

*Origin of report*

Party	ITALY
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Submission	
Signature of officer responsible for submitting report:	Aldo Cosentino
Date of submission:	September 9, 2005

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

This report has been prepared by the Italian National Competent Authority for the release of genetic modified organisms with the involvement of the National Interministerial Advisory Committee for Biosafety, which includes experts and representative of several Ministries (including Agriculture and Health Ministries), Research Institutes and Regional Governments.

## *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):

Italy has provided an initial set of information to the central portal of the BCH. More comprehensive, effective and updated information will be available once the Italian node of the BCH will be completed. The Italian node is presently online (at <http://bch.minambiente.it>) as a "work in progress" webpage.

However, many information concerning Italy are provided by the European Commission (EC), as far as the legislation of the European Union (EU) is concerned.

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:	
Most of the legislative measures for the activities within the scope of the Protocol have been adopted by the EU (see the EC interim Report). Italy has set up a national framework for the implementation and enforcement of such measures, including sanction for violations.	

**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:	
Italy has not exported LMOs during the reporting period.	
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:	
The EU internal legislative framework, which is fully compatible with the provisions of the Protocol, is described in the EC interim Report. Italy participates to the EU decisional mechanisms, according to the EU legislation.	

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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	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:	
Italy has not exported LMOs 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:	
The EC interim Report provides an overview of the EU legal framework in this area. This framework also applies to Italy.	

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

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

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

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:
Italy has not entered into any bilateral, regional or multilateral agreements or arrangements as per Article 14(1).
Being part of the EU, Italy relies on the EU existing legislative framework for intentional movements of LMOs within the Community and for imports of LMOs into the EC (as per Article 14(4) and 9 (2) (c)). This decision has been communicated to other Parties through the Biosafety Clearing-House by 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:	
<p>A general overview of the mechanisms for the risk assessment and risk management in the EU is provided by the interim Report of the EC. As EU Member State, Italy participates to the LMOs risk assessment and risk management procedures established in the Community for the placing in the market of such products.</p> <p>For the experimental release of LMOs, Italy has a national procedure according to Dir. 2001/18/EC. The procedure includes a risk assessment by the National Interministerial Advisory Committee (Commissione Interministeriale di Valutazione). The Committee must take in consideration the opinion of the public, which is informed through the Italian node of the Biosafety Clearing House. A decision on the request for experimental release of LMOs is taken by the National Competent Authority, based on the opinion of the Advisory Committee.</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:	
No unintentional release of LMOs has occurred in Italy during the reporting period.	
The Comando Carabinieri Tutela Ambientale (CCTA, which deals with environmental risks and	

monitoring and is under direct control of the Minister for the Environment), has been charged of the task of National Contact Point for notifications under Article 17 of the Protocol.

**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:	
The questions above address issues which are mainly of competence of the EU. An overview of the issues related to Article 18 of the Protocol is therefore provided in the EC interim report.	

***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:

The Italian node of the Biosafety Clearing House includes functions requested by the Cartagena Protocol and by the EU and National Law for the public information and participation, also in compliance with the Aarhus Convention on access to information, public participation in decision making and access to justice in environmental matters.

*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:	
The relevant legislation is provided by Dir. 2001/18/EC, Reg. EC/1829/2003 and Reg. EC/1946/2003. A general overview of such legislation is provided in the EC interim Report.	
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:	
Italy has not exported LMOs during the reporting period.	

*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)	X
b) no	
b) not applicable – not a developed country Party	
37. If yes, how has such cooperation taken place:	
Italy has cooperated on the issue of capacity building on Biosafety with several partners and/or institutions including through funding of: <ul style="list-style-type: none"> <li>- the GEF;</li> <li>- the European Union;</li> <li>- the Secretariat of the Convention of Biological Diversity; the International Centre for Genetic Engineering and Biotechnology (ICGEB).</li> </ul>	
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)	
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

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)	
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
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:	
Not further comments.	

*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>The general outline of the EU mechanisms for the public consultation and participation for the placing on the market of LMOs products is included in the EC interim report.</p> <p>In Italy, the mechanism in place concerns the experimental release of LMOs, and includes a dedicated web page for the information of the public and a 30 day period to allow the public consultation. Public hearing may be decided by the National Interministerial Advisory Committee) or the National Competent Authority.</p> <p>The Italian node of the BCH is still in progress. We plan specific initiatives to inform the public about the means of access to the BCH at a later stage.</p>	

### **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:
Italy has not exported LMOs during the reporting period.
About the import of LMOs, in the past a non authorised presence of LMOs has been discovered in non-LMO seeds from non Parties. After a large effort for sampling and analysis of non-LMOs seed lots of certain crops (maize and soybeans) the level of LMO contamination has been greatly reduced.
Other cases of presence of non authorised LMOs have been more recently discovered in LMOs-FFP from a non Party. A specific protocol for sampling and analysis is now in place in the EU.

### **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:	
A full set of measures is in place for the import of LMOs in Italy.	

*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	X
c) no	
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:	
<p>The issue of socio economic impacts (both positive and negative) of LMOs is, as appropriate, taken in consideration in the risk management of LMOs.</p> <p>In particular, Italy has enacted a National Law to allow co-existence of transgenic , traditional and organic crops, based on a EC Recommendation on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming issued by the EC (Recc. 2003/556/EC).</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:	
Italy provides funds to several agencies and institutions (see answer 36) involved in capacity building activities.	

*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:

Nor 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:

We had no difficulty in interpreting the wording of the question of this questionnaire.