Origin of report

Party	**SPAIN**
Contact officer for report	
Name and title of contact officer:	***ANA FRESNO*** ***BIOTECHNOLOGY COORDINATOR*** ***BCH FOCAL POINT***
Mailing address:	***MINISTERIO DE MEDIO AMBIENTE*** ***PLAZA SAN JUAN DE LA CRUZ, S/N*** **28071 - MADRID**
Telephone:	***34-914535362***
Fax:	***34-915340582***
E-mail:	***Afresno@mma.es***
Submission	
Signature of officer responsible for submitting report:	
Date of submission:	

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:

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):
Spain has submitted the following to the Biosafety Clearing House: – **Existing national legislation for the implementation of the Protocol** – **Contacts for the competent national authority (Articles 19.2 and 19.3) and national focal point (Articles 19.1 and 19.3)** – **Address of national biosafety Website** – **1 final decision concerning importation of LMOs (maize NK603) intended for direct use as food or feed or for processing, taken under domestic regulatory frameworks (Article 11.4)** – **Summary of risk assessment of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).**

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:	
Since the introduction of the basic legislation on GMOs by the European Union in the early 1990s, Spain has gradually implemented the legislation and adapted to subsequent legislative modifications and to adaptations to scientific and technical progress, via the following: **- Law 9/2003, 25 April, regulating the confined use, deliberate release and placing on the market of GMOs.** **- Royal Decree 178/2004, 30 January, approving general Regulations for the implementation of Law 9/2003 regulating the confined use, deliberate release and placing on the market of GMOs.** **- Instrument of Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, done in Montreal on 29 January 2000 (Official State Journal 181, 30.07.2003).** **The texts of the above legislation can be consulted on the Website of the Spanish Ministry of the Environment:** http://www.mma.es/calid_amb/seg_bio/index.htm	

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 1/ 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. Spain 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:	
Spain implements Community and domestic legislation governing the authorisation of LMOs to be released into the environment, both for experimental or commercial purposes. The legislation is compatible with the provisions of the Protocol. In the former case, importation of genetically modified seeds for use in experimental testing requires an import licence issued by the Ministry of Agriculture, which is not granted until the experimental release is authorised in accordance with domestic legislation on GMOs. **For the placing on the market of GMOs, the Community authorisation procedure is followed.**	

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:	
Not applicable.	
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:	
On 18 October Spain, as the country requesting the consent, published a Resolution authorising the importation and processing of maize NK603, following approval under the Community authorisation procedure (Commission Decision of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product, *Zea mays L.*, line NK603, genetically modified for glyphosate tolerance - OJ L 295, 18.9.2004). **All the recently approved 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.** **Generally we have no problems with seeds and mixture for feed having in account the new requirements of the traceability and labelling of GMOs.**	

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	**X**
b) no (please clarify below)	
c) not a Party of import	
17. If yes, did you require the exporter to carry out the risk assessment?	
a) yes – in all cases	**X**
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	**X**
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:	
All activities within the framework of the Protocol and intended for deliberate release into the environment in Spain are subject to prior risk assessment and management. This assessment, conducted on the basis of scientific aspects in accordance with the procedures established in Community and domestic legislation, is carried out in the first instance by the notifier and then studied and evaluated by the Spanish Biosafety Commission, which is the national scientific-technical advisory body. **Spain has cooperated with other European Union countries for the purposes specified in Articles 15 and 16 of the Protocol.**	

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:	
Spain has incorporated into domestic legislation and is implementing the measures and regulations approved at European Union level concerning the requirements for handling, packaging and transport and identification of LMOs.	

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:
Spain has designated the Directorate General for Environmental Quality and Assessment (Ministry of the Environment) as its national focal point for the BCH. **Spain is currently incorporating more data into the information 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	**X**
If yes, please give number of cases	
b) no	
c) not applicable – not a Party of import	
34. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
Under the procedures set out in Law 9/2003 (Article 20) and Royal Decree 178/2004 (Article 48) - in both cases in compliance with EU Directive 2001/18 - it is permitted in Spain to identify which information may be treated as confidential. Other provisions concerning confidentiality set out in other Community Regulations are implemented also. **No imple mentation difficulties or impediments have been encountered in the case of this article.**	
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)	**X**
b) no	
c) not applicable – not a developed country Party	
37. If yes, how has such cooperation taken place:	
Spain organised and funded the I Latin American Workshop on Biosafety Capacity-building, which took place in Cartagena de Indias (Colombia) in June 2001. The workshop was held within the framework of an Interministerial Programme on International Cooperation in the area of Conservation of Biological Diversity for Latin America (Araucaria Programme), with the aim of developing in situ activities representing a genuine advantage with respect to conservation of biological diversity that involves local communities in their own development. **The workshop helped strengthen the institutional capacities of Latin American countries to address and comply with the provisions and obligations established in the Protocol by developing their own legal and administrative framework. This includes (i) designation of a focal point, (ii) training in risk assessment and management, and (iii) appropriate decision-making procedures for transboundary movements of GMOs.** **Spain has also taken part in the Biosafety training course-workshop entitled 'Biosafety for the environment sector'.** **Univ. Nacional de Colombia and Ministry for the Environment, Housing and Regional Development. Bogotá, Colombia, 16-26 November 2004. (UNEP-GEF 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)	
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**
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	
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	
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:	
Spain promotes public participation as an integral part of environment policy generally and Biosafety in particular, in compliance with Community and national regulatory frameworks. Spain has been a Party to the Aarhus Convention since February 2005. Moreover, a draft Bill on access to information, public participation and access to justice is currently at the consultation stage. **In accordance with Community and national legal requirements, Spain complies with the information exchange system established at Community level and provides public information on activities with GMOs undertaken in the country by publishing details on the Ministry of the Environment Website. A Social Committee on GMOs, with public participation, is currently being set up**.	

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:
Spain imports transgenic maize and soya from countries who are not Parties to the Protocol (Argentina, Brazil etc). Generally, it has been found that, with LMO imports, information is provided that the product contains LMO, although in the majority of cases none is provided on the unique identifier, which is a compulsory requirement under Community legislation. **Controls are carried out at border inspection facilities, which fall within the competence of Spain's regions and difficulties still persist as regards the interpretation and application of regulations concerning traceability and labelling depending on whether the import is an LMO or a product obtained or derived from an LMO.** **Samples are taken of animal feed at borders and quantitative and qualitative tests are used to check for the possible adventitious or accidental LMO presence in excess of 0.9% and 0.5% (the thresholds established by European legislation). However, the tests are quite expensive and there are still very few approved laboratories and at times these do not have available validated methods for all LMOs that might be used in feed, whether or not authorised by the European Union**.

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:	
Spain's domestic legislation on GMOs provides for sanctions for breaches of the Cartagena Protocol, specifically in relation to imports/exports without the corresponding authorisation from the country of destination in accordance with current Community and international regulations (Article 34 and 35 of Law 9/2003).	

Article 26 – Socio-economic considerations

51. If during this reporting period your country has taken a decision on import, did it take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities? (Article 26.1)	
a) yes – significant extent	
b) yes – limited extent	
c) no	**X**
d) not a Party of import	
52. Has your country cooperated with other Parties on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities? (Article 26.2)	
a) yes – significant extent	
b) yes – limited extent	**X**
c) no	
53. Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Article 26, including any obstacles or impediments encountered:	
As in the case commented on by the European Commission, in risk assessment carried out prior to decisions on the placing on the market of GMOs 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 coexisting. In this regard, Spain is about to adopt a Royal Decree on coexistence in order to regulate such crops in Spain, particularly 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	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:	

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:
Financial support to help Latin-American countries for the participation in the ICCP 3.

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