

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

Origin of report

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<i>Submission</i>	
Signature of officer responsible for submitting 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:

The draft was drawn out by the seven government ministries responsible for implementation of the Cartagena Protocol on Biosafety. Then this report was authorized after getting public comments to the draft.

Obligations for provision of information to the Biosafety Clearing-House

<p>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):</p>			
<p>Japan has been providing relevant information to the BCH.</p>			
<p>2. Please provide an overview of information that is required to be provided to the Biosafety Clearing-House:</p>			
<i>Type of information</i>	<i>Information exists and is being provided to the Biosafety Clearing-House</i>	<i>Information exists but is not yet provided to the Biosafety Clearing-House</i>	<i>Information does not exist /not applicable</i>
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
<i>Type of information</i>	<i>Information exists and is being provided to the Biosafety Clearing-House</i>	<i>Information exists but is not yet provided to the Biosafety Clearing-House</i>	<i>Information does not exist /not applicable</i>
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			X

regarding products thereof (Article 20.3(c)).			
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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:	
The domestic law for the implementation of the Cartagena Protocol on Biosafety was promulgated in June 2003, and has been fully implemented since February 2004 when the Cartagena Protocol on Biosafety came into force for Japan.	
The law requires that persons who wish to use new LMOs in the environment (developers and importers, etc.) to carry out a prior risk assessment on their impacts on biodiversity and then to obtain approval of the competent ministers.	

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	
b) no	X
7. Is there a legal requirement for the accuracy of information provided by exporters ^{1/} under the jurisdiction of your country? (Article 8.2)	
a) yes	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)	

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

b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	X
9. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
10. If your country has been a Party of export of LMOs intended for release into the environment during the reporting period, please describe your experiences and progress in implementing Articles 7 to 10 and 12, including any obstacles or impediments encountered:	
LMOs intended for intentional introduction into the environment has not been exported so far.	
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:	
Japan has not taken decisions on import in accordance with the advance informed agreement procedure.	

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

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

12. Is there a legal requirement for the accuracy of information provided by the applicant with respect to the domestic use of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing? (Article 11.2)	
a) yes	X
b) not yet, but under development	
c) no	
d) not applicable (please give details below)	
13. Has your country indicated its needs for financial and technical assistance and capacity-building in respect of living modified organisms intended for direct use as food or feed, or for processing? (Article 11.9)	
a) yes (please give details below)	
b) no	X
c) not relevant	
14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	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:
No export of LMOs intended for direct use as food or feed, or for processing has been made so far.
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:
Under the domestic law for the implementation of the Protocol, biological diversity risk assessment regarding domestic use of LMOs intended for direct use as food or feed, or for processing is carried out on the basis of the Biological Diversity Risk Assessment Report submitted by the applicant, and approval is given if it is recognized that there is no possibility of adverse effect on biodiversity. When Japanese government approved LMOs, the information of the LMOs has been notified to the BCH with relevant information.

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:	
Japan has not used simplified procedure.	

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:	
Japan has not entered into any agreement or arrangement in question.	

Articles 15 and 16 – Risk assessment and risk management

21. If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2)	
a) yes	
b) no (please clarify below)	
c) not a Party of import / no decisions taken under Article 10	X
22. If yes to question 21, did you require the exporter to carry out the risk assessment?	

a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	X
23. If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3)	
a) yes – in all cases	
b) yes – in some cases (please specify the number and give further details below)	
c) no	
d) not a Party of import / no decisions taken under Article 10	X
24. Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)	
a) yes – fully established	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)	
b) no (please give further details below)	X

28. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered:

Under the domestic law for the implementation of the Protocol, persons who wish to use new LMOs in the environment (developers and importers, etc.) must carry out a prior risk assessment of adverse effect on biological diversity in accordance with the Guidance of Implementation of Assessment of Adverse effect on Biological Diversity. The competent ministers may grant approval when recognizing, taking account of the content of consultation with experts, that no adverse effect on biological diversity could arise. Persons who wish to export LMOs to Japan from a foreign country and to make them used in Japanese environment, may appoint a Domestic Manager who has an address in Japan and obtain such approval.

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:

No such case has been reported.

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
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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 domestic law for the Protocol stipulates that the package, vessel and invoice, etc. of LMOs intended for export to a Party must be accompanied by the descriptions of the required specific matters. Their specific formats are set forth in the Regulations of the Law. What has to be described differs, based on the provision of the Protocol, depending upon whether they are LMOs intended for contained use, or LMOs intended for use as food or feed or for processing, or LMOs intended for other use.	

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:
Any information required to be made available to the BCH under the Protocol has been directly conveyed to the BHC through its management center. As an equivalent to BCH at national level, the Japanese version of the Biosafety Clearing-House (J-BCH) is operated, where information on the Protocol and Japanese legislation as well as database on LMOs approved in Japan are posted. On the website, information on the legal mechanisms under Japanese legislation and on LMOs (the usage of LMOs approved in Japan and the outlines of risk assessments) are also available in English.

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:	
No import of LMOs intended for intentional introduction into the environment has been made from any Party to the Protocol.	
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:	
No export of LMOs intended for intentional introduction into the environment has been made.	

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:	
Japan has been contributing financial resources to the GEF, which has been implementing a number of projects to build capacity on biosafety.	
Japan has been implementing a capacity-building project on biosafety in the Asian region through contributions to the trust fund of the UN Food and Agriculture Organization (FAO).	

Ten Japanese experts are inscribed on the Roster of Biosafety Experts posted on the BCH.	
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:

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	
b) yes – limited extent	X
c) no	
51. Does your country endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported? (Article 23.1(b))	
a) yes – fully	
b) yes – limited extent	X
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	
b) yes – limited extent	X
c) no	
54. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 23, including any obstacles or impediments encountered:	
Information on LMOs including the status of development and uses of LMOs in Japan is made available on the websites of the ministries concerned and J-BCH.	
Furthermore, access to the information posted on the BCH is facilitated through links to the BCH.	

In approving the use of LMOs in the environment, the outline of the Biological Diversity Risk Assessment Report as well as the content of consultation of the experts on the application concerned are released for public comments and the outcome of the decision is also released on J-BCH and other relevant websites.

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:	
<p>Japan imports genetically engineered crops and LMOs intended for contained use from Non-Parties. A person who wishes to use LMOs in the environment in Japan (including the distribution of living seeds as food or as feed) must obtain approval under the domestic law for the Protocol. Therefore, any LMO that has not been approved in Japan can not be used in the environment even if it is imported from a Non-Party.</p> <p>Having obtained the information that some genetically engineered corns (Bt 10) which were inadvertently cultivated in the United States, a Non-Party, were likely to have been exported to Japan, Japanese competent authorities checked the corns being imported into Japan from the US at borders, based on the relevant laws and regulations, and confirmed that Bt 10 were detected from some cargos. Accordingly, measures have been taken to prevent their distribution in Japan.</p>	

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:	
<p>Having obtained the information that some genetically engineered corns (Bt 10) which were inadvertently cultivated in the United States, a Non-Party, were likely to have been exported to Japan, Japanese</p>	

competent authorities checked the corns being imported into Japan from the US at borders, based on the relevant laws and regulations, and confirmed that Bt 10 were detected from some cargos. Accordingly, measures have been taken to prevent their distribution in Japan.

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:	
No decision has been taken.	

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:	
Japan has been contributing financial resources to the GEF, which has been implementing a number of projects to build capacity on biosafety.	

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:
To enable the Parties to share information on LMOs likely to be distributed internationally, we propose that the Parties make available to the BHC as much information as possible on the following matters on a voluntary basis:

Information on LMOs that are at a field experiment stage (limited field testing and large-scale field testing): information on the recipient organism, introduced trait, conductor of the experiment , cultivation area and period of implementation, etc.

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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