

Origin of report

Party	FINLAND
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Submission	
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:

Ministry of the Environment (Cartagena Protocol on Biosafety National Focal Point) has prepared the interim national report of Finland. The Board for Gene Technology/Ministry of Social Affairs and Health (Competent National Authority), Ministry of Agriculture and Forestry, Ministry of Trade and Industry and Ministry of Foreign Affairs have also involved in the preparation work.

It should be noted that this interim national report should be read in conjunction with the interim report produced by the European Commission on the implementation of the Protocol at EU level. The Finnish interim report describes only aspects related to the national implementation of the Protocol.

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):

Finland has submitted the following information to the BCH:

- Existing national legislation (further information will be submitted when translated in English)
- Contact information on the Cartagena Protocol on Biosafety National Focal Point (art 19), Competent National Authority (Art 19), BCH National Focal Point (Art 19) and Emergency Measures Contact Point (art 17)
- Addresses of the national biosafety websites

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>Finnish legislation implements the present GMO legislation in the EU (especially Directives 2001/18/EC, 90/219/EC, 98/81/EC and Regulations (EC) No. 1829/2003, 1830/2003, 1946/2003) fulfilling also the requirements of the Protocol.</p> <ul style="list-style-type: none"> • Gene Technology Act (377/1995; amended in 2000 and 2004) regulating contained use, deliberate release and placing on the market of GMOs • Government Decree on Gene Technology (928/2004) issues further provisions specified in the Gene Technology Act • Penal code (578/1995) contains e.g. sanction and punishment provisions concerning illegal import of GMOs • Decree of the Ministry of Social Affairs and Health (110/2005) on deliberate release of GMOs • Decree of the Ministry of Social Affairs and Health (90/2005) on differentiated procedures related to deliberate release of GMOs • Decree of the Ministry of Social Affairs and Health (184/2005) on inspection procedure laid down by the Gene Technology Act • Decree of the President of the Republic (130/2004) on the ratification of the Cartagena Protocol on Biosafety under the Convention on the Biological Diversity and on the entry into force of the Act implementing the provisions related to the field of legislation of the Protocol • Government Decree (277/2005) on the chargeable services in accordance with the Gene Technology Act • Several specific laws, e.g. Pesticide Act (327/1969), Food Act (361/1995) and Feed Act (396/1998), issue specific provisions concerning GMOs • Decree of the Ministry of the Trade and Industry on the national arrangements provided the entry into force of the Regulation (EC) 1829/2003 • Regulations (EC) No. 1946/2003, 1829/2003 and 1830/2003 shall apply directly in Finland <p>The content of the regulations (mainly in Finnish) can be found on the following website of the Competent National Authority: www.geenitekniikanlautakunta.fi</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 - Finland has not been 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:	
<p>Not applicable – no decisions taken during the reporting period.</p> <p>Finland applies its domestic legislation which implements also the relevant Community legislation governing the authorization of GMOs to be released to the environment. The legislation is compatible with the provisions of the Protocol.</p> <p>Introduction of GMOs in to the environment for the experimental purposes obtain an authorization from the competent authority in Finland in accordance with the Gene Technology Act.</p> <p>Placing on the market of GMOs (product authorization) will follow the Community authorization procedure.</p>	

1/ 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	
b) no	
c) not applicable – no decisions taken during the reporting period	x
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 Party of export during the reporting period.	
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:	
Not applicable.	

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:
The simplified procedure has not been used during the reporting period.

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:
Not applicable.

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)	
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:	
<p>All activities within the framework of the Protocol and intended for release into the environment or placing on the market of GMOs in Finland are subject to the prior risk assessment and management. Comprehensive risk assessment is conducted in accordance with the procedures established in the Community and domestic legislation with a view to identify if there is a need for risk management. The risk assessment is carried out by the notifier and evaluated by the competent authority in Finland, which can consult relevant scientific expert institutions on a case-by-case basis.</p> <p>Finland has cooperated with the EU member states for the purposes specified in Articles 15 and 16.</p>	

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)	x
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.	

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:	
Finland has introduced in the domestic legislation the measures and regulations approved in the European Community concerning the requirements of handling, transport, packaging and identification of GMOs.	

Article 19 – Competent national authorities and national focal points

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

Competent National Authority:

Board for Gene Technology; subordinate to the Ministry of Social Affairs and Health

- All functions pursuant to the Cartagena Protocol on Biosafety
- Advisory functions in environmental safety issues
- Gene technology and ethical expertise
- Supervises the use of GMOs both for research and commercial purposes
- Animals, Fishes, Microorganisms, Plants

National Focal Points:

- Mr. Jyrki Pitkälä; Senior Adviser, Ministry of the Environment -- Cartagena Protocol on Biosafety National Focal Point
- Mrs. Irma Salovuori; Secretary General, Board for Gene Technology, Ministry of Social Affairs and Health -- Biosafety Clearing-House Focal Point, Emergency Measures (Article 17) Contact Point

All information on the competent national authority and national focal points has been provided to the BCH.

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:
Finland has designated the Secretary General (Mrs. Irma Salovuori) of the Board for Gene Technology as the BCH National Focal Point.

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:	
Any information or documents produced in the context of the implementation of the Protocol are subject to the provisions on publicity and confidentiality of documents laid down in the Act on the Openness of Government Activities (621/1999) and Gene Technology Act (377/1995).	
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.	

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	x
c) not applicable – not a developed country Party	
37. If yes, how has such cooperation taken place:	
Finland is currently analyzing options to participate in the development and enforcement of a biosafety capacity building 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	
b) yes – limited extent	x
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>Finnish legislation promotes public participation as an integral part of environmental policy in compliance with the Community legislation. Finland has been a Party of the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters since 2004. Finnish legislation is compatible with the provisions of the Convention.</p> <p>Gene Technology Act provides provisions of the public participation concerning the decisions making process of a) contained use and b) deliberate release into the environment of GMOs:</p> <p>a) The Board for Gene Technology may decide that the public must be consulted in regard to certain circumstances related to the proposed contained use. The consulting and the supplying of documents are subject to the provisions on confidentiality laid down in the Act.</p> <p>b) The Board for Gene Technology shall consult the public in regard to a planned deliberate release into the environment for any other purpose than for placing on the market. The Board shall inform about having received the above-mentioned application at least in the Official Gazette.</p> <p>At least the following particulars shall be reported in the Official Gazette or other media:</p> <ol style="list-style-type: none"> 1) the right of access of the public to documents regarding the deliberate release for any other purpose than for placing on the market; 2) at which agency and how the access to the documents is arranged; 3) possibility to obtain a copy of the application document; 4) to which authority written opinions shall be addressed; and 5) 60 days' time limit for consulting and when the time limit expires. <p>The consulting and the supplying of documents are subject to the provisions on confidentiality in the Act.</p> <p>In cases of GMO notifications for placing on the market of GMOs the Commission of the EU is responsible for the public consultation procedure according to the Community legislation. Regulation (EC) No 1829/2003 issues the public participation procedures in cases of GM food and feed products.</p> <p>According to the Government Decree on Gene Technology the Government appoints the Advisory Board for Biotechnology which has in its capacity of an advisory body e.g. a duty to organize information and training in the field of biotechnology and in particular gene technology.</p>	

The Board for Gene Technology (Competent Authority of the Protocol and BCH National Focal Point) maintains website (<http://www.geeniteknikanlautakunta.fi>), in which information (mainly in Finnish so far) on the Board, national and Community GMO legislation, topical issues, public participation procedures, notification materials, and authorized field releases and GMO products can be obtained. This information includes also specific data on the provisions of export and import of GMOs based on the Cartagena Protocol, domestic and EU legislation. This biosafety information is also available in the LUMONET database (Finnish Clearing-House Mechanism of the Convention on Biological Diversity; <http://www.ymparisto.fi/default.asp?node=5318&lan=fi>) maintained by the Finnish Environment Institute (SYKE).

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 movements of GMOs between Finland and non-Parties during the 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:

Finland has adopted domestic measures to prevent and penalize illegal transboundary movements of GMOs. The illegal import and export of GMOs have been regulated by the Penal Code and Gene Technology Act.

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	
c) no	x
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:	
<p>In risk assessment carried out prior to decisions on import of GMOs no account is taken of socio-economic considerations. However, these aspects may be considered in such a risk analysis process where issues of coexistence between GM and non-GM agricultural planting are concerned. In this regard, Ministry of Agriculture and Forestry of Finland has established an expert working group and a steering group to consider national strategies, measures and guidelines to ensure the coexistence of GM crops with conventional and organic farming. The groups will end their work during the year 2005.</p>	

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:

Finland has contributed the BI Trust Fund to facilitate participation of Parties in the OETEG on Art. 18.2(a) and MOP2 meetings.

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:

No further comments.

Comments on reporting format

The wording of these questions is based on the Articles of the Protocol. Please provide information on any difficulties that you have encountered in interpreting the wording of these questions:

No difficulties encountered.