, the Federal Office of Consumer Protection and Food Safety (BVL) is the Competent National Authority (Art. 20 of the Protocol) and the Point of Contact (Art. 17 of the Protocol) for the BCH. 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.

As defined by the EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] the Federal Office of Consumer Protection and Food Safety [Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL] as the Competent National Authority (CNA) has implemented the provisions for the German BCH.

Implementation of Article 20.3 of the Protocol requests translation of existing German documents into an official UN-language. The necessary administrative steps to fulfil this laborious task have been taken.

Further impediments encountered in the implementation of Article 20 (and others) of the Protocol are the shortage of human resources of the CNA.

The BVL has organised and hosted a meeting among the BCH national Focal Points in the EU Member States to review the modalities of collaboration. The focus of the meeting, held in Berlin in May 2007, was the exchange of views on practical aspects to meet the requirements of the Protocol and the Biosafety Clearing House mechanisms.

One outcome of the meeting was the finding that Germany and other EU Member States experienced capacity constrains in submitting existing information to the BCH-CP about their experiences in the area of deliberate releases of GMO because of the necessity to serve several different information systems already existing. Information about decisions on GMO to be used for deliberate releases (many) and to be placed on the market (few) and about their risk assessments have to be posted to: WEB-SNIF, BCH, existing national systems. The EU Member States together with the EU Commission and the JRC will put effort on this issue to streamline the provision of information.

Article 21 – Confidential information			
37. Does your country have procedures to protect confidential information received up and that protect the confidentiality of such information in a manner no less favourable of confidential information in connection with domestically produced living modified 21.3)	than its treatment		
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 noting information submitted under the procedures of the Protocol or required by the Party of the advance informed agreement procedure that was to be treated as confidential? (Article Protocol or Pro	f import as part of		
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 including description of any impediments or difficulties encountered:	experience		
EU legislation on GMOs contains confidentiality provisions that apply equally to domestic and foreign producers of GMOs. Germany has implemented the relevant EU legislation in the Gene Technology Act (§§ 17, 17a Gentechnik-Gesetz).			
For further details please see the report of the EU.			
40. If you were a Party of export during this reporting period, please describe any imputifficulties encountered by you, or by exporters under your jurisdiction if information			

The exporter that notified the transboundary movement of LMOs for release into the environment for the purpose of field trials or developments did not contact the National Competent Authority of Germany in order to complain about any impediments or difficulties encountered in this respect.

implementation of the requirements of Article 21:

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	

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. Besides the workshop on capacity building on Article 18 of the Cartagena Protocol held in November 2004 in Bonn, Germany has cooperated in the following EU Twinning projects during the reporting period:

As lead partner:

- 1. EC Twinning Project PL 01/EN/IB/03 "Biological Safety System in Poland"
- 2. EC Twinning Project BG04/IB/EN/02 Transposition and Implementation of the Environmentsl Acquis on GMOs ant National Level"

The overall objective of these projects (Poland: November 2002 - November 2004, Bulgaria: January 2005-May 2007) was to assist Poland and Bulgaria in improving their 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 the legal review and assessment of the state of approximation of the Polish and Bulgarian legislation to the EC' Acquis Communautaire, issues related to decision-Making and inspection and assistance in establishing accredited laboratories, an electronic information system and assistance in promoting public information and public participation.

2. EC Twinning Project EE05-IB-AG-01 – "Development of GMO chain management for co-existence of genetically modified, conventional and organic crops"

The overall aim of this project (July 2006 - July 2007) was to assist Estland in improving the administrative capacity in the field of biological safety by development of a national biosafety system in line with EU standards in checking the organisation structure, in particular, creating an infrastructure needed for risk assessment and monitoring of GMOs; reinforcing capacity on biosafety issues with the special attention to testing, monitoring and risk assessment; set-up of laboratory capacity for the determination, identification and quantification of GM crops in Estonia; enhancing public awareness on biosafety and related issues; guarantee the implementation of the relevant legal acts. This all in the light to develop the national strategy for the best practices for co-existence of genetically modified, conventional and organic crops.

Furthermore in the context of development cooperation, Germany acting through the Federal Ministry for Economic Cooperation and Development (BMZ) has launched a Capacity Building Initiative for the implementation of the Cartagena Protocol on Biosafety. This initiative includes main elements such as policy advice, assistance in the formulation of biosafety legislation and implementation of new or existing legislation, institutional capacity building, information management and public-awareness raising. Activities involve policy makers, government and representatives of non-governmental organizations,

scientists, trainers and teachers.

The special GTZ project "Implementing the biodiversity convention" is in charge for the implementation of the capacity building initiative. Within the context of this initiative, the following projects are in the process of being implemented:

African Union (AU): Capacity Building Programme for an Africa-wide Biosafety System: Support of the AU in matters of Biosafety so that the African Union can support their member states with the implementation of the Cartagena protocol.

China: Biosafety Capacity Building in China: Data Management, Promoting Expertise and Awareness Raising together with the State Environmental Protection Administration (SEPA) and the Nanjing Institute for Environmental Science (NIES).

The following projects have been finalized as scheduled:

Algeria: Civil Society Participation in Algeria's Biosafety Process, together with the non-governmental organization "Association de Réflexion, d'Echanges et d'Actions pour l'Environnement et le Développement (AREA ED)

Peru: Elaboration of studies focusing on the implementation of a Biosafety regime in Peru, dealing with the Precautionary Principle, Consumers Rights and Liability, together with the "Sociedad Peruana de Derecho Ambiental (SPDA)"

Colombia: Increase the biosafety-related knowledge of multiplicators working in educational and civil society organisations and of journalists to support their work in biosafety awareness raising in the Colombian society. Implemented in cooperation with GTZ Colombia, the Colombian Ministry for the Environment, Housing, and Spatial Planning (Ministerio de Ambiente, Vivienda y Desarrollo Territorial, MAVDT) together with the Institute for Biotechnology of the National University of Colombia (Instituto de Biotecnología, Universidad Nacional de Colombia, IBUN) and the NGO Corporation of Democratic Units for Peace and Development (Corporación Unidades Democráticas para el Desarrollo, CEUDES).

Details about the projects with the African Union, China and Algerie (objectives, acitivities, and status of implementation) can be found on the BCH capacity building projects database.

Germany has also commissioned InWEnt Capacity Building International to implement a long-term training on development-oriented and environmentally sound plant biotechnology for developing countries that integrates elements relevant to the implementation of Cartagena Protocol as well. It addresses young professionals and managers from governmental and non-governmental organisations, businesses and universities and aims at technology transfer and the development of management capacities in the biotechnology and biosafety sector. Partner organisations are supported in their efforts to make biotechnology an asset in national development, while assessing and managing possible risks. For this training, Germany invested aprox. € 3 million between 1996 and 2007 (with an increased amount since 2003) for participants from developing countries. Using the capacity building instrument of short-term events, InWEnt contributed to the execution of the following courses:

- A Training of trainers course in Malaysia within the UNEP-GEF BCH Project,

- A Global Training of Trainers Workshop on Law and Policy of Relevance to the Management of Plant Genetic Resource together with IPGRI, ISNAR, GTZ, SGRP, FAO & IRRI,
- A Regional Training of Trainers Workshop on Law and Policy of Relevance to the Management of PGR in Eastern and Central Africa
- Together with the International Livestock Research Institute (ILRI), the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and the Food and Agriculture Organisation (FAO) a dialogue seminar on "Best Practices in the Management of Animal Genetic Resources in Central America".

Furthermore, an integrated expert was funded to assist the Namibian Government in its biosafety projects.

Through its "Funds in Trust Programme", the IUCN Regional Biodiversity Programme Asia in Sri Lanka has launched a biosafety project involving South Asian Countries.

As one of the main contributors to the Global Environment Facility (GEF), Germany supports the various GEF biosafety projects and actively contributes to the development of the GEF biosafety strategy.

In order to support capacity building for the implementation of the Protocol, the BMZ has supported the third session of the coordination mechanism for capacity building that took place in Lusaka in February 2007, together with the Government of Sambia and the SCBD.

Furthermore, BMZ initiated together with the Norwegian GenOk Institute a dialogue on the development of an European approach on biosafety capacity building. A first meeting took place in Koenigswinter in November 2005, and a second meeting shall be convened before MOP 4.

In addition, the AU-German biosafety capacity building project cooperated with the SCBD regarding the realisation of the African regional workshop on capacity building and exchange of experiences on risk assessment and risk management of living modified organisms. This workshop took place in Addis Ababa from 23<sup>rd</sup> to 25<sup>th</sup> August 2007, back to back with the AU expert meeting on the revised African model law on safety in biotechnology.

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 be cooperation for technical and scientific training in the proper and safe management of the extent that it is required for biosafety?	
a) yes – capacity-building needs fully met (please give details below)	
b) yes – capacity-building needs partially met (please give details below)	

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

# Article 23 – Public awareness and participation

49. Does your country promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health? (Article 23.1(a))		
a) yes – significant extent X		
b) yes – limited extent		
c) no		
50. If yes, do you cooperate with other States and international bodies?		
a) yes – significant extent	X	
b) yes – limited extent		
c) no		

51. Does your country endeavour to ensure that public awareness and education encon information on living modified organisms identified in accordance with the Protocol th 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 decision-making process regarding living modified organisms and make the results of available to the public? (Article 23.2)	
a) yes – fully	X
b) yes – limited extent	
c) no	
53. Has your country informed its public about the means of public access to the Biosa House? (Article 23.3)	afety Clearing-
a) yes – fully	X
b) yes – limited extent	
c) no	
54. Please provide further details about your responses to the above questions, as well your country's experiences and progress in implementing Article 23, including any obsimpediments encountered:	
Regarding the legal and political decisions in this field taken on European level, the alia extensive online information systems that provide the public with up-to-date information raise public awareness and to facilitate public participation,. For further details so report of the EC.	mation on this issue
At the national level generating to the German Gane Technology. Act and the correspond	nding Dogulations

At the national level, according to the German Gene Technology Act and the corresponding Regulations, public participation is mandatory in decision making processes regarding deliberate releases of LMO in cases of field trials and regarding contained use of LMO of higher risk classifications.

In addition to that, German governmental institutions and non-governmental organizations provide information on numerous web pages in German language, for example:

http://www.bvl.bund.de/cln\_027/nn\_495478/DE/06\_\_Gentechnik/gentechnik\_\_node.html\_\_nnn=true (sit e of the Federal Office for Consumer Protection and Food Safety acting as the German National Competent Authority to the BCH and Point of Contact for Art. 17 of the Protocol)

http://www.biosafety-bch.de/

http://www.biosicherheit.de/schule/

http://www.transgen.de/home/

Article 24 – Non-Parties

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

55.	Have there b	been any	transbound	lary movei	ments of liv	ing modified	organisms	between	your o	country
anc	d a non-Party	during th	e reporting	g 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:

Authorised LMO are imported into Germany to a very large extent from non-Parties of the Protocol such as the USA and Argentina.

Once authorised, Germany did not get notice of any impediments or difficulties encountered regarding the import of these LMO.

## 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)

measures? (Article 25.1)	or its domestic
a) yes	X
b) no	
58. Have there been any illegal transboundary movements of living modified organism country during the reporting period?	ms into your
a) yes	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:

# Question 57:

b) no

Germany has implemented domestic measures to prevent and penalize illegal transboundary movements (for details see answer to question 4 above). Additionally see EC-report.

#### Ouestion 58:

Several cases of unintentional transboundary movement of GMOs and products thereof were made public in Germany:

- 1) In 2003, genetically modified papaya with provenance Hawaii, USA, were detected on the market. Genetically modified papaya is not authorized for placing on the market in the EU. Detected fruits were withdrawn from the market. Likewise, the respective lots were withdrawn from the market.
- 2) In 2006, adventitious presence of genetically modified long corn rice of two different events with the origin of US (non-party to the Protocol) was detected in rice and rice products already on the market in Germany (and many other member states). Genetically modified rice is not authorized for placing on the

#### market in the EU.

After the detection of these LMO,

- b) all EU Member States were informed about this occurrence,
- c) intensive communication took place at different levels including:
  - institutions involved in risk analysis and risk management
  - administrative institutions
  - inspection and control services
  - technical services
  - private sector

in order to minimise the possibility of market infiltration of these products, and to prevent further submission of affected lots. Respective lots were and are still withdrawn from the market.

3) At the turn of 2006/2007, genetically modified ornamental fishes (*Danio rerio*) were detected on the market in Germany. Inspection and control services of the competent authorities of the Federal Länder withdrew these fishes from the market and are tracing the origin of these fishes.

Obstacles in these cases are:

- lack of time
- information flow in the beginning of an incident
- access to validated detection methods in case of LMO not authorised for placing on the market in the EU
- to obtain (certified) reference material
- agreement on sample protocols
- fast product distribution chains

#### *Article 26 – Socio-economic considerations*

60. If during this reporting period your country has taken a decision on import, did it to socio-economic considerations arising from the impact of living modified organisms of and sustainable use of biological diversity, especially with regard to the value of biological genous and local communities? (Article 26.1)	n the conservation
a) yes – significant extent	
b) yes – limited extent	X
c) no	
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:

The EC's domestic legislative framework includes Socio-economic considerations. This framework is compatible with the provisions of the Protocol.

Socio-economic considerations have been i.e. relevant at Member State level for the question of coexistence. In Germany a regulation dealing with the good technical farming practice including coexistence measures for maize is currently under parliamentary discussion.

Additionally see EC-report.

#### 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:

In the context of bilateral technical cooperation, financial resources were made available as follows:

Africa: Support of the AU, project costs: 2.000.000 Euro

Sri Lanka: Support IUCN Regional Biodiversity Project, project costs: 1.636.000 Euro

China: Support of NIES/SEPA, project costs 215.000 Euro Algeria: Support of AREA ED, project costs 153.000 Euro

Peru: Support of SPDA, project costs: 17.000 Euro

Colombia: Biosafety Capacity Building and Awareness Raising, 20.000 Euro

Furthermore, additional financial resources were made available from the project "Implementing the biodiversity convention", although no exact figures can be given since the project offers policy advice for the implementation of the CBD and its Cartagena protocol.

In the field of capacity building in development-oriented plant biotechnology (technology transfer and management training), Germany has executed training with a value of approx. 2.5 million Euro between 1996 and 2006 (with an increased amount since 2003) for participants from developing countries.

Taking into account that 40,5% of all the GEF contribution are spent towards the biodiversity focal area, the German contribution towards biodiversity issues can be calculated as approximately 365 million US \$ over the period 1991-2006, or approx. 23 million Dollar per year. With view to GEF biosafety activities, it is not possible to compute the precise contribution.

# 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:

#### ANNEX 1

#### German legislative acts and measures submitted to Biosafety Clearing House

- 1. Gesetz zur Regelung der Gentechnik (Gentechnikgesetz GenTG)
- 2. Gesetz zur Durchführung der Verordnungen der Europäischen Gemeinschaft auf dem Gebiet der Gentechnik und zur Änderung der Neuartigen Lebensmittel- und Lebensmittelzutaten-Verordnung (EG-Gentechnik-Durchführungsgesetz EG-GenTGDurchfG)
- 3. Gesetz zur Anpassung von Zuständigkeiten im Gentechnikrecht
- 4. Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Gentechniksicherheitsverordnung GenTSV)
- 5. Verordnung über die Zentrale Kommission für die Biologische Sicherheit (ZKBS-Verordnung ZKBSV)
- 6. Verordnung über Aufzeichnungen bei gentechnischen Arbeiten und bei Freisetzungen (Gentechnik-Aufzeichnungsverordnung GenTAufzV)
- 7. Verordnung über Antrags- und Anmeldeunterlagen und über Genehmigungs- und Anmeldeverfahren nach dem Gentechnikgesetz (Gentechnik-Verfahrensverordnung GenTVfV)
- 8. Verordnung über Anhörungsverfahren nach dem Gentechnikgesetz (Gentechnik-Anhörungsverfahren GenTAnhV)
- 9. Verordnung über die Beteiligung des Rates, der Kommission und der Behörden der Mitgliedstaaten der Europäischen Union und der anderen Vertragsstaaten des Abkommens über den Europäischen Wirtschaftsraum im Verfahren zur Genehmigung von Freisetzungen und Inverkehrbringen sowie im Verfahren bei nachträglichen Maßnahmen nach dem Gentechnikgesetz (GentechnikBeteiligungsverordnung -GenTBetV)
- 10. Verordnung über die Erstellung von außerbetrieblichen Notfallplänen und über Informations-, Meldeund Unterrichtspflichten (Gentechnik-Notfallverordnung - GenTNotfV)
- 11. Bundeskostenverordnung zum Gentechnikgesetz (BGenTGKostV)
- 12. Verordnung zur Durchführung gemeinschaftsrechtlicher Vorschriften über neuartige Lebensmittel und Lebensmittelzutaten und über die Kennzeichnung von Erzeugnissen aus gentechnisch veränderten Sojabohnen und gentechnisch verändertem Mais sowie über die Kennzeichnung ohne Anwendung gentechnischer Verfahren hergestellter Lebensmittel (Neuartige Lebensmittel- und Lebensmittelzutaten-Verordnung NLV)

# 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