NIUE LAWS
LEGISLATION AS AT DECEMBER 2006

ENVIRONMENT

BIOSAFETY (GENETICALLY MODIFIED ORGANISMS) REGULATIONS 2006

2006/4 – 4 July 2006

21 The Director

SCHEDULE

PART 1
PRELIMINARY

1 Short title

These are the Biosafety (Genetically Modified Organisms) Regulations 2006.

2 Interpretation

(1) In these Regulations –

"Act" means the Environment Act 2003;

"Advanced Informed Agreement" (AIA) means the procedure prescribed in Article 7 of the Cartagena Protocol relating to the notification requirements for transboundary movements of genetically modified organisms;

"Authority" means the Council; "biological diversity" has the same meaning as in the Convention on Biological Diversity;

"Biosafety Clearing-House" means the Clearing-House established under Article 20 of the Cartagena Protocol;

"Cartagena Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted at Montreal in January 2000;

"Competent National Authority" has the same meaning as in the Cartagena Protocol;

"contained use" means any activity, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by approved measures to limit their contact with, and their impact on, the external environment;

"Convention on Biological Diversity" means the 1992 Convention on Biological Diversity adopted at Nairobi in May 1992;

"Council" means the Environment Council established under section 15 of the Act;

"Department" means the Environment Department established by section 5 of the Act;

"develop" means genetic modification of a living organism; field testing or fermentation of a genetically modified organism;

"Director" means the Director for Environment;

"environment officer" means an environment officer appointed under the Act;

"export" means intentional transboundary movement from Niue to a place outside Niue;

"exporter" means a person who exports or arranges the export of a genetically modified organism.

"import" means intentional transboundary movement into Niue from a place outside Niue;

"importer" means a person who imports or arranges the import of a genetically modified organism;

"genetically modified organism" has the same meaning as" living modified organism" in the Cartagena Protocol; and includes genetically modified human cells and tissues maintained outside the human body, and animal cells and tissues maintained in laboratories for research and investigation;

"living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"micro-organism" means any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic materials, including viruses, viroids, human, animal and plant cell in culture;

"Minister" means the Minister responsible for environment matters;

"modern biotechnology" means the application of –

(a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;

(b) Fusion of cells beyond taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"notifier" means any person giving notification of an intended transboundary movement of a genetically modified organism;

"Office of External Affairs" means the office responsible for external

administrative matters; "Party" means a Party to the Cartagena Protocol; "Technical Advisory Group" means any group of technical and/or scientific

experts which is appointed by the Council to assess risks associated with the application of GMO’s as required in the Regulations and the NBF;

"transboundary movement" means the movement of genetic modified organisms from Niue to another State, or from another State to Niue whether or not that State is a member of the Cartagena Protocol.

(2) Words used in these Regulations, shall have the same meaning as is given to them in the Convention on Biological Diversity and the Cartagena Protocol, unless a contrary intention appears.

3 Objectives

The objectives of these Regulations are to –

(a) Protect Niue's people, environment (including biodiversity) and culture from the adverse effects of genetically modified organisms;

(b) Facilitate Niue's economic development by providing for beneficial uses of genetically modified organisms and modern biotechnology after appropriate scientific assessment and analysis; and

(c) Provide for public awareness and participation in matters relating to genetically modified organisms and modern biotechnology.

4 The precautionary approach

(1) All persons exercising functions, powers and duties under these Regulations shall recognise and provide for the precautionary approach.

(2) For the purposes of paragraph (1), the precautionary approach means that in the event of threat of harm to the environment or human health, a lack of scientific certainty regarding the extent of adverse effects shall not be used to postpone a decision to minimise the potential adverse effects or threat of harm.

PART 2
IMPORTING

Genetically Modified Organisms

5 Approval required for import of genetically modified organisms

No person shall import any genetically modified organism into Niue unless prior written approval has been given by the Council under these Regulations.

6 Procedure for application to import genetically modified organisms

(1) Every person intending to import a genetically modified organism shall, before importation, apply to the Council for approval.

(2) The application shall include a risk assessment which shall –

(a) Be undertaken in a scientifically sound manner taking into account internationally recognised risk assessment methodologies and techniques;

(b) Be based upon the information supplied in the application, and other available scientific evidence to identify and evaluate possible adverse effects on the environment and risks to human health;

(c) Identify all risks and benefits relevant to the genetically modified organism.

(3) The application shall be in the form specified in the Schedule and shall be accompanied by the required fee.

(4) An applicant may indicate that certain information is of a confidential nature, if it is information other than –

(a) The name and address of the notifier;

(b) A general description of the genetically modified organism;

(c) A summary of the risk assessment; and

(d) Proposed methods and plans for emergency response.

(5) If the Director is satisfied that the nature of the information justifies it being kept confidential, the information may only be provided to members of the Council and Technical Advisory Group, undertaking the relevant risk assessment and environment officers.

(6) No person to whom the information has been provided under paragraph (4) may disclose it to any other person, and it may not be used for any commercial purpose except with the written consent of the notifier.

(7) If the Director is not satisfied that the nature of the information justifies it being kept confidential –

(a) The notifier shall be advised of the reasons for the decision;

(b) The Director shall consult with the notifier if requested; and

(c) The decision may be reviewed under regulation 9.

(8) Upon receipt of a decision under paragraph (7) (a) the applicant may withdraw the application and have returned all information, documents and reports provided in support of the application.

7 Processing the application

(1)

(a) The Director shall acknowledge receipt of the application within 90 days.

(b) Failure to acknowledge receipt does not constitute consent to the importation of the genetically modified organism.

(2) The Director shall notify the application by radio and newspaper, and invite submissions from the community.

(3) The Council shall review and assess the application and any submissions.

(4) The Council may at any time –

(a) Request additional information from the notifier;

(b) Require verification by statutory declaration of any information provided;

(c) Seek additional information from any source;

(d) Advise the notifier that the time required for the determination of the matter is to be extended by a stated period;

(e) Defer its decision until costs associated with the application have been paid.

8 Deciding the application

(1) The Council may approve the development, field testing, contained use, fermentation or processing of a genetically modified organism if –

(a) There are no adverse effects of the organism; or

(b) There is a demonstrable benefit to Niue; or

(c) The requirements of other applicable laws are sufficient to manage the risks of the organism; or

(d) The activity is necessary as an emergency response to threats to human health or the environment.

(2) The Council may impose such conditions on the approval as it thinks fit.

(3) Any approval given by the Council shall be endorsed by Cabinet before the activity may be commenced.

(4) The Council shall provide its decision, with reasons, no later than 270 days after considering the application.

(5) An approval given under this regulation may be withdrawn or suspended by the Council on the grounds that there is a significant risk to the environment (including biodiversity), or human health.

9 Review of decisions

(1) Any person may request a review of any decision made under these Regulations, on the grounds that –

(a) A change in circumstances has occurred relating to the risk assessment on which the decision was based;

(b) Significant additional relevant scientific or technical information has become available; or

(c) The person is adversely affected by the decision.

(2) The Council shall decide whether to review the decision within 30 days of receiving the request, and shall –

(a) Give reasons in writing for its decision;

(b) Indicate whether a further risk assessment is to be undertaken.

(3) The Council may decide to review any decision made under these Regulations on its own motion, and in that event the applicant shall be informed of the review within 30 days.

(4)

(a) The Council may decide to advertise on radio or TV Niue indicating the request for reviewing of decision.

(b) The Council shall, in exercising its functions under the Act, observe reasonable standards of procedural fairness, act in a timely fashion and observe the rules of natural justice, and without prejudice to the generality of the foregoing, the Council shall –

(i) give to persons who are or who are likely to be affected by such decision an opportunity to make submissions to and to be heard by the Council, or otherwise consult with such persons in good faith;

(ii) have regard to all the evidence adduced and to the matters contained in any such submissions or otherwise received in the course of such consultations;

(iii) give a written statement of its reasons for making such a decision.

(5) No change of decision made under this regulation shall avoid the requirement to give notice of, or provide risk assessments for, subsequent imports of the genetically modified organism.

PART 3
OTHER ACTIVITIES RELATING TO GENETICALLY MODIFIED ORGANISMS

10 Export of genetically modified organisms

(1) No person shall export a genetically modified organism to any Party unless –

(a) The export has been notified to and approved by that Party's Competent National Authority;

(b) The export complies with any conditions imposed by that Party's Competent National Authority.

(c) The Department has been notified of the export.

(2) A notification given under paragraph (1) shall contain –

(a) The information specified in Annex 1 to the Cartagena Protocol;

(b) Any further information required by the Department or the relevant overseas Competent National Authority.

(3) No genetically modified organism may be exported to a non-Party without the approval of the Council, which shall take into account the requirements of these Regulations, and the objectives of the Cartagena Protocol and which has been endorsed by Cabinet.

(4) A genetically modified organism shall not be exported to a non-Party until the approval has been endorsed by Cabinet.

11 Transit of genetically modified organisms

No genetically modified organism may be brought into Niue in transit to any other country unless –

(a) Regulation 6 has been complied with;

(b) Any condition imposed under regulation 6(4) (b) is met; and

(c) The requirements of any law relating to customs and excise, quarantine and any other relevant matter are complied with.

12 Use for food, feed and for processing

(1) No person may import any genetically modified organism for use as food, feed or for processing unless –

(a) Regulation 6 has been complied with, if it is being imported into Niue for the first time; and

(b) All relevant laws regulating its use are complied with.

(2) Where approval is given for the importation of a genetically modified organism for use as food, feed or for processing under any other Act, and the organism will be exported from Niue, the Department shall arrange with the Office of External Affairs;

(a) To notify the Biosafety Clearing-House in accordance with Annex II of the Cartagena Protocol, within 15 days of an approval for export being given; and

(b) To give other notifications and information in accordance with Article 11(1) and (3) of the Cartagena Protocol.

13 Development, contained use and testing of genetically modified organisms

(1) No person shall engage in any activity relating to the development, field testing, contained use, fermentation or processing of a genetically modified organism without prior written approval from the Council.

(2) Any contained use, development, field testing, fermentation or processing of a genetically modified organism within Niue shall be in accordance with any condition, requirement or restriction –

(a) Imposed by the Council; and

(b) Required under any other relevant law.

(3) Applications for approvals under this regulation shall –

(a) Be in an approved form;

(b) Contain such information as is determined by the Director;

(c) Be supported by such further information and verification as may be required by the Council; and

(d) Be accompanied by the fee set in regulation 19(5) (e).

PART 4
EXEMPTIONS, ENFORCEMENT AND OFFENCES

14 Unintentional releases and transboundary movements

(1) Any person who causes or becomes aware of the unintentional release or transboundary movement of a genetically modified organism shall immediately notify the Department and provide such information as the Director may require.

(2) An unintentional release or transboundary movement for the purposes of this regulation, is one which –

(a) Has not been approved under these Regulations; or

(b) Arises from the breach of a condition of any approval given under these Regulations.

(3) Upon notification under paragraph (1), the Department shall –

(a) Give notice of the unintentional release or transboundary movement to –

(i) the members of the Council;

(ii) the Biosafety Clearing-House;

(iii) any affected or potentially affected person; and

(iv) such international organisations which the Director sees fit; and

(b) Consult with any affected or potentially affected country to enable them to determine appropriate responses, including the taking of emergency measures.

(4) A notification given under paragraph (3) shall comply with Article 17(3) of the Cartagena Protocol.

15 Illegal releases and transboundary movements

(1) No person may permit, arrange, assist with, counsel, procure, aid or abet a release or escape, or transboundary movement of a genetically modified organism unless in accordance with these Regulations.

(2) In addition to any other penalty imposed for a breach of this regulation, the person responsible for the breach may be ordered to pay the costs associated with the disposal of the genetically modified organism, including all costs associated with its repatriation from or destruction in any country to which it has been permitted to move.

16 Offences

(1) A person commits an offence shall be liable upon conviction to a fine not exceeding 1,000 penalty units or to imprisonment for a term not exceeding 10 years, or to both who –

(a) Imports a genetically modified organism into Niue in respect of which no notification has been given as required by regulation 7;

(b) Does not obtain the approval required under regulation 6;

(c) Fails to fully disclose all information known to be relevant to genetically modified organism in an application relating to it;

(d) Imports a genetically modified organism into Niue without having an approval required under regulation 8 or 11

(e) Fails to comply with any condition or requirement imposed under regulation 8;

(f) Fabricates any risk assessment, or misrepresents any matter associated with a risk assessment undertaken in accordance with these regulations;

(g) Fabricates or misrepresents any scientific or technical information relied upon for the purposes of requesting a review of any decision under regulation 9;

(h) Exports a genetically modified organism in respect of which no notification has been given as required by regulation 10;

(i) Exports a genetically modified organism without having an approval required under regulation 10;

(j) Provides any false or misleading information in relation to a notification of export given in accordance with regulation 10;

(k) Fails to obtain an approval for an activity related to the development, contained use, field testing, fermentation or processing of a genetically modified organism in accordance with regulation 13;

(l) Fails to comply with any condition, requirement or restriction applying to the development, contained use, field testing, fermentation or processing of a genetically modified organism under regulation 13;

(m) Undertakes any activity relating to a genetically modified organism when the approval required under these Regulations is suspended or has been withdrawn;

(n) Breaches regulation 14 in relation to an unintentional release or transboundary movement of a genetically modified organism;

(o) Breaches regulation 15 in relation to an illegal release or transboundary movement of a genetically modified organism; or

(p) Fails to comply with any other obligation or requirement imposed under these Regulations.

(2) Any person who provides false information in respect of an application or notification commits an offence and shall be liable upon conviction to a fine not exceeding 50 penalty units.

(3) Any person who divulges or deals with confidential information contrary to regulation 6 commits an offence and shall be liable upon conviction to a fine not exceeding 50 penalty units.

(4) In addition to any penalty imposed under this Regulation, an offender may be ordered to pay to or reimburse the Government the costs of any remedial action taken or needed to rectify the consequences of any breach.

17 Dealing with genetically modified organisms contravening these Regulations

(1) For the purposes of enforcing these Regulations, all environment officers may exercise the powers relating to investigating, monitoring, prosecuting and preventing the continuation of any breach that are vested in them in any law.

(2) In relation to any genetically modified organism which has been imported into Niue, or developed, tested, used, released, fermented or processed in contravention of these

Regulations, or which is or remains in Niue in breach of these Regulations or any condition applying to the organism under these Regulations, an environment officer may –

(a) Seize the organism;

(b) Destroy the organism as determined by the Council or the Director; or

(c) Deliver up the organism to an officer of another Department to be dealt with in accordance with the law.

(3) The cost of destroying any seized genetically modified organism, and of rectifying any adverse effects from a genetically modified organism as a result of breach of these Regulations may be recovered as civil debt from any person making use of the organism in contravention of these Regulations.

(4) Nothing in these Regulations shall affect the powers to search, seize and deal with items under laws relating to plant and animal quarantine, customs and excise and any other law that has application to the development, use, handling, storage or movement of genetically modified organisms.

18 Exemptions

(1) The Council may exempt the importation of a genetically modified organism from the need for approval if the genetically modified organism is –

(a) To be in transit through Niue;

(b) To be the subject of contained use within Niue;

(c) For direct use as food, feed or for processing;

(d) Agreed by Parties to the Cartagena Protocol to be unlikely to have adverse effects on biological diversity or pose a risk to human health or the environment;

(e) Of a type that the Council, with the endorsement of Cabinet, has determined falls under the scope of any notification given under Article 13 of the Cartagena Protocol, and if all requirements of other laws are met in relation to its import into Niue; or

(f) A pharmaceutical for human consumption or emergency animal treatment that is addressed by other relevant laws or agreements and subject to the control of other international organisations.

(2) The Director of Health may apply to the Council for an exemption from the requirement to obtain an approval of any pharmaceutical containing a genetically modified organism on the grounds of a medical emergency.

(3) When granting an exemption under this regulation, the Council may impose any conditions or requirements relating to the use, storage, handling or movement of the genetically modified organism to minimise any impact on the environment, including biological diversity or human health.

(4)

(a) The Council may require the first import of an organism under regulation 6 (2) to be subject to a risk assessment in accordance with Annex III of the Cartagena Protocol and decision by the Council.

(b) The Council's decision shall be given in writing not later than 270 days after notification is received.

(c) Failure to make or communicate a decision within 270 days is not consent to the importation of the genetically modified organism.

(5) Exemptions under this regulation shall not take effect until endorsed by Cabinet.

PART 5
ADMINISTRATIVE FRAMEWORK

19 The role of the Council

(1) The Council shall perform the functions of the Competent National Authority under the Cartagena Protocol.

(2)

(a) The Council may appoint a Technical Advisory Group to advise it in relation to genetically modified organisms and the applications of modern biotechnology.

(b) The functions of the Technical Advisory Group may include –

(i) considering and reporting on any application made under these Regulations, including applications to review decisions;

(ii) considering and reporting on any other matter relating to the use of genetically modified organisms in Niue;

(iii) investigating any matter relating to the implementation of the Cartagena Protocol in Niue; and

(iv) recommending policies in relation to genetically modified organisms and the applications of modern biotechnology in Niue.

(3) The Council shall –

(a) Oversee implementation of the requirements of the Cartagena Protocol, including the Advanced Informed Agreement Procedure (AIA);

(b) Establish appropriate and cost effective means for undertaking risk assessments, including determining–

(i) the appropriate bodies within Niue or elsewhere to undertake the risk assessments;

(ii) the scope of risk assessments and the methodologies to be applied; and

(iii) the cost of risk assessments, and the persons liable to pay these costs.

(c) Make decisions under these Regulations, including –

(i) exempting certain genetically modified organisms from the requirements of Part I (Article 13 of the Cartagena Protocol;) and

(ii) reviewing decisions (Article 12 of the Cartagena Protocol;)

(d) approve any forms required to implement these Regulations,

(e) set fees for processing applications under these Regulations.

(6) The Council may develop policies, standards and procedures in relation to these Regulations including –

(i) monitoring the development, field testing, fermentation, release, use, handling and transboundary movement of genetically modified organisms within Niue, and other matters related to the application of modern biotechnology;

(ii) risk assessment and risk management applying to any aspect of the development, field testing, fermentation, release, use, handling and transboundary movement of genetically modified organisms within Niue, and other matters related to the application of modern biotechnology;

(iii) identification and evaluation of adverse effects associated with genetic modification and the introduction of genetically modified organisms into Niue;

(iv) containment standards to be applied to any authorised use, development, field testing or release of a genetically modified organism;

(v) responding to unintentional and unlawful transboundary movements;

(f) In developing such policies, standards and procedures, the Council shall take into account –

(i) the impacts of genetically modified organisms on communities and areas within Niue;

(ii) the customs and traditions of Niue.

20 The Department

(1) The Department shall be the National Focal Point for all purpose associated with the Cartagena Protocol.

(2) For the purposes of these Regulations the Department may –

(a) Provide secretariat and support services to the Council and any advisory committee;

(b) Deal with requests for the review of decisions in accordance with Article 12 of the Cartagena Protocol, and refer such matters to the Council with such reports and additional information as required;

(c) Arrange for certain information to be treated as confidential in accordance with these Regulations and the Cartagena Protocol;

(d) Conduct programs of public awareness and education in relation to genetically modified organisms and applications of modern biotechnology, and facilitating public participation in relation to the processes prescribed by these Regulations and envisaged by the Cartagena Protocol in relation to their use and development within Niue;

(e) Liaise with other Departments and agencies, and work collaboratively with them to –

(i) establish and maintain appropriate mechanisms, measures and strategies for the regulation, management and control of risks associated with genetically modified organisms and the application of modern biotechnology within Niue;

(ii) implement measures to control and prevent unintentional and illegal transboundary movements of genetically modified organisms, and to respond to such movements, including the taking of necessary emergency responses;

(iii) ensure that genetically modified organisms which are subject to transboundary movement are handled, packaged and transported under conditions of safety, and that relevant international standards and rules are applied in this regard;

(iv) ensure that genetically modified organisms within Niue, or proposed to be imported into Niue, are packaged and labelled so as to disclose their genetically modified organism content, and otherwise identified as being or containing genetically modified organisms as required by any law and by the Cartagena Protocol; and

(v) facilitate the development and strengthening of human resources and institutional capacities within Niue in the field of biosafety; and

(f) Facilitate appropriate bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of genetically modified organisms, and for the sharing of information and the enhancement of institutional capacities for the purposes of applying the provisions of the Cartagena Protocol.

21 The Director

(1) For the purposes of these Regulations, the Director may –

(a) Approve the provision of assistance and support to the Council and advisory committees;

(b) Require further information to be provided under the Advanced Informed Agreement Procedure;

(c) Make arrangements for the keeping of certain information confidential in accordance with the provisions of these Regulations and the Cartagena Protocol;

(d) Prepare information and reports required by the Cartagena Protocol;

(e) Arrange for the monitoring and reporting of the effects to the environment and on human health arising from genetically modified organisms and the application of modern biotechnology within Niue;

(f) Approve and implement any appropriate program of public information and education concerning genetically modified organisms and the implementation of the Cartagena Protocol; and

(g) Do any other act or thing necessary to manage the risks and maximise the benefits associated with genetically modified organisms and the application of modern biotechnology within Niue.

(2) The powers of the Director shall be exercised consistently with decisions of the Council.

SCHEDULE

NOTIFICATION OF TRANSBOUNDARY MOVEMENT OF A GENETICALLY MODIFIED ORGANISM TO NIUE

Annex 1 of Cartagena Protocol

1 Name, address, telephone and facsimile numbers and email address of –

(a) Notifier
(b) Exporter
(c) Importer(s)

(state the nature of the relationship between the notifier and the exporter or importer)

2 Name and identity of the LMO–

(a) Domestic classification
(b) Biosafety Level of LMO in the state of export

3 Purpose of the transboundary movement to Niue –

(a) Import for release
(b) Import for contained use
(c) Transit through the Niue (if so, give full details of destination and other relevant approvals)
(d) Direct use for food, feed or for processing (Give full details of proposed purpose and means of release, contained use, transit or use as food, feed or for processing.)

4 Intended date/s and means of transboundary movement –

5 Taxonomic status –

(a) Common name
(b) Point of collection
(c) Characteristics recipient organism/or parental organism

6 Centres of origin -(Describe the habitats where the organisms may persist)

7 Describe the nucleic acid or the modification introduced –

(a) What was the modification technique used for the development of the organism?
(b) What are the resulting characteristics of the genetically modified organism?

8 Give full details of the intended use of the Genetically Modified Organism.

9 Give full details of the quantity and volume of LMO to be transferred.

10 Has your organisation undertaken a risk assessment of the transferred LMO? (Attach any available report and all supporting information and data)

11 Give full details of proposed method(s) for –

(a) safe handling
(b) storage
(c) transport and use
(d) packaging and labeling
(f) monitoring and reporting on effects
(g) disposal and emergency procedures

12 Regulatory status of LMO within the country of export –
(State any reason for any previous rejection of approval or ban of the LMO, and give full details of any breaches of any relevant law in another jurisdiction, or any criminal prosecution under such law)

13 Purpose, status and outcome of any notification by the exporter to any other country.

14 State or provide any other information known to the notifier, importer or exporter that is relevant to this application.

I .....declare that all the above information is correct.

Signature..... Date.....