

### ***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:

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## ***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 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 European legislation is either directly applicable in Germany or has been implemented into German law. Therefore the comprehensive information given by the EU to the BCH also covers the situation in Germany.  
Additional German legislation and information in this area will be provided soon.

Information required to be provided to the Biosafety Clearing-House:

- (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))
- (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);
- (c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);
- (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));
- (e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);
- (f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));
- (g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);
- (h) Illegal transboundary movements of LMOs (Article 25.3);
- (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));
- (j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);
- (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);

(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))

(m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)

(n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);

(o) LMOs granted exemption status by each Party (Article 13.1)

(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);  
and

(q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).

## Article 2 – General provisions

2. 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	
3. 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:	
<p>Germany has implemented existing EU-legislation into national law through the German Gentechnikgesetz [Gene Technology Act] and the EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs]. The final part of the implementation is currently under parliamentary negotiations.</p> <p>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.</p> <p>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.</p> <p>As defined by the EG-Gentechnik-Durchführungsgesetz [German Law regulating the implementation of the European provisions in the field of GMOs] the Federal Office for Consumer Protection and Food Safety [Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL] acts as national contact point. A unit is dedicated to meet the tasks required by the Biosafety Protocol.</p>	

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

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

4. Is there a legal requirement for the accuracy of information provided by exporters <u>1/</u> under the jurisdiction of your country? (Article 8.2)	
a) yes	X
b) no	
c) not applicable – not a Party of export	
5. 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) no	
c) not applicable – not a Party of export	X
6. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
7. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Not applicable - not a party of export	
8. If your country has taken decisions on import of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
Not applicable - no decision taken during the reporting period.	

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

**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.

9. 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) no	
c) not applicable (please give details below)	
10. 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
11. 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	
12. 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 - not a party of export	
13. 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:	
As a member of the EU Germany applies EU legislation. For further details please see the reply in the report of the EU.	

**Article 13 – Simplified procedure**

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

14. If your country has used the simplified procedure during the reporting period, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:

Not applicable

**Article 14 – Bilateral, regional and multilateral agreements and arrangements**

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

15. If your country has entered into bilateral, regional or multilateral agreements or arrangements, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:

Please see the reply in the report of the EC.



**Articles 15 and 16 – Risk assessment and risk management**

16. 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	X
17. If yes, 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	X
18. 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	
19. 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	X
b) no	
20. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes	X
b) no	
21. 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)	

22. 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)	
23. 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 assessments on the basis of the relevant EU legislation. 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.

24. 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) partially (please clarify below)	
c) no (please clarify below)	
25. 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 – no such occurrence	

**Article 18 – Handling, transport, packaging and identification**

26. 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) no	
c) not applicable (please clarify below)	
27. 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) no	
28. 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) no	
29. 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) no	
30. 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 18, including any obstacles or impediments encountered:	
Germany has implemented the relevant EU legislation including provisions on handling, transport and packaging. See reply of the EU for further details.	

***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.

31. 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:

See reply of the EU.

**Article 21 – Confidential information**

32. 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) no	
33. 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	X
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
35. 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	

**Article 22 – Capacity-building**

36. 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	
37. If yes, how has such cooperation taken place:	
<p>Germany has taken part in EU Twinning projects for economies in transition.</p> <p>Germany hosted a workshop on capacity building and exchange of experiences on the safe handling, transport, packaging and identification of living modified organisms, as related to the implementation of paragraph 2 of Article 18 of the Protocol in Bonn, 1 -3 November 2004</p> <p>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. Within the context of this capacity building initiative, the following projects are in the process of being implemented:</p> <p>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)</p> <p>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)</p> <p>African Union: Capacity Building Programme for an Africa-wide Biosafety System, support of the AU in matters of Biosafety</p> <p>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)”</p> <p>Details about the projects objectives, activities, and status of implementation can be</p>	

found on the BCH capacity building projects database.

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

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.

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

As one of the main contributors to the Global Environment Facility (GEF), Germany supports the various GEF biosafety projects. Additionally, InWEnt Capacity Building International contributed to the execution of a Training of trainers in Malaysia within the UNEP-GEF BCH Project.

38. 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)	
b) no – we have no unmet capacity-building needs in this area	
e) not applicable – not a developing country Party or a Party with an economy in transition	X

39. 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

40. 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
41. 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:	



### **Article 23 – Public awareness and participation**

42. 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	
43. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
44. 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	
45. 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	
46. Has your country informed its public about the means of public access to the Biosafety Clearing-House? (Article 23.3)	
a) yes – fully	
b) yes – limited extent	X
c) no	
47. 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:	
<p>As the legal and political decisions in this field are taken on European level, public interest focuses on developments in Europe. To raise public awareness and to facilitate public participation, the EU maintains inter alia extensive online information systems that provide the public with up-to-date information on this issue. For further details see the reply in the report of the EC.</p> <p>Auch zur Verbesserung der Übersichtlichkeit wird vorgeschlagen, die Antwort nach dem ersten Absatz wie folgt zu fassen:</p>	

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/clin\\_027/nn\\_495478/DE/06\\_Gentechnik/gentechnik\\_node.html\\_nnn=true](http://www.bvl.bund.de/clin_027/nn_495478/DE/06_Gentechnik/gentechnik_node.html_nnn=true) (site of the Federal Office for Consumer Protection and Food Safety acting as the German contact point to the BCH)  
<http://www.biosicherheit.de/schule/>  
<http://www.transgen.de/home/>

The Federal Office for Consumer Protection and Food Safety intends to translate relevant information of the BCH homepage into German language. Information regarding results of German risk assessments will be translated at least into one official UN-language."

**Article 24 – Non-Parties**

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

48. 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:

No transboundary movement during reporting period

**Article 25 – Illegal transboundary movements**

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

49. 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

50. 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:

Germany has implemented domestic measures to prevent and penalize illegal transboundary movements (for details see answer to question 3 above).

**Article 26 – Socio-economic considerations**

51. 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	
52. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	X
c) no	
53. 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 are part of a wider discussion on the use and impact of genetically modified organisms. These issues are currently discussed in connection with drafting national rules for coexistence as well as European guidelines for coexistence (see EU answer).	

**Article 28 – Financial mechanism and resources**

54. 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	
55. 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:	
<p>In the context of bilateral technical cooperation, financial resources were made available as follows:</p> <p>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 205.000 Euro          Algeria, Support of AREA ED, project costs 153.000 Euro          Peru, Support of SPDA, project costs: 17.000 Euro</p> <p>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.</p> <p>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. 30 million Euro per year. With view to GEF biosafety activities, it is not possible to compute the precise contribution.</p>	

***Other information***

56. 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:

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***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:

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