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

Origin of report

Party:	New Zealand
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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:

New Zealand's Ministry for the Environment oversaw preparation of this National Report (the Report).

- The Ministry for the Environment (www.mfe.govt.nz) is a Competent National Authority, responsible for oversight of New Zealand's domestic regulatory regime in relation to the implementation of the Protocol, and is the Government's principal adviser on the New Zealand environment and international matters that affect the environment;

The following government agencies were consulted on and assisted in the preparation of the Report:

- The Ministry of Foreign Affairs and Trade (www.mfat.govt.nz) (National Focal Point) - the Government's key adviser on foreign, security and trade policy issues, the Ministry represents New Zealand in its relationships with foreign governments and organisations, and at international forums and provides overseas development assistance;

- The Environmental Risk Management Authority (ERMA New Zealand) (www.ermanz.govt.nz) (Competent National Authority: Approvals; Biosafety Clearing House Focal Point) - the agency responsible (under the Hazardous Substances and New Organisms (HSNO) Act 1996) for assessing and deciding on applications to introduce new organisms (including genetically modified organisms) into New Zealand, or for their development or domestic use);
- The Ministry of Agriculture and Forestry (www.maf.govt.nz) – (Competent National Authority: Enforcements and Compliance; Unintentional and Illegal transboundary movements of LMOs; Emergency Notifications Focal Point) - the government agency responsible for advancing agriculture, horticulture and forestry and for biosecurity, including enforcement of legislation in relation to genetically modified organisms;
- The Ministry of Research, Science and Technology (www.morst.govt.nz) - the government policy agency that develops research and innovation policies and oversees the publicly funded component of the Research, Science and Technology system on behalf of the Government);
- The Ministry of Economic Development (www.med.govt.nz) - the government's primary adviser on the operation and regulation of specific markets and industries, leading the production and co-ordination of policy advice related to economic, regional and industry development);
- The Ministry of Justice (www.justice.govt.nz) - the government agency whose primary role is to administer legislation and provide services to contribute to safer communities and a fairer, more credible justice system;
- The Department of Conservation (www.doc.govt.nz) - the government organisation charged with conserving the natural and historic heritage of New Zealand on behalf of, and for the benefit of, present and future New Zealanders;
- The New Zealand Customs Service (www.customs.govt.nz) - the government agency with the job of protecting the community from potential risks arising from international trade and travel, while facilitating the legitimate movement of people and goods across the border).
- Te Puni Kōkiri (the Ministry of Māori Development) (www.tpk.govt.nz) - the government organisation responsible for promoting increases in levels of achievement attained by Māori with respect to education, training and employment, health and economic resource development; andmonitoring and liaising with each department and agency that provides, or has a responsibility to provide, services to or for Māori, for the purpose of ensuring the adequacy of those services.

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):

This First Regular National Report constitutes the second report submitted by New Zealand on the implementation of the Protocol (Article 20.3(e)), the first being the interim National Report submitted to the Secretariat prior to the Third Meeting of the Parties (www.cbd.int/doc/world/nz/nz-nr-cpbi-en.doc).

The Environmental Risk Management Authority (ERMA New Zealand) acts as New Zealand's Biosafety Clearing House Focal Point and is the Competent National Authority (approvals) with responsibility for assessing and deciding on applications to introduce new, genetically modified organisms into New

Zealand, either for contained use, or for release into the environment. All ERMA's decisions are notified to the BCH, and are separately available on ERMA's website (www.ermanz.govt.nz). Information relating to some decisions taken by regulatory agencies in the period before entry into force of the Protocol for New Zealand is also accessible through ERMA's website. Populating the BCH has not in itself proved problematic; resource constraints do effectively limit the ability of officials to proactively back-capture information generated through domestic decision-making processes before New Zealand became a Party.

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- Established procedures are in place
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:

The Cartagena Protocol on Biosafety came into effect for New Zealand on 25 May 2005. New Zealand either had in place already, or introduced in time for entry into force of the Protocol, the necessary legal, administrative and other measures to provide for a full domestic regulatory framework for implementation of the Protocol.

Complete versions of all current New Zealand laws are accessible through the New Zealand government legislation website (http://www.legislation.govt.nz/) – website access has been made available to the BCH. Regulatory control for LMOs is effected through the following key laws:

- Hazardous Substances and New Organisms (HSNO) Act 1996
- Hazardous Substances and New Organisms (Methodology) Order 1998
- Hazardous Substances and New Organisms (Low-risk Genetic Modification) Regulations 2003
- Imports and Exports Restrictions Act 1988
- Import and Exports (Living Modified Organisms) Prohibition Regulations 2005
- Customs and Excise Act 1996
- Biosecurity Act 1993 (including Ministry of Agriculture and Forestry (MAF)/Environmental Risk Management Authority (ERMA) Containment Standards; MAF Import Health Standards)
- Agricultural Compounds and Veterinary Medicines Act 1997
- Medicines Act 1981
- Food Standards Australia New Zealand Act 1991
- Official Information Act 1982
- Crimes Act 1961

New Zealand's obligations under the Protocol in relation to the importation of living modified organisms (LMOs) that are genetically modified organisms (GMOs) are effected through the Hazardous Substances and New Organisms Act (HSNO) 1996 and Biosecurity Act 1993.

The Environmental Risk Management Authority (ERMA) is an independent, quasi-judicial decision-making agency established under the HSNO Act to make decisions on the import and domestic use of all genetically modified organisms (GMOs) (as well as all other new organisms and hazardous substances).

All GMOs are prohibited from entry to New Zealand unless they have been formally approved by ERMA. To date, ERMA has not granted any approvals for import of any GMO for release. All GMOs approved for importation or domestic use in New Zealand are subject to containment controls and must be kept in registered containment facilities, approved under the Biosecurity Act 1993.

The provisions of both the HSNO Act and the Biosecurity Act 1993 are enforced by the Ministry of Agriculture and Forestry (MAF).

Prior to entry into force of the Protocol for New Zealand, to ensure compliance with the requirements of the Protocol regarding export of LMO, New Zealand developed and enacted new legislation. The Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (the Prohibition Order) is a statutory regulation under the Imports and Exports (Restrictions) Act 1988. The export from New Zealand of any LMO is prohibited unless it has been approved under the Prohibition Order. The Prohibition Order entered into force on 25 May 2005, concurrent with entry into force for New Zealand of the Protocol. The New Zealand Customs Service enforces the Prohibition Order through the provisions of its superior (parent) Act, the Imports and Exports (Restrictions) Act 1998 and the Customs and Excise Act 1996.

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
6. Were you a Party of export during this reporting period?	
a) yes	
b) no	X
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- see Question 65 re: Other Information
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)	
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	
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	

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.

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- see Question 65 re: Other Information
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	
c) not relevant	X
14. Did your country take decisions regarding import under domestic regulatory frameworks as allowed by Article 11.4?	
a) yes	
b) no	
c) not applicable – no decisions taken during the reporting period	X
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:	
Not applicable	
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	

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	X- refer below
b) no	

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:
New Zealand has not entered into any bilateral, regional and multilateral agreements and arrangements in direct response to our obligations as a Party to the Cartagena Protocol on Biosafety. However, in relation to cooperation on the identification of living modified organisms, or assessment of specific traits of living modified organisms, we note the information provided to the BCH on Food Standards Australia New Zealand (FSANZ). FSANZ is a bi-national independent statutory authority operating under the Food Standards Australia New Zealand Act 1991. This Act provides a focus for cooperation between the governments, industry and the community in the two countries to establish and maintain uniform food regulation in Australia and New Zealand. The FSANZ works to protect the health and safety of the people in Australia and New Zealand by maintaining a safe food supply, by developing food standards for composition, labelling and contaminants, including microbiological limits, that apply to all foods produced or imported for sale in Australia and New Zealand, including food products that are or contain genetically modified organisms. Genetically modified food, food products and ingredients can only be sold in New Zealand and Australia if they have been assessed for safety and approved by the FSANZ. Detailed information on the FSANZ is available on its website (www.foodstandards.gov.au), access to which has been made available to the BCH. Any viable genetically modified organism must also gain approval from the Environmental Risk Management Authority (www.ermanz.govt.nz).

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	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)	
27. Has your country cooperated with others for the purposes specified in Article 16.5?	
a) yes (please give further details below)	X- refer below
b) no (please give further details below)	

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:

All decisions on the importation and domestic use of living modified organisms that are genetically modified organisms are made by the Environmental Risk Management Authority (the ERMA Authority) on the basis of a thorough assessment of the potential risks posed by the organism, under the stringent requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996.

Risk assessment requirements under the HSNO Act are fully consistent with the requirements under the Protocol, and as are provided for in Annex III. The HSNO Act provides that, in determining whether to approve applications to import or use domestically any genetically modified organism, the Environmental Risk Management Authority must evaluate the potential risks of the organism according to strict minimum standards designed to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of new organisms. In particular, the HSNO Act requires that the Environmental Risk Management Authority shall decline an application, if the new organism is likely to:

- cause any significant displacement of any native species within its natural habitat;
- cause any significant deterioration of natural habitats
- cause any significant adverse effects on human health and safety
- cause any significant adverse effect to New Zealand's inherent genetic diversity; or
- cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless that is the specific purpose of that importation or release.

ERMA New Zealand, the operational agency supporting the ERMA Authority, maintains links with relevant agencies, experts and organisations both nationally and internationally to ensure the production of high quality robust risk assessments. There are also publicly funded research programmes in place to better understand the potential environmental and social impacts of living modified organisms. Additionally, the HSNO Act requires that all persons exercising functions, powers, and duties under that Act shall take a precautionary approach, and shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. All decisions under the HSNO Act are made and notified in a manner that meets or exceeds the requirements of the Protocol, including, but not limited to the time requirements for communication of receipt of notification and for confirmation of decisions, as provided for under Articles 9 and 10.

Risk assessments, based on identification of nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that goods of the kind or description specified in the import health standard may bring into New Zealand, are integral to the development of Import Health Standards (IHSs) under the Biosecurity Act 1993. IHSs specify the requirements to be met to effectively manage risks associated with the importation of risk goods before those goods may be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance.

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:	
During the reporting period, there were no known occurrences under New Zealand 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 other States.	

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)	X
b) not yet, but under development	
c) no	
d) not applicable (please clarify below)	
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	X
b) not yet, but under development	
c) no	
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	X
b) not yet, but under development	

c) no	
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	X
b) not yet, but under development	
c) no	
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:	

The export from New Zealand of all living modified organisms (LMOs) within the scope of the Protocol is prohibited unless the export has been approved under the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (the Prohibition Order).

The Prohibition Order is a statutory regulation (under the Imports and Exports Restrictions Act 1988) that was promulgated specifically to provide a mechanism whereby New Zealand can ensure there is a legal requirement that exports covered by the Protocol are carried out in compliance with the obligations on Parties as specified under Articles 18 (1) and 18(2) of the Protocol. The Prohibition Order entered into force on 25 May 2005, to coincide with entry into force for New Zealand of the Protocol. The Prohibition Order applies equally to Parties and non-Parties, and provides that the export of LMOs is prohibited unless the Minister for the Environment has consented to the export. Such a ministerial consent will not be granted unless the Minister is satisfied that the LMO will be transported in a manner consistent with New Zealand's obligations under the Protocol.

Specifically, the Prohibition Order provides that the Minister may consent to the export of a LMO that is intended for (1) contained use; (2) for direct use as food or feed, or for processing; or (3) for intentional introduction into the environment, if the Minister is satisfied that the LMO is:

(a) handled, packaged, and transported under conditions of safety and according to relevant international rules and standards; and

(b) accompanied by documentation in conformity with New Zealand's obligations under the Protocol; and

(c) otherwise exported in conformity with New Zealand's obligations under the Protocol.

For living modified organisms intended for direct use as food or feed, or for processing (LMO-FFP), if the LMO is being exported for the first time into the importing country, the Minister may only consent if the following additional requirements are also satisfied:

(i) if the importing country is a Party to the Protocol, the requirements of Article 11 of the Protocol have been complied with; and

(ii) the exporter complies with any conditions or requirement imposed by the importing country that are consistent with the Protocol or other relevant international instruments.

Further, for LMOs intended for intentional introduction into the environment, if the LMO is being exported for the first time into the importing country, the Minister may only consent to the export if the following additional requirements are also satisfied:

(i) if the importing country is a Party to the Protocol, the advance informed agreement procedure in Articles 8, 9, 10, and 12 of the Protocol have been complied with; and

(ii) the exporter has complied with any conditions or requirement imposed by the importing country that are consistent with the Protocol or other relevant international instruments.

To date, the Environmental Risk Management Authority has granted only contained use approvals for genetically modified organisms under the HSNO Act. All approved genetically modified organisms must therefore be held in containment, registered containment facilities, under supervision by the Ministry of Agriculture and Forestry (MAF). MAF is the government agency responsible for compliance and enforcement under the HSNO Act. MAF requires authorized signoff and receipt, prior to transfer of any genetically modified organism out of a registered containment facility, whether the organism is intended for use in another domestic containment facility, or if it is intended for export.

The Prohibition Order notes that the relevant provisions relating to advance informed agreement do not apply if the LMO has been identified in a decision of a Conference of Parties to the Convention serving as the meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

In addition, the Prohibition Order provides that if the export of a LMO falls into more than one of the above mentioned categories of export, the separate consent of the Minister must be obtained for each category of export.

The Prohibition Order provides that a LMO that is a pharmaceutical for humans and that is addressed by relevant international agreements or organisations other than the Protocol may be exported, otherwise, a LMO that is a pharmaceutical for humans may be exported only if it falls within one of the above mentioned categories, and the relevant requirements for such an export have been met.

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:

Prior to ratification of the Protocol, New Zealand already had in place a formal system for public reporting both of risk assessments undertaken and of decisions made on the import and domestic use of living modified organisms that are genetically modified organisms. The information provided to the Biosafety Clearing-House serves as a means to provide access to existing information made available by decision-makers and regulatory authorities in relation to the domestic management of the products of biotechnology, and to other matters relevant to New Zealand's implementation of the Protocol.

- Information on general legislative requirements and the New Zealand regulatory environment in relation to the products of biotechnology covered by the Protocol is provided to the public through the websites of the Ministry for the Environment (www.mfe.govt.nz) and the Ministry of Research, Science and Technology (www.morst.govt.nz) – these websites provide links to other agencies involved in the management of living organisms that are the products of biotechnology, and both

have been made available to the BCH.

- Information on specific applications to import or use domestically of living modified organisms that are genetically modified organisms is made public through the website of the Environmental Risk Management Authority (www.ermanz.govt.nz).

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:

New Zealand has procedures in place 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.

To date, we have not received any relevant information in this regard.

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:

We have no identified impediments or difficulties to report regarding the implementation of the requirements of Article 21 during this reporting period, either in relation to exports or imports of LMOs.

During the reporting period, New Zealand has approved a number of LMOs for export from registered containment research facilities to indoor contained-use facilities overseas, pursuant to the requirements of the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (refer response to question regarding Article 18 – Handling, transport, packaging and identification).

In relation to imports, the Hazardous Substances and New Organisms (HSNO) Act 1996 provides for the Environmental Risk Management Authority (ERMA) to consider in its assessment of risks, information provided in relation to an application for the domestic use or importation of a living modified organism that is a genetically modified organism, even though that information may be able to be withheld under the Official Information Act 1982 and thereby not released publicly.

Under New Zealand law, the Official Information Act 1982 deals with access to official information

(including information received by government officials for the purposes of administering laws and regulations). Key purposes of this Act are to increase progressively the availability of official information to the people of New Zealand in order to enable their more effective participation in the making and administration of laws and policies; and to promote the accountability of Ministers of the Crown and officials and thereby to enhance respect for the law and to promote the good government of New Zealand. The presumption is that all information received or held for official purposes will be publicly available unless specific reason and justification for withholding it has been identified. Therefore, all information submitted as part of an application, under the HSNO Act, to import into New Zealand a living modified organism that is a genetically modified organism will be made available unless there is good reason for withholding it. Confidentiality or commercial requirements are given weight when assessing whether there is good reason to withhold the information.

All information held by ERMA for the purposes of an application under the HSNO Act is subject to the Official Information Act 1982. However, information supplied to ERMA before an application is lodged formally is not subject to the Official Information Act 1982 (section 55 (1)). Therefore another person cannot request this information under the Official Information Act.

To be protected from disclosure to third parties the information need not be "commercially sensitive". However, once the application has been lodged the Official Information Act will apply. (For an applicant to have information returned after an application had been lodged, the application would need to be formally withdrawn.)

The public notice of an application under the HSNO Act does not contain any information that is "commercially sensitive" – the HSNO Act (section 57 (1)) provides that information which could be withheld under section 9 (2) (b) of the Official Information Act is not to be released when an application is publicly notified. The HSNO Act sets out a process (section 57 (2) to (4)) for ERMA to follow if a request is made under the Official Information Act for information that may be commercially sensitive. The decision about whether the information should be released rests solely with ERMA.

Additionally, the HSNO Act contains some specific provisions regarding confidential information that provide protection over and above that provided by the Official Information Act 1982 for commercially sensitive information The provisions of the Act vary from case to case.

- The HSNO Act contains provisions (section 55(3) to (7)) intended to implement New Zealand's obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). These obligations refer to the relevant provisions in the Medicines Act 1981 and Animal Remedies Act 1967. The TRIPS agreement covers only information relating to "innovative" medicines, animal remedies and pesticides. Therefore, information relating to a large number of hazardous substances and new organisms controlled under the HSNO Act is not entitled to protection under the TRIPS agreement.
- Certain information about "innovative" medicine or animal remedies intended for import to, or manufacture in, New Zealand may be protected from disclosure to any person outside the Environmental Risk Management Authority (ERMA). The HSNO Act (section 55 (3) to (7)) protects information that "includes trade secrets or information that has commercial value that would be, or would be likely to be, diminished by disclosure". Generally this information is protected for a period of five years. The details can be found in the Medicines Act 1981 and Animal Remedies Act 1967.
- The protection provisions of the HSNO Act also cover pesticides. The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 amended the HSNO Act to extend the protection required under the TRIPS agreement to all innovative agrichemicals.

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:	
No new initiatives have been undertaken during the reporting period (2005-2007). We note however, that in early July 2005, Dr Abdul Moeed, Senior Scientific Adviser, New Organisms, ERMA New Zealand, a nominated Biosafety Expert at that time, visited the Republic of Yemen to review and advise Yemen on its National Biosafety Framework (NBF) project under the United Nations Environment Programme – Global Environment Facility (UNEP-GEF) programme.	
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:	
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:	
New Zealand has no impediments or difficulties to report regarding the implementation of the requirements of Article 22 during this reporting period.	

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	X
b) yes – limited extent	
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	X
b) yes – limited extent	
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:
In New Zealand, consultation with the public is an integral component both of the process leading to the development of laws and regulatory mechanisms, and of the case-by-case decision-making process in relation to the Environmental Risk Management Authority's consideration of applications for the import or domestic use of living modified organisms. The results of such decisions are made available to the public through the Environmental Risk Management Authority website (www.ermanz.govt.nz), and directly to any members of the public who have been engaged in making submissions during the decision-making process. All relevant information on applications and decisions (see responses to questions 32-34 above) is also able to be accessed through the Biosafety Clearing House. Officials actively engage with stakeholders both prior to and during the development and establishment of New Zealand's legislative framework, and information on new provisions are provided to interested members of the public both through direct communication with affected parties known to authorities, as well as through publication on the websites of the key government agencies, such as the Ministry for the Environment (www.mfe.govt.nz). Public input was requested prior to consideration by government of whether to ratify the Cartagena Protocol on Biosafety. Information on the ongoing developments of the Protocol and New Zealand's obligations are provided directly to those who have expressed an interest and more generically on the relevant government websites. In relation to public consultation in the decision-making process on genetically modified living modified organisms, the Hazardous Substances and New Organisms (HSNO) Act 1996 provides for the Environmental Risk Management Authority to publicly notify applications where it considers there is likely to be significant public interest in the application. The public notice provides a means by which any person may make a written submission on the application. A public hearing of an application may also be held if one is requested by the applicant, by a person who has made a submission, or if the Authority considers that a hearing is necessary to ensure due consideration of all the relevant matters.

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:
We have no impediments or difficulties to report regarding the implementation of the requirements of Article 24 during this reporting period. The New Zealand regulatory systems applies equally to Parties and non-Parties alike, both for importation and for export – there is no distinction in the manner in which the legislation applies. During the reporting period, New Zealand has approved a number of LMOs for export from registered containment research facilities to indoor contained-use facilities overseas, pursuant to the requirements of the Imports and Exports (Living Modified Organisms) Prohibition Order 2005. (Please refer response to question regarding Article 18 – Handling, transport, packaging and identification to further information.)

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:
We have no impediments or difficulties to report regarding the implementation of the requirements of Article 25 during this reporting period. Consistent with the requirements of Article 25 (1) of the Protocol, New Zealand has in place appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol (illegal transboundary movements). Such measures are legislatively provided for through the provisions of the following key laws: • the Hazardous Substances and New Organisms (HSNO) Act 1996; • the Biosecurity Act 1993 • the Imports and Exports Restrictions Act 1988 and the subordinate Imports and Exports (Living Modified Organisms) Prohibition Order 2005 and • the Customs and Excise Act 1996.

Importation and domestic use of genetically modified living modified organisms covered by the Protocol is controlled under the HSNO Act.

Among other provisions, the HSNO Act provides that a person commits an offence against the Act who: knowingly imports or releases a new organism in contravention of the Act, or possesses or disposes of any new organism imported, manufactured, developed, or released in contravention of the Act.

Breaches of the HSNO Act, are liable on summary conviction to imprisonment for a term not exceeding 3 months or a fine not exceeding $500,000 and, if the offence is a continuing one, to a further fine not exceeding $50,000 for every day or part of a day during which the offence has continued. It is not necessary to prove that the offence was committed intentionally.

Consistent with the provisions of Article 25(2) of the Protocol, the HSNO Act has specific provisions to require that a Party of origin dispose, at its own expense, of a living modified organism in question by repatriation or destruction, as appropriate.

Additionally, the Biosecurity Act 1993 has provisions that could be applied, in some circumstances, to prevent and penalise, transboundary movements of living modified organisms carried out in contravention of its provisions.

- Under the relevant provisions of the Biosecurity Act, a person who commits an offence is liable, on summary conviction, (a) in the case of an individual person, to imprisonment for a term not exceeding 12 months, a fine not exceeding $50,000, or both, and (b) In the case of a corporation, to a fine not exceeding $100,000.

Exports from New Zealand of all living modified organisms within the scope of the Protocol are prohibited unless the export complies with a consent to export granted under the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 (the Prohibition Order), a statutory regulation, under the Imports and Exports Restrictions Act 1988.

- Any breach of the Prohibition Order is liable to the penalty provisions under the parent Act, including: a fine not exceeding, (a) in the case of an individual, $5,000, and in the case of a body corporate, $25,000; or (b) in either case, an amount equal to 3 times the value of the goods to which the offence relates, whichever is the greater. Further, any goods in respect of which any such offence is committed shall be forfeited.

Enforcement of the provisions of the HSNO Act and the Biosecurity Act are carried out by the Ministry of Agriculture and Forestry, while the New Zealand Customs controls transboundary movement of goods across the border by enforcing the export provisions of the Imports and Exports (Living Modified Organisms) Prohibition Order 2005 and Imports and Exports Restrictions Act 1988, and through the more generic provisions of the Customs and Excise Act 1996.

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	
d) not a Party of import	X

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	X
c) no	

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:

We have no impediments or difficulties to report regarding the implementation of the requirements of Article 26 during this reporting period.

All decisions on the import to New Zealand of LMOs that are GMOs, including but not limited to those during this reporting period, are made under the Hazardous Substances and New Organisms (HSNO) Act 1996, and 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.

An overall purpose of the HSNO Act, the legislation under which such importations are considered, is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of new and genetically modified organisms.

The HSNO Act requires that all persons exercising functions, powers, and duties under the Act shall recognise and provide for the following principles:

- the safeguarding of the life-supporting capacity of air, water, soil, and ecosystems; and
- the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

Also they shall take into account the following matters

- the sustainability of all native and valued introduced flora and fauna;
- the intrinsic value of ecosystems;
- public health;
- the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred places), valued flora and fauna, and other taonga (sacred or treasured things);
- the economic and related benefits and costs of using a particular new organism; and
- New Zealand's international obligations.

The HSNO Act also establishes a committee called Nga Kaihautu Tikanga Taiao, whose function is to provide advice and assistance, given from the Maori perspective, to the Environmental Risk Management Authority on matters relating to policy, process, and applications.

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:
We have no impediments or difficulties to report regarding the implementation of the requirements of Article 28 during this reporting period.

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:
Regarding Question 7 ("Is there a legal requirement for the accuracy of information provided by exporters under the jurisdiction of your country? (Article 8.2))": All exports from New Zealand of living modified organisms (LMOs) that are covered by the Protocol are controlled under the Imports and Exports (Living Modified Organisms) Prohibition Order. All imports to New Zealand (and releases to the environment from containment within New Zealand) are controlled under the Hazardous Substances and New Organisms (HSNO) Act 1996. At the time of writing, regulatory approval has not been granted for any intentional transboundary movement of LMOs intended for introduction into the environment of the Party of import, nor for import for introduction into the New Zealand environment. We therefore have no practical experience in implementing Articles 7 to 10 and Article 12 of the Protocol. In relation to legal requirements for the accuracy of information, it is an offence under the Imports and Exports (Restrictions) Act 1988, and therefore under the subordinate Imports and Exports (Living Modified Organisms) Prohibition Order 2005, to knowingly make a false declaration or statement in relation to the importation or export of regulated goods. Specifically, under the Imports and Exports (Restrictions) Act 1988, it is an offence: to export, or transport with intent to export, goods from New Zealand in breach of the Prohibition Order; to knowingly make a false declaration or statement for the purpose of obtaining an approval to export under the Prohibition Order; or to otherwise knowingly make a false declaration or statement in relation to the export of organisms covered by the Prohibition Order. Where goods have been given a biosecurity clearance for entry to New Zealand (under section 26 of the Biosecurity Act 1993) by an inspector following receipt by that inspector of false, incomplete, or misleading information concerning those goods, the imported goods are deemed to be unauthorised goods under the Biosecurity Act. Failure or refusal to comply with section 25 of the Biosecurity Act is an imprisonable offence under section 154 (b) of that Act. Additionally, the Crimes Act 1961 contains generic offence provisions relating to the making of false

statements or declarations.

Regarding Question 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)"):

Article 11 (2) of the Protocol sets out 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. In that regard, we note the following:

Final decisions regarding the domestic use, including placing on the market, of living modified organisms that may be subject to transboundary movement for direct use as food or feed, or for processing are made by the Environmental Risk Management Authority under the Hazardous Substances and New Organisms (HSNO) Act 1996. There is provision under that Act to ensure the accuracy of information provided by the applicant, if this is considered necessary, as the Act provides for the Environmental Risk Management Authority to require an applicant to verify an application by statutory declaration. (This provision is supplemented by a power under the HSNO Act to require an importer to make a statutory declaration that any organism is not a genetically modified organism.) The making of false statements or declarations is an imprisonable offence under the New Zealand Crimes Act 1961.

For a living modified organism that is a genetically modified organism to be used domestically where it may be subject to transboundary movement for direct use as food or feed, or for processing, it will need to have obtained previously an approval for release to the environment under the HSNO Act. Once released, it will no longer be subject to legislative control, unless it has been released conditionally. However, for it to be exported where it may then be the subject of a transboundary movement for direct use as food or feed, or for processing, it will require an authorization granted under the Imports and Exports (Living Modified Organisms) Prohibition Order.

In relation to the Prohibition Order, it is an offence: to knowingly make a false declaration or statement for the purpose of obtaining the license or permit; to knowingly make a false declaration or statement as to compliance with a condition on, or subject to, which a licence or permit is granted; and to otherwise knowingly make a false declaration or statement in relation to the importation or export of the goods.

The Ministry of Agriculture and Forestry (MAF) is responsible for controlling and managing the importation to New Zealand of grain for consumption, stock feed or processing. In this context grain is defined as a commodity class for seed intended for processing or consumption and not for planting (e.g. release to the environment). The integrated organisational structure, responsibilities, operational procedures, processes and resources for implementing activities associated with importation of grain for processing are specified in the Grain Import System (GIS), overseen by MAF. The GIS must also cover all aspects of required certification and notifications to MAF prior to arrival of grain at the border and for transfer to approved transitional facilities.

An approved transitional facility is any place approved as a transitional facility in accordance with section 39 of the Biosecurity Act for the purpose of inspection, storage, treatment, quarantine, holding, or destruction of uncleared goods.

Uncleared goods are those imported goods for which no biosecurity clearance has been given. Such 'uncleared' goods must remain in a transitional facility or biosecurity control area and must not be permitted to leave that facility or area until such a time as clearance is granted. MAF Import Health

Standards specify the requirements that must be met before the goods can be imported, moved from a biosecurity control area or a transitional facility, or given a biosecurity clearance.

Approved transitional facilities constitute containment facilities as defined under the Cartagena Protocol on Biosafety. Any approved transitional facilities used to treat, store or process imported grain must be approved as part of the GIS. Strict specifications for the transportation of 'uncleared' grain to approved transitional facilities and for the unloading, treatment, storage and processing of 'uncleared' grain are contained in the MAF Operational Standard for Grain for Processing: Import System Requirements. Transitional facilities are operated under strict MAF-specified conditions. Additionally, operators of approved transitional facilities must also be approved to specified MAF Standards, e.g. *Requirements for holding and processing facilities (Class: Transitional Facilities) for uncleared risk goods*.

Viable seed brought into New Zealand for food, feed or for processing, must be placed in a transitional facility for quarantine purposes. Irrespective of purpose, all viable seed that is a LMO must receive a specific ERMA approval. Grain held in a transitional facility following entry to New Zealand is not deemed as cleared for release to the New Zealand environment unless it has been granted Biosecurity clearance (under section 26 of the Biosecurity Act 1993) for entry into New Zealand. For viable genetically modified organisms (that constitute LMOs) biosecurity clearance is not able to be granted unless there is also a separate approval granted by ERMA under the HSNO Act.

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:

Some difficulty was encountered in interpreting the appropriate level of detail required for this report. A comprehensive approach was taken in its preparation and additional information has been provided where this was considered appropriate for purposes of clarification.