FIRST REGULAR NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Origin of report

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Submission	
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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:

Consultation with Australian Government Agencies including the Office of the Gene Technology Regulator(OGTR), Food Standards Australia New Zealand (FSANZ) and the Department of Agriculture, Fisheries and Forestry. Consultation with relevant industries including the cotton and cut flower industries.

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 Biosafety Clearing-House (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):
As Australia is not a signatory to the protocol, relevant information is provided to the OECD Bio Track Product Database. Information will be updated on a ongoing basis.

2. Please provide an overview of information that is required to be provided to the Biosafety Clearing-House:

Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
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))			X
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);	X		
c) Bilateral, multilateral and regional agreements and arrangements (Articles 14.2, 20.3(b), and 24.1);			X
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));	X		
e) In cases of multiple competent national authorities, responsibilities for each (Articles 19.2 and 19.3);			X
f) Reports submitted by the Parties on the operation of the Protocol (Article 20.3(e));			X
g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17.1);			X

Type of information	*Information exists and is being provided to the Biosafety Clearing-House*	*Information exists but is not yet provided to the Biosafety Clearing-House*	*Information does not exist /not applicable*
h) Illegal transboundary movements of LMOs (Article 25.3);			X
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));	X		
j) Information on the application of domestic regulations to specific imports of LMOs (Article 14.4);			X
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);	X		
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))	X		
m) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11.6)			X
n) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12.1);			X
o) LMOs granted exemption status by each Party (Article 13.1)			X
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);			X
q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20.3(c)).	X		

Article 2 – General provisions

3. 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	
4. 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:	
Although Australia is not a signatory to the protocol, Australia has a robust integrated legislative framework for the regulation of the development and use of genetically modified organisms (GMOs), which includes the Office of the Gene Technology Regulator (OGTR). The *Gene Technology Act 2000,* which is administered by the OGTR, is the legislation which underpins the national scheme for the regulation of live and viable GMOs in Australia and which generally meets the provisions for national implementation of the protocol. The object of the Act is "to protect the health and safety of people and to protect the environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms".	

Articles 7 to 10 and 12: The advance informed agreement procedure

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

5. Were you a Party of import during this reporting period?	
a) yes	
b) no	X- not a party to Protocol
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	X- not a party to Protocol
7. 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) not yet, but under development	
c) no	
d) not applicable – not a Party of export	
8. 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)	

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

b) not yet, but under development	
c) no	
d) not applicable – not a Party of export	X
9. 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
10. 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 – export was to a non-party to the protocol.	
11. 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:	
Not Applicable – export was to a non-party to 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.

12. 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) not yet, but under development	
c) no	
d) not applicable (please give details below)	
13. 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	
14. 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	

15. 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:
Australia is not a party to the protocol and so has not implemented Article 11. Under Australia's legislative framework, if a licence is issued by Australia's Gene Technology Regulator for the commercial release in Australia of a LMO including those that may be used as food, feed or for processing, information that generally meets the requirements of Annex II and Annex III is made available to the public on the Office of the Gene Technology Regulator's website.
16. If your country has been a Party of import of LMOs intended for direct use for food or feed, or for processing, during the reporting period, please describe your experiences and progress in implementing Article 11, including any obstacles or impediments encountered:
Not applicable as Australia is not a party to the protocol.

Article 13 – Simplified procedure

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

17. Have you applied the simplified procedure during the reporting period?	
a) yes	
b) no	X
18. If your country has used the simplified procedure during the reporting period, or if you have been unable to do so for some reason, please describe your experiences in implementing Article 13, including any obstacles or impediments encountered:	
Not Applicable	

Article 14 – Bilateral, regional and multilateral agreements and arrangements

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

19. Has your country entered into any bilateral, regional or multilateral agreements or arrangements?	
a) yes	
b) no	X
20. If your country has entered into bilateral, regional or multilateral agreements or arrangements, or if you have been unable to do so for some reason, describe your experiences in implementing Article 14 during the reporting period, including any obstacles or impediments encountered:	
N/A	

Articles 15 and 16 – Risk assessment and risk management

21. 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 / no decisions taken under Article 10	X
22. If yes to question 21, 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 / no decisions taken under Article 10	X
23. 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	
d) not a Party of import / no decisions taken under Article 10	X
24. 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 – fully established	X
b) not yet, but under development or partially established (please give further details below)	
c) no	
25. Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)	
a) yes – fully adopted	X
b) not yet, but under development or partially adopted (please give further details below)	
c) no	
26. 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	
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)	X
27. 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

28. 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:
Australia's *Gene Technology Act (2000)* and the associated *Gene Technology Regulations 2001*, provide a comprehensive process for the Gene Technology Regulator to assess proposed dealings with live and viable GMOs ranging from contained work in certified laboratories to general releases of GMOs in the environment. Legislation requires the Gene Technology Regulator to prepare a comprehensive Risk Assessment and Risk Management Plan (RARMP) for every licence application for intentional release a GMO into the environment. The development of the RARMP is informed by extensive consultation with the public and a wide range of experts, agencies and authorities, and forms the basis of the Regulator's decision of whether or not to issue a licence and what, if any, conditions will be imposed if a licence is issued. A licence to deal with a GMO must not be issued unless any identified risks are able to be managed so as to protect the health and safety of people and the environment. RARMPs are publicly available on the OGTR website. The functions of Australia's Gene Technology Regulator includes to harmonize risk assessments relating to GMOs and GM products by regulatory agencies; to monitor international practice in relation to the regulation of GMOs; and to maintain links with international organisations and agencies that deal with the regulation of GMOs and gene technology in countries outside Australia. Australia participates in international fora such as the OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology.

Article 17 – Unintentional transboundary movements and emergency measures

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

29. 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) yes – partially consulted, or consultations were delayed (please clarify below)	
c) no – did not consult immediately (please clarify below)	
d) not applicable (no such occurrences)	X

30. 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:
Implementation of Article 17 is not applicable as Australia is not a party to the protocol.

Article 18 – Handling, transport, packaging and identification

31. 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)	
b) not yet, but under development	

c) no	
d) not applicable (please clarify below)	X
32. 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	
b) not yet, but under development	
c) no	X
33. 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	
b) not yet, but under development	
c) no	X
34. 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	
b) not yet, but under development	
c) no	X
35. Please provide further details about your responses to the above questions, as well as a description of your country's experiences and progress in implementing Article 18, including any obstacles or impediments encountered:	
Article 18 is not applicable as Australia is not a party to the Protocol. However, Australia's framework for regulation of genetically modified organisms generally meets the provisions for national implementation of the Protocol.	

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.

36. 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:
See Question 1.

Article 21 – Confidential information

37. 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) not yet, but under development	
c) no	
38. 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 / no such requests received	X
39. If you answered yes to the previous question, please provide information on your experience including description of any impediments or difficulties encountered:	
To allow information to be treated as confidential, the information must meet the requirements of relevant Australian laws. For example, the *Gene Technology Act 2000* has specific provisions for declaring information confidential.	
40. 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:	
No difficulties were identified.	

Article 22 – Capacity-building

41. 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	
42. If yes to question 41, how has such cooperation taken place:	

In 2007, Australia hosted the sixth meeting of the APEC High Level Policy Dialogue on Agricultural Biotechnology; as well as contributed to the APEC workshop on liability and redress held in Vietnam. In 2006, Australia participated at the APEC conference on Biosafety policy options. In 2005, Australia ran a course for representatives from southeast Asia and Pacific nations on *Risk Analysis for Genetically Modified foods*. In 2004, Australia contributed to the 8th APEC Workshop on Technical Cooperation, Capacity Building, Risk Management and Emerging Issues in Agricultural Biotechnology held in Korea.	
43. If a developing country Party, or Party with an economy in transition, during this reporting period has your country contributed to the development and/or strengthening of human resources and institutional capacities in biosafety for the purposes of the effective implementation of the Protocol in another developing country Party or Party with an economy in transition?	
a) yes (please give details below)	
b) no	
c) not applicable – not a developing country Party	X
44. If yes to question 43, how has such cooperation taken place:	
Not Applicable	
45. 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
46. 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
47. 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
48. 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 Applicable	

Article 23 – Public awareness and participation

49. 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	
50. If yes, do you cooperate with other States and international bodies?	
a) yes – significant extent	X
b) yes – limited extent	
c) no	
51. 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	
52. 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	
53. 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	
54. 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:	
Australia's gene technology regulatory system incorporates significant legislative requirements for	

transparency in decision making and providing opportunity for public input. into the risk assessment process for all applications for release of a GMO into the environment. The Regulator is required to consult with a range of experts and authorities and the public before finalising risk assessments. The legislation also established statutory Committees to advise the Regulator on issues pertaining to ethics and community consultation. The OGTR maintains an comprehensive website including the Record of GMO and GM Product Dealings which details approvals in Australia, as well as information on applications for environmental release under evaluation, and other information about the regulatory system.

Article 24 – Non-Parties

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

55. Have there been any transboundary movements of living modified organisms between your country and a non-Party during the reporting period?	
a) yes	X
b) no	
56. If there have been transboundary movements of living modified organisms between your country and a non-Party, please provide information on your experience, including description of any impediments or difficulties encountered:	
No difficulties identified.	

Article 25 – Illegal transboundary movements

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

57. 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	
58. Have there been any illegal transboundary movements of living modified organisms into your country during the reporting period?	
a) yes	
b) no	X
59. 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:	
Australia's *Gene Technology Act* provides extensive powers to monitor and enforce compliance with the Act, including strict penalties for unauthorised dealings with GMOs.	

Article 26 – Socio-economic considerations

60. 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	
61. 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
62. 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:	
The scope of Australia's *Gene Technology Act* does not include consideration of socio-economic impacts of LMOs.	

Article 28 – Financial mechanism and resources

63. 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
64. 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:	
N/A	

Other information

65. 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:
Although Australia is a not a signatory to the Protocol, Australia has some of the most rigourous regulation in the world concerning gene technology. Australia's *Gene Technology Act* provides the framework for the Australian system of regulation of genetically modified organisms. The framework generally meets the provisions for 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:

The reporting format was user friendly and clear.