

Origin of report

Party	Portugal
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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:

This report has been prepared by the Portuguese Competent Authority for the release of genetically modified organisms and for the implementation of Cartagena Protocol on Biosafety (Institute for the Environment).

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):

Portugal is gathering all the information required to be provided to the Biosafety Clearing-House. The information will reflect current status.

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>As a member of the European Union, Portugal is subject to EU regulations on GMOs. Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment has been incorporated into Portuguese law by the Decree law no. 72/2003, of 10th April, which regulates the deliberate release and placing on the market of GMOs.</p> <p>At EU level, it has been developed a comprehensive legal framework on GMOs, which also addresses handling, transport, packaging and identification requirements. Of the recently adopted legal acts, the following are of direct relevance to implementation of Cartagena Protocol:</p> <ul style="list-style-type: none"> - Regulation (EC) 1946/2003 of 15th July 2003 on transboundary movements of genetically modified organisms; - Regulation (EC) 1829/2003 of 22nd September 2003 on genetically modified food and feed; and - Regulation (EC) 1830/2003 of 22th September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. <p>Regulations 1829/2003 and 1830/2003 have been linked to the Portuguese GMO law where penalties can be found.</p> <p>The Instrument of Acceptance of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity was deposited by Portugal on 30th September 2004.</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?	

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

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 - Portugal has not been a Party of export of LMOs intended for release into the environment.	
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:	
Portugal implements EU and domestic legislation regulating the authorisation of LMOs intended for release into the environment, both for experimental or commercial purposes. The legislation is compatible with the provisions of the Protocol. According to EU legislation (EU Dir. 2001/18 and Reg. 1829/2003) all decisions concerning imports for placing on the market, including release into the environment, are made at the EU level. Decisions on releases in the form of field trials are made at the national level and are always based on an application that corresponds with the provisions of articles 5-11.	

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. Portugal has not been a Party of export of LMOs intended for direct use for food or feed, or for processing, during the reporting period.	
Regarding imports and according to EU legislation (Directive 2001/18/EC and Regulation 1829/2003) all decisions concerning imports for placing on the market, including release into the environment, are made at the EU level.	
Regarding exports, EU Reg. 1946/2003 stipulates the obligations of exporters of GMO-FFPs from an EU member-state to a third country. The exporter must comply with decisions of the importing country regarding GMO-FFPs.	
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:	
Portugal has not been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period.	
All the recently approved European Community Regulations concerning genetically modified food and feed, transboundary movements, and the traceability and labelling of GMOs, as well as the traceability of products made using GMOs are directly 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:
Portugal has not used the simplified procedure 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:
Portugal has not entered into bilateral, regional or multilateral agreements or arrangements, during the reporting period.

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	
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>Portugal has not been a party of import during the reporting period. But several notifications for placement on the market have been made via the EU application system. EU legislation stipulates that all notification must contain a risk assessment as outlined in EU Dir. 2001/18. This implies an assessment of the LMO on a lifetime basis. Risk assessments are to be evaluated by all member-states.</p> <p>This assessments conducted on a “case by case” basis in accordance with the procedures laid down in EU and national legislation, are carried out firstly by the notifier and then evaluated by the national scientific advisory technical bodies that support decisions taken by ministries responsible for GMO's management.</p> <p>As a EU Member State, Portugal performs risk assessment and risk management following the procedures laid down in the European legal framework concerning placing on the market of LMO.</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:	
Portugal has incorporated into domestic legislation, measures concerning the requirements for handling, storage, packaging and transport and identification of LMOs and is implementing the measures and regulations approved at European Union level	

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:
Portugal is currently gathering information in order to incorporate into the exchange mechanism, and is in the process of creating a national BCH portal for the Protocol and studying the interoperability between this and the central portal.

Article 21 – Confidential information

32. Does your country have procedures to protect confidential information received under the Protocol and that protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms? (Article 21.3)	
a) yes	X
b) no	
33. If you were a Party of import during this reporting period, did you permit any notifier to identify information submitted under the procedures of the Protocol or required by the Party of import as part of the advance informed agreement procedure that was to be treated as confidential? (Article 21.1)	
a) yes	
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import	X
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
35. If you were a Party of export during this reporting period, please describe any impediments or difficulties encountered by you, or by exporters under your jurisdiction if information is available, in the implementation of the requirements of Article 21:	
Not applicable – Portugal was not a Party of export during this 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)	
b) no	
c) not applicable – not a developed country Party	X
37. If yes, how has such cooperation taken place:	
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:	
No additional information.	

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	
b) yes – limited extent	X
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	
b) yes – limited extent	X
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	X
b) yes – limited extent	
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:

As foreseen by article 9 of Directive 2001/18, Portugal has to consult the public on the proposed deliberate release. It has been laid down a time-period of 60 days maximum for the public express its opinion. The procedure defined for public information integrates the following actions:

- Informing the mayors of the towns where the deliberate release is to take place;
- Advertising in national newspapers;
- Highlighting the public consultation and putting available the non confidential part of the notification in the website of Institute for the Environment (www.iambiente.pt).

Afterwards, we also put available on the website, the decisions taken and a list of the field trials in place.

Portugal has put available in the website of the Institute for the Environment information regarding GMO regulations, news, field trials, etc. This website is not yet fully developed but the BCH mechanism is described and a link to the central BCH is provided.

Moreover, Portugal is a Party to the Aarhus Convention on Access to information, public participation in decision-making and access to justice in environmental matters.

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:
There have not been transboundary movements of living modified organisms between Portugal and a non-Party.

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:	
As an EU Member State, Portugal is obliged to apply adequate standards, determining the application of penalties in the case of infringement of European and national law on GMOs. The main legal measures include: -Article 33 of the EC Directive 2001/18 on the deliberate release into the environment of GMOs; -Article 18 of Regulation No 1946/2003 on transboundary movements of genetically modified organisms; -Article 45 of Regulation No 1829/2003 on genetically modified food and feed. Portuguese legislation on GMOs foreseen penalties and sanctions for the previous situations. However, in what concerns to Regulation No 1946/2003, it was already prepared a legal act proposing penalties, but it has not yet entered into force.	

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:	
According to the EU system, risk assessment is carried out prior to decisions on the placing on the market of GMOs. In this process, no account is taken of socio-economic considerations, although these are included in a subsequent risk analysis process, in the case of transgenic, conventional and ecological crops coexistence. In this regard, Portugal is about to adopt a Decree-law that will introduce coexistence measures in Portugal, namely for transgenic maize.	

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	
b) yes – received financial resources from other Parties or financial institutions	
c) both	
d) neither	X
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:	
Not applicable.	

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:

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 have been encountered in interpreting the wording of these questions.