

*Origin of report*

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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 was jointly compiled by the Department of Environmental Affairs and Tourism, the focal point for the Cartagena Protocol on Biosafety and the Department of Agriculture, the Competent National Authority. All responses in the report refer to progress made up to the end of August 2005.

The report was distributed to a number of stakeholders for feedback and verification, including the Ad Hoc Committee on the Cartagena Protocol Biosafety, Departments of Foreign Affairs, Trade and Industry, and Science and Technology; and non-governmental organisations.

*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):

Although South Africa has submitted certain information to the BCH, there is still information which is to be submitted, with special reference to information pertaining to risk assessments of Living Modified Organisms (LMOs) that have been approved in accordance with the Advanced Informed Agreement (AIA) procedure before the Protocol became effective for South Africa.

The information on South Africa on the BCH currently includes:

- Environment Conservation Act, 1989, Regulations: The Identification under Section 21 of activities which may have a substantial detrimental effect on the environment.
- Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)
- Regulations: Genetically Modified Organisms Act, 1997: Intentional introduction into the environment (AIA), LMOs for use as food or feed or for processing, Transit and contained use

South Africa is also in the process of setting up a website that will be dedicated to activities with regard to genetically modified organisms (GMO's), which includes LMO's, which should facilitate personnel dedicated to this function and the timeous submission of required information to the BCH.

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>South Africa implemented its Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) in 1999. Since then all activities with GMO's are regulated in accordance with this Act. The GMO Act, regulations, guidelines and operating procedures to a large extent, already encompasses many of the provisions of the Protocol. The remaining provisions will be incorporated into the Act during a legislative review of the Act, which is currently being conducted.</p> <p>While South Africa has implemented the GMO Act, as yet South Africa does not have an operational structure for long term monitoring of GMO's. This is being addressed in the National Environmental Management Biodiversity Act 10 of 2004 under the Department of Environmental Affairs and Tourism.</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 Completion of an affidavit to declare that information is true and accurate
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	x
c) not applicable – not a Party of export	
6. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 9.2(c).	
a) yes	x
b) no	

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

c) not applicable – no decisions taken during the reporting period	
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:	
South Africa did export LMO's intended for environmental release. However, this was only of LMO's that already have commercial release status in the Party of Import, hence the Parties of Import did not require AIA procedures before consenting to the importation.	
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 GMO Act makes provision for AIA requirements that is consistent with the Protocol, which were followed in taking decisions on the proposed importation of LMO's intended for environmental release. This system is in operation since 2000, but is continuously improving as more and more applications are assessed.	

***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	x
c) not relevant	
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:

SA did export LMO's intended for FFP, but only of LMO's that already have similar approval status in the Party of Import. No obstacles or impediments were encountered.

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:

All decisions pertaining to FFP's are taken in accordance with the provisions of the GMO Act. Obstacles experienced are being sure of what LMO's may be in the consignment based on the information available on the BCH. How can a country be absolutely sure that the Party of Export has submitted all the required information to the BCH? Bearing this in mind, a Party of Export is often required to formally indicate to Party of Import what LMO's are commercially available in the country.

#### ***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:

This is a very useful Article to prevent unnecessary delays in trade.

#### ***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:

South Africa did not enter into any bilateral, regional or multilateral agreements or arrangements

#### ***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	x
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)	x
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 applicants (notifiers) are required to conduct risk assessments at their own cost and submit this with any application for contained use, release into the environment or food, feed and	

processing. This information is reviewed through an extensive process before authorization is approved.

***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)	
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:	
South Africa did not experience any unintentional transboundary movements during this reporting period.	

***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:	
All requirements pertaining to this Article have been incorporated into export permits issued by South Africa.	

***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:
Not all countries have submitted complete information to the BCH, which makes it very difficult to make decisions, especially with regard to proposed imports for FFP. It will be useful to share information on GMO environmental risk assessments with countries that have similar environments. At this stage, South Africa is the only southern African nation that is approving GMO's for environmental and commercial release.

**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	All
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:	
In South Africa the Genetically Modified Organisms Act as well as the Promotion of Access to Information Act, make provisions for the protection of confidential business information. All applicants are therefore afforded the opportunity to indicate, within the provisions of the GMO Act as well as the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), when information should be treated as confidential and may therefore not be disclosed.	
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:	
South Africa did not experience any impediments or difficulties with regard to Article 21 for exports 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)	x
b) no	
c) not applicable – not a developed country Party	
37. If yes, how has such cooperation taken place:	

<p>South Africa is an economy in transition, but nevertheless South Africa has hosted from Lesotho, Angola, Zambia, France and the US Grains Council during this reporting period. It is noted that South Africa is often seen as the leader in applying GMO's in the context of the developing world, and especially Africa, seeks South Africa's experience to develop their domestic legislation in this regard.</p>	
<p>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?</p>	
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	x
e) not applicable – not a developing country Party or a Party with an economy in transition	
<p>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?</p>	
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	x
e) not applicable – not a developing country Party or a Party with an economy in transition	
<p>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?</p>	
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	x
e) not applicable – not a developing country Party or a Party with an economy in transition	

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	
c) no	x
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	
b) yes – limited extent	x
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:	
The GMO Act makes specific provisions for a process of public participation. In accordance	

with the National Biotechnology Strategy for South Africa, there is also a Public Understanding of Biotechnology Programme, which aims to create public awareness on biotechnology and enable informed debates on GMO's. The Department of Health also had a GMO public awareness campaign (2001/2002), but has been suspended due to a lack of sufficient funding.

There are several non-government initiatives that are aimed at communicating biotechnology to the public. These include stakeholder organizations as well as non-governmental organizations and institutions of higher learning.

**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:

Yes. As an exporter to non-parties during this reporting period, we experienced that the non-parties prefer not to follow the provisions of the Protocol and are very reluctant to adhere to national requirements that are beyond the requirements provided for by the Protocol.

**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:

South Africa makes use of inspectors to monitor all imports into South Africa and the GMO Act makes provision for penalties in cases of illegal transboundary movements.

**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	
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:	
Although socio-economic factors are taken into consideration when taking decisions in South Africa, there is a need for an international framework with regard to the socio-economic factors that should be taken into account during decision-making.	

**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:	

**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:

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