

**FINAL DRAFT**

**PLANT AND ANIMAL QUARANTINE --  
BIOSAFETY REGULATIONS**

**REPUBLIC OF PALAU**

**APRIL 2004**

## GENERAL PROVISIONS

### 11.1 Authority

The Republic of Palau, Ministry of Resources and Development, promulgates these regulations pursuant to the authority granted it by Title 34 Palau National Code. These regulations shall have the force and effect of law.

### 11.2 Applicability

These regulations shall apply to all protocols relating to biosafety, with the focus on the transboundary movement, handling, and use, of any living modified organism (hereinafter referred as “ LMO’ s” ) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity. These regulations shall apply to all of the above stated activities as defined herein that began on or after the effective date of these regulations.

### 11.3. Definitions

As used herein, unless the context otherwise requires, the term;

- (a) “ Contained Use” means any operation, undertaken within a facility, installation or other physical structure, which involves LMO’ s that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
- (b) “ Export” means international transboundary and movement from one party to another party;
- (c) “ Exporter” means any legal, juridical or natural person who arranges for LMO’ s to be exported;
- (d) “ Import” means international transboundary movement of an LMO from one country to another country;
- (e) “ Importer” means any legal, juridical or natural person, under the

jurisdiction of a government of import, who arranges for an LMO to be imported into that country;

- (f) “ Living Modified Organism” (hereinafter referred to as LMO) means any living organism that possess a novel combination of genetic material that came into existence by way of modern biotechnology;
- (g) “ Living Organism” refers to any biological entity which is capable of transferring or replicating genetic material, which can include all types of viruses, viroids and other sterile organisms;
- (h) “ Modern Biotechnology” means the application of In vitro nucleic acid techniques, including DNA as well as the direct injection of nucleic acid into cells or organelles, as well as the fusion of cells beyond the taxonomic family, which overcome natural physiological reproductive or recombination barriers, that are not traditional breeding and selection techniques;

- (i) “ Transboundary Movement” means the movement of any LMO between countries;
- (j) “ Biosafety Clearing House” means that entity that was established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention on Biological Diversity; (1) whose duties are to facilitate the exchange of scientific, technical, environmental and legal information pertaining to LMO’ s; and (2) to assist in the implementation of the Cartagena Protocol on Biosafety.
- (k) (“ Biosafety Coordinator” means that person who has been appointed by the President of the Republic of Palau whose duties are to monitor and coordinate all issues concerning LMO’ s between the ROP and other countries, the Biosafety Clearing House, all importers and exporters and all other agencies within the ROP.
- (l) “ National Competent Authority” (*Minister of Resources and Development-Should have an advisory body of several scientists either ad*

*hoc or standing, to provide the basis for his decisions and diversify authority). . . .*

#### **11.4 Scope**

These regulations shall apply to the transboundary movement, handling and use of all LMO' s imported to or exported from the Republic of Palau (hereinafter referred to as “ ROP” ).

The goal of these regulations is to provide for the safe transfer and handling of LMO' s in a manner that prevents or reduces the risk to bio-diversity and human health.

These regulations do not apply to the movement of LMO' s within the ROP. Nor do they apply to the transboundary movement of human or veterinary pharmacological LMO' s that are addressed by other international agreements or organizations.

## 11.5 Notification

Exporters of LMO' s shall be required to give written notification to the Biosafety Coordinator and any other Importer that they intend to ship to the ROP a product containing LMO' s. The information required to be given to the Biosafety Coordinator is attached to these regulations as Appendix One, which is incorporated by reference to these regulations. The information contained in Appendix One, shall be received by the Biosafety Coordinator prior to the LMO' s leaving the exporting country. No LMO may leave any exporting country bound for the ROP without prior approval from the ROP.

The Biosafety Coordinator shall give written acknowledgement of receipt of the above referenced notification of the proposed shipment of LMO' s within ninety (90) days of receipt of said notification. The Biosafety Coordinator shall state the following information in its acknowledgment to the exporter of the LMO;

- (1) The date of receipt of the above referenced notification;
- (2) Whether the notification on its face contains all the required information as set forth in Appendix One;

- (3) Whether the exporter may, or may not proceed with the importation process. If the importer may proceed with the importation process the Biosafety Coordinator may make a request for additional information including requiring the Importer to provide a risk assessment of the LMO' s.
- (4) A failure by the Biosafety Coordinator to acknowledged receipt of the above stated notification shall not imply consent for the entry of the LMO' s. All information to be provided pursuant to Appendix One shall be made under oath and under penalty of perjury, under the laws of the country of the exporter and the ROP.

## **11.6 Decision Procedure**

Within two hundred seventy (270) consecutive days from the receipt of the notification by the Exporter, the Biosafety Coordinator shall have sent written communication to the Exporter and to the Biosafety Clearing House notice of the ROP' s decision as to whether the LMO' s may be imported into the ROP. This decision shall do one of the following:

- (1) Approve the import, with or without conditions, including how the decision will apply to subsequent imports of the same LMO' s;
- (2) Prohibit the import;
- (3) A Request for additional information, coupled with an extension of time to respond, not to exceed \_\_\_\_\_days, within which to comply with the Biosafety Coordinators request for additional information. As set forth above, the ROP will render a decision as to the importation of the LMO within two hundred and seventy (270) days from receipt of the additional information.
- (4) Any decision not to admit the LMO by the ROP, will be supported by the reasons upon which the decision was based upon;
- (5) Any failure by the ROP to communicate a decision concerning the importation of LMO' s within two hundred seventy (270) days from the receipt of the notification, is not an implied consent to the international transboundary movement of the LMO' s.
- (6) Insufficient scientific information regarding the potential adverse effects of any LMO is not grounds for ROP not to make and communicate a decision as to the importation of the LMO, however said lack of information may be

used as a factor in deciding whether or not the import shall or shall not be allowed.

### **11.7 Procedure For Using LMO' s That Are Intended For Direct Use As Food, Feed Or Processing**

Any person, party or legal entity that decides to place LMO' s on the domestic or international market and subject to trans-boundary movement for use as Food, Feed or Processing shall within 15 days of its decision, inform the Biosafety Coordinator and Biosafety Clearing House. The information to be provided to the Biosafety Coordinator and the Biosafety Clearing House shall contain that information as specified in Appendix Two to these regulations, which is incorporated by referenced hereto. A copy of the above stated information as set forth in Appendix Two shall also be provided to all other interested parties by the Biosafety Coordinator. This provision shall not apply to domestic field trials of LMO' s. All information provided pursuant to Appendix Two shall be made under oath and under penalty of perjury within the Republic of Palau and the country in which the application was made.

Insufficient scientific information regarding the potential adverse effects of any LMO shall not be grounds for a failure of the ROP to make a decision as to the importation of the LMO which is intended for direct uses as food, feed or processing. A failure by the Biosafety Coordinator to communicate any decision as to the importation of any LMO shall not imply its consent to the import of any LMO, whether it is for direct use of food, feed or processing, or any other use.

### **11.8 Review Of Decisions**

Any exporter may request the Republic of Palau to review any decision it has made under these regulations so long as: (1) there has been a change in circumstances that may influence the outcome of the risk assessment upon which the decision was made; (2) additional scientific evidence or technical information has become available.

The office of the Biosafety Coordinator must respond to said request for reconsideration within ninety days and set forth the reasons for its decision within the above said ninety day period.

Additionally the ROP, upon receipt of any new information as described above, may choose to review and change any decision regarding the international transboundary movement of LMO' s. In such cases the ROP shall notify the Biosafety Clearing House and any other interested parties of the reasons for this reconsideration.

### **11.9 Other Agreements**

Notwithstanding the information as contained in Section 11.8, nothing shall prohibit the ROP from entering into Bilateral, Regional or Multilateral Agreements regarding the international transboundary movements of LMO' s, provided such agreements are consistent with the rules set forth in these regulations and do not result in a lower level of protection as provided for by the Cartagena Protocol on Biosafety.

Any other agreements relative to LMO' s shall be kept on file with the office of the Biosafety Coordinator, who shall provide copies of the same to the Biosafety Clearing House and all other relevant parties.

## 11.10 Risk Assessment

All risk assessments undertaken pursuant to this regulations shall be carried out in a scientifically sound manner, based on recognized risk assessment techniques and in accordance with the information contained in these regulations and attached Appendices. Appendix Three, which is incorporated by reference hereto, contains an analysis of Risk Assessment procedures. The overall goal of a Risk Assessment is to evaluate all possible negative effects of the LMO' s on the conservation and sustainable use of biological diversity, but at the same time evaluate all possible risks to human health. All importers and exporters shall endeavor to ensure that any LMO whether imported, locally developed, or exported, has undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.

All expenses and causes associated with the risk assessment process shall be borne by the importer or exporter of the LMO' s. The ROP may, at its discretion, choose to require that either the importer or exporter carry out the risk

assessment and bear all associated costs and expenses.

### **11.11 Unintentional Trans-boundary Movements**

Any person or entity having direct or indirect knowledge of an unauthorized or unintentional transboundary movement of an LMO shall immediately take appropriate measures to notify the Biosafety Coordinator of all said necessary information pertaining to said transboundary movement. The Biosafety Coordinator shall promptly notify the Biosafety Clearing House and any and all other affected parties and or countries of all relevant details of said transboundary movement. The notification required shall include:

- (1) Information on the estimated quantities, characteristics and or traits of the LMO;
- (2) Information on the circumstances and date of release;
- (3) Information all possible adverse effects on biological diversity and human health.

### **11.12 Handling, Transport, Packaging and Identification**

Any importer or exporter of LMO' s shall take all necessary measures to

require that all LMO' s are handled, packaged and transported safely under relevant international rules and standards. Said measures are as follows:

- (1) All LMO' s that are intended for direct use as food, feed or processing must be clearly identified that they “ may contain” LMO' s and are not intended for intentional introduction into the environment as well as provide a contact point and telephone number for further information.
- (2) All LMO' s that are intended for contained use must be clearly identified and the specifics for any requirements for the safe handling, transport, storage and use as well as a contact point for further information along with the name, address and telephone number of the consignee or recipient of the LMO shall be included;
- (3) LMO' s that are intended for the intentional introduction into the environment of the importer as well as any other LMO' s must be clearly identified as LMO' s and specifically identified with all relevant traits and/or characteristics and requirements for safe handling, storage, transport and use. Further a contact point and telephone number for further information must be provided along with the name and address, and telephone numbers of all importers, exporters, and consignees

coupled with the declaration that the movement is in conformity with the Cartagena Protocol on Biosafety.

### **11.13 Penalties**

Pursuant to 34 PNC Section 2010 any person who violates any provision of these regulations shall be subject to imprisonment for a period not to exceed 6 months or fined not more than \$100.00 or both.

### **11.14 Severability**

If any provision of these regulations or the application of any provision of these regulations to any person, entity or country is held invalid, the application of such provision to other persons, entities or countries and the remainder of these regulations shall not be affected thereby.

## APPENDIX ONE

### NOTIFICATION INFORMATION

Pursuant to Section 11.5 all applications are required to provide the following information:

- (a) Name, address, telephone number and any other relevant contact details of the exporter.
- (b) Name, address, telephone number and any other relevant contact details of the importer.
- (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the country of export.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (f) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats

where the organisms may persist or proliferate.

- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- (i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- (j) Quantity or volume of the living modified organism to be transferred.
- (k) Any previous risk assessment reports.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.
- (m) Regulatory status of the living modified organism within the country of export (for example, whether it is prohibited in the country of export, whether there are other restrictions, or whether it has been approved for

general release) and, if the living modified organism is banned in the country of export, the reason or reasons for the ban.

- (n) Results and purpose of any notification by the exporter to other countries regarding the living modified organism to be transferred.
- (o) A declaration under penalty of perjury that the above-mentioned information is factually correct.

## APPENDIX TWO

### INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

Pursuant to Section 11.7, the following information is required of any person or entity that intends to place LMO' s on domestic or international market for direct use as food, feed or processing:

- (a) The name and all contact details of the applicant for a decision for domestic use.
- (b) The name and all contact details of the authority responsible for the decision.
- (c) Name and identity of the living modified organism.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
- (e) Any unique identification of the living modified organism.

- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centers or origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (i) Approved uses of the living modified organism.
- (j) Any previous risk assessment reports.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.

## **APPENDIX THREE**

### **RISK ASSESSMENT**

#### **Objective**

1. The objective of risk assessment, under these regulations, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

#### **Use of Risk Assessment**

2. Risk Assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

#### **General principles**

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level or risk, an absence of risk, or an acceptable risk.
5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organisms origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

### **Methodology**

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand

information on other subjects may not be relevant in some instances.

8. To fulfill its objective, risk assessment entails, as appropriate, the following steps:
  - (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
  - (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposures of the likely potential receiving environment in the living modified organism;
  - (c) An evaluation of the consequences should these adverse effects be realized;
  - (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
  - (e) A recommendation as to whether or not the risks are acceptable or

manageable, including, where necessary, identification of strategies to manage these risks; and

- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

#### **Points to consider**

- 9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

- (a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centers of origin and centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

- (b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- (c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) *Living modified organism.* Identity of the living modified organism, and the difference between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
- (f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;
- (g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental

organisms; and

- (h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment.

**Note:** Parts of these regulations were taken from the text and annexes of the Secretarial of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to The Convention On Biological Diversity: text and annexes.