

# National Government of the Federated States of Micronesia



Draft  
**Draft**

## National Biosafety Framework

Department of Economic Affairs  
Biological Diversity/ Biosafety Enabling Activities Grant Project

Funded by the United Nations Environment Program (UNEP) and the  
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\*2007\* Draft National Biosafety Framework (NBF)

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## **SECTION ONE: BIOSAFETY POLICY**

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### **Part 2. Cartagena Protocol- Status Report**

As of the date of the release of the Final NBF draft, the Federated States of Micronesia has not signed, nor ratified the Cartagena Protocol on Biosafety (CPB). There is internal debate going on, and the state high level policy-makers who attended the National Biosafety Framework workshop recommended that FSM become a member party to CPB.

### **Part 3. Sustainable Development Policy within the FSM**

The President's Council on Environmental Management and Sustainable Development (SD Council) was established by Executive Order on 1995.

The interdepartmental council, representing the National government and the four Micronesian states, originally met monthly, and by design, is chaired by the Vice President. In the absence of an environmental agency in Micronesia, the council takes on the role of coordinating across sectors, following up on international environmental treaty commitments ensuring compliance with treaties that FSM has signed and ratified. The SD Council was intentionally expanded in 1996 to include NGOs, the private business sector, and representatives for the traditional leaders. At the state level, municipalities or island councils are often tasked with carrying out the enforcement of national level treaties.

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# National Government of the Federated States of Micronesia



Title 23. Resource Conservation- Chapter [4]

## Biotechnology and Biosafety Act of [2007?]

Draft  
**Draft**

Drafted by: L. Heidi Primo, National Project Coordinator

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Federated States of Micronesia (FSM)  
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Containment of Living Modified Organisms



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**Biotechnology and Biosafety Act of [2007?]**

Congressional Bill No. [ ]

AN ACT

To introduce and administrative and legal framework for environmental safety with respect to the import, export and use of living modified organisms (LMOs) within the National borders of the Federated States of Micronesia.

BE IT ENACTED by the Congress of the Federated States of Micronesia

Commencement: 2007

**SHORT TITLE.** Title 23. Resource Conservation- Chapter [4]

This chapter is known and may be cited as the "Biotechnology and Biosafety Act of 2007."

**FINDINGS.**

The Congress of the Federated States of Micronesia has determined that in order to comply with International obligations under the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), an effective National Biosafety Framework (NBF) with sufficient operative regulations needs to be implemented.

**POLICY**

The biological diversity of endemic plants and animals of the FSM are of esthetic, ecological, historical, recreational, scientific, medicinal and economic value. It is the policy of the FSM Government to foster conservation and sustainable use of these plants and animals, and to limit activities that could adversely impact biological diversity.

To encourage the economic development in FSM by facilitating the beneficial use of the applications of modern biotechnology, a transparent and predictable process for review and decision-making on living modified organisms (LMOs) and related activities is required.

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**PREAMBLE**

Biotechnology, as defined in the text of the Convention on Biological Diversity (CBD) is any *“technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products and processes for specific use.”* The United National Conference on the Environment and Development (Rio Earth Summit, 1992) recognized the role of biotechnology for sustainable development in Chapter 16 of Agenda 21. *“Biotechnology promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. It offers new opportunities for global partnerships.”*

The Pacific Island Working Biotechnology Group (PIBWG) includes members from major regional organizations (SPREP, SPC) and United Nations agencies (UNEP, GEF, FAO, UNESCO). At their meeting in Nadi, Fiji in February 2005, the PIBWG agreed to *“promote biotechnology as an essential element in Pacific Islands sustainable development- closely linked with biodiversity conservation, traditional agriculture, food and nutritional security.”*

The people of the Federated States of Micronesia (FSM) wish to ensure our island resources are utilized sustainably for this generation and those to come. The FSM National Biodiversity Strategy and Action Plan (NBSAP) was completed and signed by the President on March 13<sup>th</sup>, 2002. The NBSAP Vision is: *“The FSM will have more extensive, diverse, and a higher quality of marine, freshwater and terrestrial ecosystems, which meet human needs and aspirations fairly, preserve and utilize traditional knowledge and practices and fulfill the ecosystem functions necessary for all life on Earth.”*

The NBSAP also states: *“The possible adverse impacts of genetically modified organisms on the native biodiversity could be drastic and therefore mechanisms need to be developed and implemented to regulate these activities in the future.”* Objective 1 under Theme 6 of the NBSAP (Biosecurity) mandates actions to *“develop National and State policies, legislation and actions for the management of genetically modified organisms;”* and correspondingly to *“develop National and State policies and actions for the management of all Biosafety issues.”*

The FSM constitution gives the executive branch of the FSM National Government the authority to enter into international environmental treaties, such as the Convention on Biological Diversity and the Cartagena Protocol

on Biosafety (CPB). The Congress of FSM then must ratify them, as the national legislative body.

In FSM, environmental activities are primarily implemented by the four states: Chuuk, Kosrae, Pohnpei and Yap. State legislative bodies are responsible for developing policies, regulations and monitoring regimes that may exceed the minimum Biosafety standards, which are articulated in this Act.

## **SECTION ONE: GENERAL PROVISIONS**

### **Part 1. Objective**

The objective of this act is to encourage the economic development of the FSM by facilitating the beneficial uses of LMOs and application of modern biotechnology, after appropriate scientific assessment and analysis, to fulfil the Federated States of Micronesia's obligations under the Cartagena Protocol. It is crucial to ensure an adequate level of protection for the safe transfer, handling, and use of LMOs resulting from modern biotechnology that could have an adverse effect on the conservation and sustainable use of biodiversity, taking into account risks to human health.

Its key aims are to:

- ◆ Focus the resources of the FSM National Government, Department of Economic Affairs (as the Competent Authority) on the areas of greatest potential risk to FSM people or the environment;
- ◆ Clarify all elements of the operation of this Act to minimize the administrative burdens;
- ◆ Provide for sustainable co-existence between traditional farmers and farmers employing biotechnology-derived agricultural practices;
- ◆ Ensure mechanisms for public participation in applications where a significant risk to people and or the environment is identified; and to
- ◆ Allow for flexibility in the periodic review of this Act and related regulations in the light of new advances in biological sciences and modern biotechnology.

### **Part 2. Definitions**

Words used in this Act, and in any regulations made under it, have the same meaning as given to them in the CBD and the CPB, unless a contrary intention appears.

Technical terms are defined specifically in Part 39 of the NBF document.

### **Part 3. Scope**

This Act applies to every person in the FSM irrespective of the person's nationality or citizenship.

Subject to exceptions set forth in this Act or provided for by regulation hereunder, this Act shall apply to the contained use, intentional introduction into the environment, import and export of LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health.

This Act shall not apply to:

LMOs that are pharmaceuticals or pharmacogenomics for human use that are addressed by other relevant international agreements

LMOs in transit through but not destined for use in FSM;

Bioprospecting for genetic resources in FSM;

Biosecurity legislation for quarantine border control to prevent invasive species, which are covered by other laws in FSM;

Food safety labeling requirements, which is covered by other regulations in FSM;

Any other LMOs or categories of LMOs that are exempted pursuant to Part 19 of this Act.

All human or animal reproduction biotechnology intended to create genetically modified transgenic or cloned animals or humans shall be explicitly prohibited within FSM.

## **SECTION TWO: INSTITUTIONAL ARRANGMENTS**

### **Part 4. Establishment of National Focal Points and Competent Authority (CA)**

- (a) The Secretary of the FSM National Government, Department of Foreign Affairs will be the National Focal Point for the Cartagena Protocol.

- (b) The FSM National Government, Department of Economic Affairs shall be established as the Competent Authority for purposes of the administration of this Act and any regulations promulgated thereunder. The Secretary of Economic Affairs will be the Implementation Focal Point for the Cartagena Protocol.

### **Part 5. Powers of Competent Authority**

The FSM National Government, Secretary of Economic Affairs shall serve as the National Implementation Focal Point for the Convention on Biological Diversity and also for the Cartagena Protocol on Biosafety.

The primary functions of the Competent Authority are:

- (I.) To have the ultimate authority within the FSM National Government regarding decisions pertaining to LMOs, taking into consideration the recommendations of the National Biosafety Regulator;
- (II.) To communicate with the four state Governors (of Chuuk, Kosrae, Pohnpei and Yap) requesting them to name a State Focal Point person for all matters related to Biotechnology and Biosafety;
- (III.) To establish the Biotechnology Scientific Advisory Council (BSAC) and to invite qualified FSM participants and experts to become members thereof;
- (IV.) To call for reports from the National Biosafety Regulator and the Biotechnology Scientific Advisory Council, or from external scholars or independently contracted consultants; as necessary;
- (V.) To give directions in writing to the National Biosafety Regulator concerning administrative actions needed to implement this Act.
- (VI.) To keep apprised of political negotiations within all United Nations agencies regarding Biosafety of LMOs and GMOs, and to participate as the head of or as a member of FSM delegations to relevant regional and international meetings, whenever appropriate.

**Part 6. Establishment of National Biosafety Regulator (NBR) Position**

- (a) The FSM National Government, Secretary of Economic Affairs as Competent Authority, shall request from Congress of the FSM funding to maintain a continuous, sustainable position for a National Biosafety Regulator, with all the benefits allowed to a permanent FSM National Government employee.
- (b) The NBR and any other personnel he or she supervises will be placed administratively within the FSM Department of Economic Affairs, under the Agriculture Unit, the Sustainable Development Unit, or any Science & Technology Unit or Environment Unit that may be created, as deemed appropriate, in the future.
- (c) The minimum education requirements for the person appointed as the NBR shall be a postgraduate science degree (preferably M. Sc. or Ph.D. level) from a recognized international university in one of the following fields: Biosafety, Biotechnology, Bioscience Regulatory Affairs, Molecular Biology, Bioinformatics, Plant Pathology, Agriculture, Agronomics or Biosecurity.
- (d) The NBR should also have formal training in conducting environmental impact assessments and/ or Biosafety risk assessments (including socio-cultural and economic impact assessments) or shall obtain such training within one year after hire.
- (e) The person hired as NBR should have sufficient computer skills to design, maintain and update databases, to create the National Biosafety Website, and to do required reporting to the Biosafety Clearing House established by the Cartagena Protocol, and any Pacific Island regional node that may be established.

**Part 7. Responsibilities of National Biosafety Regulator (NBR)**

- (a) The primary responsibilities of the NBR are to:
  - (l.) To establish administrative mechanisms to ensure appropriate handling, dissemination and storage of documents and data in connection with the processing of applications and notifications and other matters covered by this Act;

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- (II.) To receive, respond to and process all inquiries, applications, and approvals for import, export, contained research experiments, limited field trials, commercialization and marketing of LMOs;
- (III.) To conduct risk assessments on a case-by-case basis, according to the procedures outlined in Annex II of this Act, according the general definition of "risk" as the magnitude of harm measured against the probable occurrence of the harm;
- (IV.) To make recommendations on decisions to the Competent Authority regarding notifications pursuant to Part 12 and applications pursuant to Part 14 et seq. in consultation with the Biotechnology Scientific Advisory Council (BSAC), in conformity with the requirements of this Act;
- (V.) To serve as Secretary to meetings and deliberations of the BSAC; including taking minutes and distributing documents to participants;
- (VI.) To disseminate information to the State Focal Points for Biotechnology and Biosafety;
- (VII.) To prepare briefing papers and policy analyses for the Secretary of Economic Affairs, the Sustainable Development Council and other decision-makers on newly emerging international political issues surrounding Biosafety, biotechnology, LMOs and GMOs;
- (VIII.) To make information available to and receive comments from the general public, to issue written notices and announcements, news, and communications regarding LMO applications, decisions, policies and provisions under this Act;
- (IX.) To maintain National Biosafety Internet web site and links to SPREP, the UNEP or any other relevant agencies;
- (X.) To represent the FSM on the Pacific Islands Biotechnology Working Group (PIBWG) panel;

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- (XI.) To develop instructional materials and presentations for all levels of stakeholders and have them translated into the four indigenous FSM languages;
- (XII.) To arrange or do awareness-raising, education and capacity-building in the four FSM states regarding modern biotechnology, LMOs, Biosafety and surrounding issues for FSM citizens;
- (XIII.) To liaison with other local, regional and international agencies working on Biosafety issues, in behalf of FSM; and
- (XIV.) To enforce compliance with regulations and to process collection of fees required and deemed necessary to implement this Act.

### Part 8. Establishment of Biotechnology Scientific Advisory Council

- (a) A Biotechnology Scientific Advisory Committee (BSAC) shall be established by the Competent Authority for the purpose of conducting risk analyses and providing scientific and other technical advice and assistance to the Competent Authority, the National Government and the National Biosafety Regulator.
- (b) Members of the BSAC shall be drawn from government agencies and independent institutions, including regional research/ technical assistance advisory agencies, the College of Micronesia-FSM, or civil society including private enterprise and non-government organizations.
- (c) The BSAC should consist of a core group of scientific and legal experts appointed by the Competent Authority, who are individually appropriately qualified in at least one of the following fields:

Agronomy/Agro-ecology

Aquaculture

Biological engineering

Biosafety

Biosecurity/Quarantine

Biotechnology

Botany/ Ethnobotany

Disaster Management

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Ecology/ Ecosystems	Microbiology
Entomology	Molecular Biology
Environmental Impact Assessment	Taxonomy
Environmental law	Tissue Culture
Environment toxicology	Weed science
Food safety/ Nutrition	Plant breeding and genetics
Forestry	Plant pathology
Genetics	Soil & Water Studies
Laboratory applications of industrial processes	Social Sciences
Natural Resource Conservation	Veterinary medicine
	Virology

- (d) The Competent Authority will designate the Chairperson and alternate/ assistant Chairperson for BSAC; the BSAC members may establish appropriate subcommittees and designate chairpersons for any subcommittees, to be drawn from the members of the BSAC.
- (e) The Competent Authority also may appoint temporary non-voting expert advisors from scientific disciplines not otherwise adequately represented on the BSAC or its subcommittees.
- (f) The BSAC should meet minimally twice a year on a regular basis, and on an *ad hoc* basis whenever required.
- (g) A quorum of at least one half the BSAC members plus one person (51%) shall be required to take voting decisions; additional "Rules of Procedure" will be determined by the members.
- (h) For the effective and transparent operation of the BSAC and any subcommittees established hereunder, all minutes of proceedings, and

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reports from surveys, risk assessments, or information about any remuneration provided to members of BSAC and its advisors shall be publicly available, upon request.

- (i) All members of the BSAC and its subcommittees and all advisors shall be required to disclose publicly any and all actual and potential conflicts of interest relating to any risk assessment or other matter upon which the BSAC or subcommittee may be consulted by the Competent Authority. Any individual having an actual or potential conflict of interest with regard to a particular matter shall not participate in any risk assessment, discussions or deliberations concerning that matter.
- (j) In cases where multiple actual or potential conflicts impair any individual's ability to serve in an independent or impartial manner, that person shall be asked to resign from the BSAC or subcommittee.

### **Part 9. Responsibilities of the Biotechnology Scientific Advisory Council**

The responsibilities of the BSAC shall include:

Conducting risk assessments, or evaluate the sufficiency of risk conducted by the NBR;

Reviewing risk assessments provided in applications or notifications, when necessary;

Reviewing risk management measures emergency biohazard threat safety plans; when necessary;

Recommending containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures;

Providing such other expert advice and assistance as the Competent Authority may request;

Ensuring the protection of confidential information as required by Part 15 of this Act by signing a formal declaration that any information attained (by virtue of membership in the BSAC or a subcommittee, or appointment as an advisor to the BSAC), shall not be disclosed to others or used for research, development or any commercial purpose without the express written authorization of the Applicant identifying the information as confidential pursuant to Part 15.

### **Part 10. Relationship with Other Acts**

This Act is in addition to and does not derogate from any other Act. In particular, but without limited this rule-

The requirements (per FSM Code and regulations) relating to import and export, biosecurity, port quarantine, natural resource conservation, endangered species, food safety, or laws protecting human health and the environment.

FSM States may choose to adopt legislation or provisions that are in accordance with this act.

To the extent of any inconsistency between this and any other Act, every other Act must so far as possible be construed to fulfill the purpose of this Act.

### **Part 11. Regional Collaboration**

FSM will actively participate in and share experiences with regional Biosafety projects, forums for dialogue about tropical biotechnology applications and educational activities intended to build national capacity, transfer technologies, and promote biotechnology as an essential element of a sustainable development strategies within the Pacific Islands region.

**SECTION THREE: ADVANCED INFORMED NOTIFICATION PROCEDURES AND  
AUTHORIZATION REQUIREMENTS**

**Part 12. Notification Requirements & Procedures for Contained Use Activities**

No person shall import or conduct any contained use activities involving LMOs for experimental, research or commercial purposes without the prior submission of a notification (e.g., by filing a copy of Application in Annex I-B) to the Competent Authority or the National Biosafety Regulator, as set forth in this Article, except as provided under Part 19 (a).

A notification of intent to conduct activities with LMOs under contained use pursuant to paragraph (a) shall be submitted at least ninety (90) days before the activities covered by the notification are due to begin.

The notification shall include:

The name, address, fax number, phone, email, and any other contact information for the Applicant;

The location where contained use activities will be undertaken;

The nature and identity of the LMO or LMOs involved;

The nature and purpose of the activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing, or using the LMOs in any other way;

A description of the containment measures to be provided and the suitability of those measures for the LMOs and the activities to be undertaken;

A description of any potential risks associated with the LMOs and activities to be undertaken; and

A description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the LMOs that may occur as a result of the activities to be conducted.

If the Applicant receives no response within thirty (30) days, the Applicant should make contact with the office of the Competent

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Authority requesting acknowledgement of receipt of notification in writing.

If the Applicant receives no response within sixty (60) days of receipt of acknowledgement of submission of the notification, the proposed activities may commence.

In response to the submission of a notification of intent, the Competent Authority shall (in consultation with the National Biosafety Regulator and BSAC, if necessary), notify the Applicant in writing in order to:

Approve the import, with or without conditions, including an explanation of how the decision will apply to subsequent imports of the same LMO

Prohibit the import

Request additional information, including further risk assessment carried out in a scientifically sound manner at the Applicant's expense in accordance with Annex II and recognized risk assessment techniques. The NBR shall inform the applicant in writing of the additional information sought and the procedure that will be followed in taking further action on the notification.

Where additional information is sought under paragraph (e), a final written decision as to whether the proposed activities may proceed shall be provided to the Applicant no later than sixty (60) days following receipt of the additional required information, signed by the Competent Authority. In the event the proposed activities are not permitted as requested, the Competent Authority shall include in the final written decision the reasons for the prohibition or any limitations or conditions that may be placed on the proposed activities.

Regulations governing the conduct of contained use activities, including relevant definitions, risk classifications, waste and disposal requirements and procedures, and requirements for risk assessments, shall be promulgated pursuant to Part 36, according to Annex II and Annex IV of this Act.

### **Part 13. Authorization Requirements for Intentional Introduction into the Environment**

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“Intentional introduction into the environment” does not refer to living modified organisms intended for direct use as food, or feed, or for processing.

The following activities shall require authorization by the Competent Authority in conformity with this Act:

The intentional introduction into the environment of an LMO for purposes other than placing on the market; and

Placing on the market of an LMO.

No person shall import an LMO for activities subject to paragraph (a) without authorization under this Act.

Persons proposing to export LMOs covered by this Act from the Federated States of Micronesia to another country party to the Cartagena Protocol shall:

Notify the Competent Authority of the proposed party of import, in writing, prior to the first transboundary movement of an LMO for intentional introduction into the environment of the party of import by supplying, at a minimum, information specified in Annex I, in accordance with the Cartagena Protocol and any applicable legislation;

Include a declaration that all information provided in such notification is factually correct; and

Prior to shipment, provide to the FSM National Biosafety Regulator a copy of the authorization granted by the importing country where authorization is required under the Cartagena Protocol and/ or the applicable laws of that country.


### **Part 14. Application Procedures for Intentional Introduction into the Environment**

Any person proposing to intentionally introduce and LMO into the environment shall submit to the Competent Authority an application that complies with the requirements of this Article and describes the activity or activities for which authorization is sought, except as provided under Part 19. (See Applications in Annex I-C for Field Releases and Annex I-D for Commercialization Releases).

Applicants shall include in their submissions:

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- (I.) The information specified in Annex I, with the exception of any information the Competent Authority identifies as unnecessary in pre-application consultations;
  - (II.) A risk assessment in conformity with Annex II, for which the applicant will bear the cost; and
  - (III.) A declaration that all the information contained therein is factually correct.

The Applicant shall proceed with the release only when the proponent has received official approval from the office of the Competent Authority, through the NBR.

An Applicant may withdraw any application at any time prior to the issuance of a final decision by the Competent Authority without prejudice.

### **Part 15. Confidentiality and Intellectual Property Rights (IPRs)**

The Competent Authority and the National Biosafety Regulator shall:

Permit the Applicant to identify information to be treated as confidential, with justification for claims of confidentiality to be provided upon request;

Decide whether it accepts as confidential the information designated by the Applicant;

Prior to any disclosure of information identified by the Applicant as confidential, inform the Applicant of its rejection of the claim of confidentiality, providing reasons, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure; and

In the event that an Applicant withdraws or has withdrawn an application, they must respect the Applicant's entire claim of confidentiality.

It is the responsibility of the Applicant to obtain the necessary patents in their own country and to name FSM as a country for proposed intellectual property protection for agricultural or industrial applications of genetically modified LMOs.

FSM shall not recognize foreign patents on intact, entire, or complete living organisms, which occur naturally in the environment.

## **Part 16. Acknowledgement and Preliminary Response**

Upon receipt of an application under Part 13, the Competent Authority immediately shall refer the application to the NBR for prompt screening for *prima facie* completeness.

Within thirty (30) days of receipt of the application, based on information provided, the NBR shall acknowledge receipt of the application and respond, in writing, to the Applicant.

The preliminary response shall include:

The date and time of receipt of the application; and

Whether the application, *prima facie*, contains the required information or, if not, what additional information within the scope of Annex I is required.

If additional information is required, the number of days the Competent Authority must wait for the information shall not be included in calculating the timeframe for making a final decision under Part 18.

## **Part 17. Risk Assessment and Risk Management.**

The Biosafety review process is intended to screen for evidence of demonstrated risks (not hypothetical risks).

The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out by the NBR for all activities that require authorization under Part 13.

Risk assessment, including the auditing of risk assessments, shall be carried out in a scientifically sound manner, in accordance with Annex II and recognized risk assessment techniques. Risk assessments shall take into account available information concerning any potential exposure to an LMO. Such risk assessments shall be based on the information included in the application and any other available scientific evidence.

In carrying out the risk assessment activities, the NBR shall take into account any risk management measures proposed by the Applicant and any additional risk management measures that may be necessary to minimize any identified risks.

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Where additional risk assessment or auditing is required, the Applicant, the NBR, the BSAC or other experts, at the discretion of the Competent Authority may undertake it, on a case-by-case basis.

Upon conclusion of the risk assessment and auditing process, the NBR shall prepare and provide to the Competent Authority a risk assessment report. It should contain an opinion, with justifications, on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the LMO. The report should include an "Executive Summary" of the risk assessment that does not include any confidential information subject to protection under Part 15.

The Competent Authority shall ensure that the appropriate mechanisms, measures or strategies to regulate, manage and control risks identified during risk assessment process are in place. He or she shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

The Competent Authority shall provide the risk assessment report described in paragraph (f) to the Applicant within ten (10) days of receipt of the report from the NBR. The Applicant may submit comments on the report in writing within thirty (30) days after receipt of the report. Any such comments shall be considered by the NBR and the Competent Authority, in consultation with the BSAC, in decision-making under Part 18 (b).

### **Part 18. Decision-making and Communication of Decision.**

Following receipt of the risk assessment report, the Competent Authority shall make a final decision concerning the authorization requested in the application submitted under Part 14.

Any decision rendered under paragraph (a) shall be based upon:

- (I.) The information submitted by the Applicant under Part 14;
- (II.) The risk assessment report prepared by the NBR in accordance with Part 17 (f);
- (III.) Any written comments provided by the Applicant in accordance with Part 17 (h);

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(IV.) Any relevant comments submitted by the public pursuant to Part 28.

In reaching a decision, the Competent Authority also may take into account, cultural and socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Lack of scientific certainty due to insufficient relevant scientific information and knowledge shall not prevent the Competent Authority from making a decision, as appropriate in order to avoid or minimize potential adverse impacts.

A final decision shall be made and communicated to the Applicant within one hundred and twenty (120) days of receipt of the application submitted for the intentional introduction into the environment of an LMO for purposes other than placing on the market, and within two hundred and seventy (270) days of receipt of an application submitted for the placing on the market of an LMO.

The final decision of the Competent Authority shall be recorded in a decision document that:

Identifies the Applicant and summarizes the nature of the request;

Describes the procedure(s) followed in reviewing the application;

Includes the summary of the risk assessment(s) conducted by the NBR, the BSAC and/ or other experts, if deemed necessary;

States whether the requested activity is authorized, with or without conditions, or whether the requested activity is prohibited; and

Provides the reasons for the decision.

Any specific conditions, limitations or requirements related to the authorization must be clear on the face of the decision document.

No person shall vary the purpose of the authorized activity as set forth in the decision document unless he or she obtains authorization from the Competent Authority.

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LMOs or activities authorized under Part 13 et seq. shall be included in the registry to be established under Part 28 (f).

### Part 19. Simplified Authorization and Review Procedures

The Competent Authority may approve a facility, including an installation or other physical structure, for which no further notification is required under Part 12 for designated types and classes of contained use activities conducted in conformity with applicable laws, regulations and internationally recognized good laboratory practice standards. Regulatory procedures and requirements shall be established under Part 37 of this Act.

The Competent Authority may exempt any LMOs or activities from the requirements of Parts 12 and 13 when he or she determines that sufficient experience or information exists to conclude that the LMOs or activities do not pose a significant risk to the conservation and sustainable use of biological diversity or human health.

A notification of intent to conduct an activity for which a designation has been made under paragraph (b) shall be submitted to the Competent Authority at least sixty (60) days before the activity covered by the notification is due to begin and shall include:

The name and contact information for the person submitting the notification;

The location(s) where the activity will be undertaken;

The nature and identity of the LMO involved (including information on transformation, vectors, etc.);

The nature and purpose of the activity;

A description of any containment measures to be provided and the suitability of those measures for the LMO and activity to be undertaken; and

A description of remedial measures to be undertaken (with cost to be borne by Applicant) in the event of any unintentional introduction into the environment of the LMO that may occur as a result of the activity to be conducted.

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If the Applicant subject to notification under paragraph (c) receives no response within sixty (60) days of submission of the notification, the proposed activities may commence.

The Competent Authority shall publish notice of any proposal to exempt or apply simplified procedures to LMOs or activities under paragraphs (b) or (c) in accordance with Part 28 and transmit the proposal to the NBR and the BSAC for review.

The Competent Authority shall make a final decision on proposals under paragraphs (b) and (c) based upon the scientific review conducted and relevant comments submitted by the public. Any such exemptions or simplified procedures established under this Article shall apply equally to the designated LMOs or activities whether undertaken domestically or imported for such purposes.

The Competent Authority shall exempt from further regulation under this Act LMOs or categories of LMOs agreed pursuant to Article 7(4) of the Cartagena Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.

LMOs or activities exempted or subject to simplified procedures under this Part or as a result of a successful petition under Part 20 shall be included in the registry to be established under Part 28;

Information about LMOs or activities exempted or subject to simplified procedures will be communicated to the Biosafety Clearing House by the NBR, pursuant to Part 30 (c) of this Act.

### **Part 20. Petition for Exemption and Simplified Procedures**

- (a) Any person may petition the Competent Authority to exempt or to apply simplified procedures for LMOs or activities under the provisions of Part 20, at any time.
- (b) Petitions shall contain the following information:
  - (I.) Name, address and contact information for the Applicant;
  - (II.) Name and description of the LMOs or types and classes of LMOs and/ or activities for which exemption or simplified procedures are sought;
  - (III.) A comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;

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- (IV.) Any information known to the Applicant that would be unfavorable to the petition.
- (c) Within ten (10) days of receipt, the Competent Authority shall publish the petition in accordance with Part 28 and transmit the petition to the NBR for review.
- (d) The Competent Authority shall make a final decision on the petition based upon the scientific review and relevant comments submitted by the public. The final decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the Applicant within one hundred and twenty (120) days of receipt of the petition by the Competent Authority.

### SECTION FOUR: REVIEW MECHANISMS

#### **Part 21. Review of Decisions.**

The National Biosafety Regulator (NPR), in consultation with the BSAC, may review a decision at any time upon obtaining significant new scientific information indicating that the LMOs or activities involved may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health. The NPR shall inform the Applicant and the Competent Authority of reasons for initiating a review of the decision, prior to undertaking the review.

Any Applicant may request the Competent Authority to review the decision under Part 12, Part 13, or Part 19 with respect to an activity conducted or proposed to be conducted by the Applicant, where the Applicant considers that:

A change in circumstances has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or

Additional scientific or technical information has become available that may have a material effect on the decision, including any conditions, limitation or requirements imposed under an authorization.

If, upon review under paragraphs (a) and (b), in consultation with the BSAC, the Competent Authority finds that a change is warranted, he or she may issue an order changing the decision and/ or the conditions in the authorization in a manner that is consistent with

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validated scientific evidence or other internationally accepted scientific methodology.

A written decision, pursuant to a review conducted under paragraph (a), shall be provided to the Applicant, signed by the Competent Authority within ninety (90) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.

A written decision, in response to a request for a review under paragraph (b), shall be provided to the Applicant, signed by the Competent Authority within ninety (90) days from the date the Applicant is notified of the review and shall set out the reasons for the decision.

### **Part 22. Right of Appeal**

Any Applicant who is aggrieved by any decision of the Competent Authority under this Act may appeal to the [FSM Department of Justice?] on either procedural or substantive grounds.

The [FSM Department of Justice?] shall decide on such appeals within a reasonable time, not to exceed sixty (60) days and shall communicate its decision and the reasons therefore in writing to the Competent Authority and the Applicant.

An Applicant who remains aggrieved following an appeal under paragraph (a) or who does not receive a response within the timeframe stated in paragraph (b) shall have the right to appeal the decision of the Competent Authority to a suitable court.

## **SECTION FIVE: SAFEGUARDS**

### **Part 23. Monitoring and Submission of New Information**

The expectation is that a high level of inspection, information collection and monitoring shall be required during any introductory period to validate the measures introduced. Operators shall monitor the activities to ensure that they comply with the requirements of this Act and any conditions or requirements imposed in connection with the authorization or allowance of activities under this Act.

Operators that become aware of any significant scientific information indicating that authorized activities with LMOs may adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health, or pose unforeseen potential risks not previously anticipated, known or considered, shall immediately advise the NBR of the new information or newly

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identified risks and of the measures put in place to ensure the continued safe use of the LMOs.

Subject to the protection of confidential information in accordance with Part 15, Operators shall supply to the NBR upon request and in accordance with regulation promulgated under the authority of this Act such information about their activities as is necessary for the Competent Authority to carry out his or her supervisory, monitoring or enforcement tasks under this act or to deal with any emergency situations.

### Part 24. Unintentional Introduction into the Environment

- (a) Any Operator with knowledge of an unintentional or unauthorized introduction into the environment of an LMO subject to this Act that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, shall, within 24 hours of when the Operator knew of the introduction, notify the Competent Authority (CA) of the occurrence.
- (b) A notification under paragraph (a) shall include the following:
  - (I.) Available relevant information on the estimated quantities and relevant characteristics and/ or traits of the LMO;
  - (II.) Information on the circumstances and estimated date of the introduction;
  - (III.) Any available information about the possible adverse effect on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures;
  - (IV.) Any other relevant information; and
  - (V.) A point of contact, including all telephone, mobile phone, fax and email numbers, for further information.

The Competent Authority, in consultation with the NBR and the BSAC, shall consult with Operators providing notifications under paragraph (a) and determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

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Where the Competent Authority knows of an occurrence within its jurisdiction resulting in an introduction that leads or may lead to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, in another country, the CA shall notify affected or potentially affected countries, the Biosafety Clearing House, and where appropriate, relevant international organizations.

### Part 25. Cessation Orders

The Competent Authority may issue an order for the immediate cessation of any activity covered by an authorization or which has been the subject of a notification submitted under this Act for the immediate imposition of additional risk management measure with respect to such activity, if the Competent Authority determines there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, on the basis of:

One or more tests conducted and evaluated in a manner consistent with accepted scientific procedures; or

Other validated scientific evidence based on peer-reviewed scientific research journals or credible academic publications.

A Cessation Order pursuant to paragraph (a) or (b) shall be withdrawn once the Competent Authority, on the advice of the National Biosafety Regulator and/ or BSAC, determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health.

### Part 26. Declaration of Biosafety/ Biohazard Emergency

- (a) The Competent Authority shall notify the Office of the FSM President within three (3) hours in the event that a Biosafety or Biohazard Emergency is confirmed or suspected. The President is the only person who has the power to declare a Biosafety or Biohazard emergency.
- (b) The Disaster Management office in the Office of the FSM President will notify the responsible authority within the Disaster

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Management office in the State where the Biosafety or Biohazard Emergency is confirmed or suspected.

- (c) Biosafety Emergency risk management measures will be taken according to relevant national and state risk management plans.

### Part 27. Institutional Biosafety Committees

All institutions within the Federated States of Micronesia that are involved in any activity relating to LMOs, or products thereof, shall establish Institutional Biosafety Committees to ensure and control safety at the institutional level.

## SECTION SIX: PUBLIC INFORMATION, AWARENESS AND PARTICIPATION

### Part 28. Public Awareness and Participation

- (a)

### Part 29. Co-existence Measures

Applicants approved for introduction of LMOs into the environment in any FSM state bear the responsibility to notify municipal governments, island councils, traditional leaders and neighboring farmers of their intention to sow a biotechnology-enhanced crop at least thirty (30) days before any actual field release.

Information provided to neighbors shall clearly define where and what crops are being grown.

The Competent Authority under Part 37 shall determine the requirements for the timeframe for notification to neighbors.

An adjacent neighbor can request a copy of the risk assessment, minus any confidential information, paid for at his or her own expense.

A neighboring farmer can request the NBR or the Competent Authority to designate an appropriate "buffer zone" between adjacent properties, where one landowner intends to sow biotechnology-enhanced crops.

No person shall be civilly or criminally liable or may be dismissed, disciplined, prejudiced or harassed on account of disclosing confirmed evidence of any unanticipated risks posed by or

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unforeseen impacts due to LMOs on human or animal health or the environment.

The destruction of LMO crops in the field grown on someone else's property is strictly prohibited, and shall carry criminal penalties within FSM, as noted under Part 35.

### Part 30. International Information Sharing

As an obligation of the Cartagena Protocol, at intervals determined by the Conference of the Parties, the NBR will prepare full and complete summaries for the FSM national Focal Point to submit reports describing measures that have been taken to implement the Protocol.

The NBR will create and maintain an Internet web site specifically on activities within the FSM related to Biotechnology and Biosafety.

To facilitate the exchange of scientific, technical, environmental, and legal information on experiences with LMOs, FSM will submit information to the Biosafety Clearing House (BCH) via the World Wide Web and will also submit FSM data to any relevant regional nodes set up to facilitate regional Biosafety information-sharing.

## SECTION SEVEN: IDENTIFICATION AND DOCUMENTATION

### Part 31. Documentation for Imports of LMOs Intended for Contained Use

Part 32. Documentation for imports of LMOs for Direct Use as Food or Feed or for Processing

Part 33. Documentation for Imports Intended for Intentional Introduction into the Environment

## SECTION EIGHT: ENFORCEMENT

### Part 34. Enforcement

(a) The Competent Authority may appoint Biosecurity/ Quarantine and Customs Officers or Agricultural Extension Agents as Biosafety Inspectors, *if* they are *qualified* and *trained* for the purposes of ensuring compliance with this Act and its regulations.

(b) The powers of a Biosafety Inspector include:


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- (I.) at any reasonable time (or, in a situation in which the inspector's opinion there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking also into account risks to human health, at any time):
  - (A) to enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter and to take with him any person duly authorized by the Competent Authority; and
  - (B) to take with him or her any equipment or materials required for any purpose for which the power of entry is being exercised.
- (II.) to carry out such tests (according to established international procedures for genetically modified/ LMO testing) and inspections and to make such recordings, as may in any circumstances be necessary;
- (III.) to direct that any, or any part of, premises which s/he has the power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection;
- (IV.) to take sample of any organisms, articles or substances found in or on any premises which s/he has the power to enter, and of the air, water or land in, on, or in the vicinity of, the premises;
- (V.) in the case of anything found in or on any premises which s/he has power to enter, which appears to him or her to contain or to have contained LMO's which have adversely affected or are likely to adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health, to cause it to be dismantled or subjected to any process or test (but not so as to damage or destroy it, unless this is necessary);
- (VI.) in the case of anything mentioned in subparagraph (V) above or anything found on the premises which s/he has the power to enter which appears to be a LMO or to consist of or include LMOs, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, namely:

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- (A) to examine it and do to it anything s/he has the power to do under that subparagraph;
  - (B) to ensure it is not tampered with before his or her examination of it is completed; and
  - (C) to ensure it is available for use as evidence in any proceedings for an offence under Part 35 of this act;
- (VII.) to require the production of, or where the information is recorded in computerized form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him or her to see for the purposes of any test or inspection under this Article and to inspect, and take copies of, or of any entry in, the records;
- (VIII.) to require any person to afford him or her such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him or her by this Article;
- (IX.) such other powers as may be necessary for the purposes mentioned in paragraph (a) above which is conferred by regulations made by the Competent Authority.
- (c) Where goods are seized by an inspector without reasonable cause, the aggrieved person may bring an action in any competent court for appropriate relief, including an order for the return of the goods seized, and, if the claim prevails, shall be entitled to the costs of such proceedings.<sup>⊗</sup>

### Part 35. Offences and Penalties

Any person who violates a material provision of this Act or fails to comply with a Cessation Order or regulation issued pursuant to this Act shall be guilty of an offence and shall be liable, upon a conviction or finding of violation by a competent court of law or a duly appointed administrative body, or such fines as may be set by regulation, consistent with those established for violations of similar legislation or regulations, including additional penalties for each day that the offence is continued after legal service of a Cessation Order upon that person.

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<sup>⊗</sup> Note: This policy of allowing grievance claims and liability for court costs IS inconsistent with SPC's Regional Biosecurity Bill.

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Any person who repeatedly and knowingly commits offences and is found to be in violation by a competent court of law of duly appointed administrative body under paragraph (a) for such offences may be prohibited in engaging in any further activities subject to this Act.

### **Part 36. Liability and Redress**

Liability and redress for any damage that occurs as a result of activities subject to this Act shall be addressed by applicable laws.\*

## **SECTION NINE: IMPLEMENTATION MEASURES**

### **Part 37. Regulations**

- (a) Consistent with the objective and scope of this Act, the Competent Authority shall propose, and after public notice and an opportunity for public comment pursuant to Part { } finalize and publish such regulations that may be necessary for implementing the provisions of this Act.
- (b) Any regulations made thereunder shall be without prejudice to any of the following matters:
  - Applications, approvals of, and any other matters relating to the import, release, placing on the market or contained use of LMOs;
  - Transport, storage, handling and laboratory practices in relation to LMOs; and
  - Prescribing criteria, parameters or standards for risk assessment or risk management required under this Act.
- (c) The Competent Authority shall publish a schedule of fees to cover administrative costs of processing notifications, applications, risk assessment investigations, enforcement, control and petitions submitted under this Act.

### **Part 38. Effective Date**

This Act comes into force on assent by the Congress of the Federated States of Micronesia on [ \_\_\_\_\_, 2007] or on a date appointed by the President of the Federated States of Micronesia.

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\* Liability and Redress is still under negotiation amongst the Conference of the Parties (COP) to the Cartagena Protocol.

**Part 39. Transitional Provisions**

- (a) After the date of entry into force of this Act, any person carrying out an activity in relation to LMOs shall submit an application for approval for the said activity in accordance with the provisions of this Act.
- (b) The application shall be submitted to the National Biosafety Regulator within a time limit to be determined by the Competent Authority.
- (c) Activities that were ongoing at the date of the entry into force of this Act shall be permitted to continue until a decision is made, but shall be subject to the review procedure set forth in Part 21.
- (d) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.

**Part 40. Review of Act**

- (a) This Act and its regulations shall be reviewed in light of technical and scientific advances and for the purpose of improving the effectiveness of its operation every three years, with particular attention to Part 3 (c).
- (b) Reviews shall consider innovations in biological engineering and innovative medical applications of gene therapies that may be beneficial to human health, but also may carry inherent risks.
- (c) Review of the Act and its regulation shall include notice to the public of the review process and opportunity for the public to comment on proposed changes.

**Part 41. Annexes**

The Annexes and any regulations made under or pursuant to this Act shall be an integral part of this Act.

Annex I-A

Information Required in LMO Import Applications

*Printed (hard copies) of FSM Biosafety Application forms will be available from the FSM National Government Department of Economic Affairs in Palikir, Pohnpei or in any of the state Quarantine offices in Kosrae, Pohnpei, Chuuk or Yap. Application forms will also be available online on the FSM Biosafety web site in Adobe PDF format. Forms that are completely filled in can be scanned and submitted to the National Biosafety Regulator (NBR) by email attachment to the following address: [Biosafety@mail.fm](mailto:Biosafety@mail.fm) or by mail: c/o the Biosafety Competent Authority, FSM National Government, Department of Economic Affairs, P.O. Box PS-12, Palikir, Pohnpei, 96941 Federated States of Micronesia. Please do not consider application as filed until Applicant receives a dated acknowledgement of receipt.*

**FSM Biosafety LMO Import Application Forms must contain the following details:**

1. Name, address and contact details of the exporter including phone, fax, mobile phone numbers and email address.
2. Name, address and contact details of the importer including phone, fax, mobile phone numbers and email address.
3. Name and identity of living modified organism, as well as the domestic classification, if any, of the Biosafety level of the living modified organism in the country or state of export.
4. Intended date or dates of transboundary movement, if known.
5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to Biosafety.
6. 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 organism may persist or proliferate.
7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to Biosafety.
8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
9. 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.
10. Quantity or volume of the living modified organism to be transferred.

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11. A previous existing risk assessment report consistent with Annex II that also includes contact information for the persons and the agency, which carried out the prior risk assessment.
12. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.
13. Regulatory status of the living modified organism within the nation or state of export (for example, whether it is prohibited in the place of export, whether there are other restrictions, or whether it has been approved for environmental or commercial general release). If the living modified organism is banned in the nation or state of export, the application must provide the reason or reasons for the ban.
14. Result and purpose of any notification by the exporter to other nations regarding the living modified organism to be transferred.
15. A declaration signed and dated by the Applicant stating that all of the above-mentioned information is factually correct must accompany the Application.

Annex I-B

Information Required in LMO Contained Use Research Applications

*Printed (hard copies) of FSM Biosafety Application forms will be available from the FSM National Government Department of Economic Affairs in Palikir, Pohnpei or in any of the state Quarantine offices in Kosrae, Pohnpei, Chuuk or Yap. Application forms will also be available online on the FSM Biosafety web site in Adobe PDF format. Forms that are completely filled in can be scanned and submitted to the National Biosafety Regulator (NBR) by email attachment to the following address: [Biosafety@mail.fm](mailto:Biosafety@mail.fm) or by mail: c/o the Biosafety Competent Authority, FSM National Government, Department of Economic Affairs, P.O. Box PS-12, Palikir, Pohnpei, 96941 Federated States of Micronesia. Please do not consider application as filed until Applicant receives a dated acknowledgement of receipt.*

**FSM Biosafety LMO Contained Use Research Application Forms must contain the following details:**

1. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
2. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
3. Name, address and contact details of the primary researcher including phone, fax, mobile phone numbers and email address.
4. Provide C.V. of primary researcher listing academic qualifications and experience.
5. Where do you propose the contained use research will take place? Please provide precise details of the facility where field trials are planned including location, ownership, etc.
6. What level of containment does this facility have?
7. Describe additional containment measures you plan to take to insure the security of the LMO research. (ex: fencing, security guard protection, buffer zones or barriers).
8. Does this facility/ organization have an institutional Biosafety Committee (IBC)? If so, please list names and positions of the IBC members.
9. Does this facility/ organization have a contingency Biosafety Emergency Management Plan (BEMP) in place?
- 10.

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**Annex I-C**

**Information Required in LMO Experimental Field Trial Applications**

*Printed (hard copies) of FSM Biosafety Application forms will be available from the FSM National Government Department of Economic Affairs in Palikir, Pohnpei or in any of the state Quarantine offices in Kosrae, Pohnpei, Chuuk or Yap. Application forms will also be available online on the FSM Biosafety web site in Adobe PDF format. Forms that are completely filled in can be scanned and submitted to the National Biosafety Regulator (NBR) by email attachment to the following address: [Biosafety@mail.fm](mailto:Biosafety@mail.fm) or by mail: c/o the Biosafety Competent Authority, FSM National Government, Department of Economic Affairs, P.O. Box PS-12, Palikir, Pohnpei, 96941 Federated States of Micronesia. Please do not consider application as filed until Applicant receives a dated acknowledgement of receipt.*

**FSM Biosafety LMO Experimental Field Trial Application Forms must contain the following details:**

1. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
2. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
3. Have you submitted a previous application to FSM for contained use research for this product?
4. Where do you propose the field trials will take place? Please provide precise details of the farm(s) where field trials are planned including location, ownership, amount of acreage, slope, soil conditions, etc. Include a State/ district map showing exact location(s).

Annex I-D

Information Required in LMO Commercialization Applications

*Printed (hard copies) of FSM Biosafety Application forms will be available from the FSM National Government Department of Economic Affairs in Palikir, Pohnpei or in any of the state Quarantine offices in Kosrae, Pohnpei, Chuuk or Yap. Application forms will also be available online on the FSM Biosafety web site in Adobe PDF format. Forms that are completely filled in can be scanned and submitted to the National Biosafety Regulator (NBR) by email attachment to the following address: [Biosafety@mail.fm](mailto:Biosafety@mail.fm) or by mail: c/o the Biosafety Competent Authority, FSM National Government, Department of Economic Affairs, P.O. Box PS-12, Palikir, Pohnpei, 96941 Federated States of Micronesia. Please do not consider application as filed until Applicant receives a dated acknowledgement of receipt.*

**FSM Biosafety LMO Commercialization Application Forms must contain the following details:**

1. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
2. Name, address and contact details of the applicant including phone, fax, mobile phone numbers and email address.
3. Have you submitted a previous application to FSM for contained use research or experimental field trials for this product within FSM? Please provide data and results of contained use research and/ or field trials releases.
4. Were trial field releases carried out in the country of origin of the LMO? Please provide data and results of field trials releases.
5. Brief Description of Proposed Commercial Use
6. What is the aim/ objective of the proposed commercialization of this LMO? Describe benefits of this approach as compared to other possible alternatives.
7. Where do you propose the general release of this product would take place?
8. Do you intend to market the LMO as a product of FSM?
9. Describe nature of organism and Novel genetic material:
10. What is the species of LMO to be submitted for commercial release
11. Do the unmodified form(s) have any effect on humans, animals, or plants?
12. Do the unmodified form(s) have any effect on agricultural production?
13. Do the unmodified form(s) have any effect on any other aspect of the environment?

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14. Furnish a description of the genetic and resultant phenotypic modifications of the LMO. This should include the origin of the inserted DNA, the procedure used to induce the genetic modification, and the extent to which it has been characterized. Provide any explanatory figures and charts which are relevant.
15. What is the frequency of reversion, i.e. loss of genetic modification?
16. How do you verify that you have the desired LMO?
17. What methods will you use to test for batch-to-batch consistency?
18. If, at any stage in the future the FSM National Biosafety Regulator or inspectors need to ascertain whether the LMO in a field is the same as that specified in this application, what means are available?
19. Provide the protocol and materials used to detect the foreign gene(s) in surrounding microbial, plant, or animal life.
20. Results of the Field Trial Releases: Provide full details about the manner in which the trial releases of the LMO were undertaken.
21. Were there any potential hazardous or deleterious effects resulting from the field trial releases of the LMO? Address concerns about toxicity or allergenicity to humans and other organisms, weediness, and transfer of genes to other organisms.
22. Has this LMO or a similar one been approved for commercial use previously outside the FSM? (If yes, provide the names of the countries and dates.)
23. Is there any evidence that the inserted genetic trait is transferable to other organisms in the release site and surrounding environment?
24. What data are available to suggest that the inserted genetic trait has no deleterious effect in the long term upon the species into which it has been introduced or allied species or any other organisms or the environment in general?
25. Is or can the LMO intended to be commercialized modify the characteristics or abundance of other species?
26. What experimental results of information exist to show the probable consequences (Positive and negative) of the release of such a modified organism, including impacts on:
  - Human, animal or plant health?
  - Agricultural production?

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Risk of LMO establishing as a weed?

Target and non-target organisms in the test fields?

The general ecology, environmental quality, and pollution in the area?

The genetic resources (e.g. susceptibility of economic important species to herbicides, pesticides, etc.)?


Food and/ or feed safety testing including toxicity or allergenicity to humans or animals?

Nutritional data as compared to substantially equivalent food products?

27. Did the trial field releases have any unlikely or unanticipated impacts?
28. What will be the consequences if the organism remains in the environment beyond the planned period?
29. Provide a draft copy of the press release informing the public of the general release planned for this LMO.
30. Can the genetic trait be transmitted by means other than normal reproduction?
31. Does the imparted characteristic have the potential to add or subtract substances from the soil (e.g., nitrogen)?
32. Could any toxic products concentrate in the natural or human food chain?
33. With regard to the pollination characteristics of the species, do wild populations of the species, or related species with which it can interbreed, exist in the vicinity of the agricultural site?
34. With regard to the pollination characteristics of the plant, is it likely that the novel genetic material will enter a pre-existing gene pool?
35. Should the imparted characteristic (e.g., insect, herbicide, disease resistance or abiotic stress tolerance) "escape" into a wild population, would it have the potential to affect the distribution and abundance of that population?
36. Would there be any consequent problems with respect to:
  - Agriculture?
  - The environment?
  - Disease Control?

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37. IF there is any possibility of any adverse effects occurring, has any attempt been to minimize the risk (e.g., by imparting male sterility)?
  38. Could the imparted characteristic(s) (either in the cultivated population or in a wild population) provoke a genetic response in populations of other species (e.g., increase the resistance of an insect population to an insecticide)?
  39. Is it reasonable to expect that commercialization of plants with any transgenic resistance trait will have more substantial adverse effects on non-target organisms than current pest control has on these organisms? (Current pest control method can include both the uses of chemical insecticides and other non-chemically based methods)?
  - 40.



## Annex II

### Risk Assessment

#### Objective

The objective of risk assessment, under the Cartagena Protocol, 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

Risk assessment is, *inter alia*, used by Competent Authorities to make informed decisions regarding living modified organisms.

#### General Principles

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

Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail required from case to case, depending on the living modified organism concerned, its intended use, its historical applications and the likely potential receiving environment.

Risk associated with living modified organisms 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, should be considered in the context of the risk posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

#### Methodology

The process of risk assessment may give rise to a need for further information about specific subjects, which may be identified and requested from the Applicant or scientific experts during the assessment process.

To fulfil its objective, risk assessment entails, as appropriate, the following steps:

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;

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An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

An evaluation of the potential consequences should these adverse effects be realized;

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 effect being realized;

A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on 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**

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

**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 are likely to persist or proliferate;

**Donor organism or organisms.** Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

**Vector.** Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

**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;

**Living modified organism.** Identity of the living modified organism, the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

**Detection and identification of the living modified organism.** Suggested detection and identification methods and their specificity, sensitivity and reliability;

**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

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

**Annex III**

**Information Requirements for Notices to the Biosafety Clearing House (BCH)**

1. The Name and contact details of the applicant for a decision for domestic use in the FSM.
2. The name and contact details for the Competent Authority responsible for the decision.
3. The name and identity of the living modified organism.
4. Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
5. Any unique identification of the living modified organism.
6. Taxonomic status, common name, point of collection or acquisition, and characteristics of the recipient organism or parental organisms related to Biosafety.
7. Center(s) of origin and center(s) 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.
8. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to Biosafety.
9. Approved uses of the living modified organism.
10. A risk assessment report consistent with Annex III.
11. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.



**SECTION THREE: SYSTEM TO HANDLE NOTIFICATIONS & REQUESTS**

- Part 17. Processing Requests within the FSM National Government
- Part 18. Procedures in States of Kosrae, Pohnpei, Chuuk and Yap
- Part 19. Role of Custom Leaders, Island Councils & Municipal Governments
- Part 20. Role of the Local Media



**SECTION FOUR: SYSTEM FOR "FOLLOW UP" MONITORING & ENFORCEMENT**

Part 21. National Government

Part 22. State Governments of Kosrae, Pohnpei, Chuuk and Yap

**SECTION FIVE: CAPACITY NEEDS ASSESSMENT AND PRIORITIES**

Well informed, highly trained human resources are an imperative for effective implementation of Cartagena Protocol on Biosafety. Article 22 of the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) sets out a mandate for *“Parties to cooperate in development of an/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them ...”*

Capacity Building for Biosafety must be country-driven, responsive to identified needs and deficiencies within the country according to FSM priorities, rather than donor-driven. Article 22, paragraph 2 of CPB notes that *“Cooperation in capacity building shall, subject to the different situation, capabilities and requirements of each Party, include proper and safe management of biotechnology, and in the risk assessment and risk management for biosafety, and the enhancement of technological capacities in biosafety.”*

Assessments of the biosafety risks and the benefits of modern biotechnology will need to be viewed within the broader framework of agricultural, environmental and socio-economic sustainability. Ultimately, biosafety should be mainstreamed into national policies for all relevant sectors. A fully considered *FSM Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety* will be developed as a deliverable during the Implementation phase of the FSM NBF. Therefore, the information here includes only preliminary projections that will be more fully deliberated and expanded at a later time.

In order to identify internal capacity building needs to effectively implement the requirements of the Cartagena Protocol (and other biosafety-related international agreements), FSM will need to address:

- Where or what is the highest priority local need(s) for capacity-building?
- What kind of skills needs upgrading?
- What competencies & abilities which are required may be weak or absent now?
- At what academic, scientific and technical levels should training be offered?
- How can FSM address their short-term immediate needs, while preparing for long-term sustainability?
- What is a realistic timeframe for action?
- What are potential sources of funding and assistance?

**IDENTIFYING THE TARGET AUDIENCES TO ASSESS THE DEMAND FOR BIOSAFETY TRAINING**

Addressing the needs for various stakeholder groups towards implementation of biosafety obligations will require a variety of tools and strategies. This table attempts to map the different target audiences and suggests modes of delivery for capacity building schemes.

Stakeholders & Partners	Need	Biosafety Role	Types of courses	Optimal Format
High Level Policy-makers/	Basic awareness-raising about	Decide on Biosafety policy, as part of a	How to improve decision-making	Ad hoc and at a simple level, not-

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<p><b>Senior Government Officials</b>                  (Executive Branch Directors, Ministers Legislators/ Parliamentarians)</p>	<p>biotechnology benefits and risks &amp; further training for decision-making;                  Coordination of donor assistance</p>	<p>broader policy on biotechnology;                  Develop and implementation of legislative framework for their nation;                  create a regulatory regime</p>	<p>across departments (ministries);                  Multidisciplinary strategic planning</p>	<p>too-technical;                  Executive summary publications in lay language</p>
<p><b>CBD focal points- political &amp; implementation</b></p>	<p>Build institutional capacities to ensure safe handling, transfer and use of LMOs</p>	<p>Communication with the BCH, disseminating information to the public</p>	<p>How to Access and submit information to the Biosafety Clearing House; evaluating information at BCH web site</p>	<p>Interactive lessons on DVD or CD; ad hoc training</p>
<p><b>Legal Community</b></p>	<p>To understand the legal issues surrounding biosafety so they can advise policy-makers and delegations that do negotiating for their country</p>	<p>Write bills and regulations; advice policy-makers who develop strategies and laws for protecting intellectual property and endemic germplasm</p>	<p>Intellectual property issues; patent law; confidentiality issues; liability and redress; access &amp; benefit sharing and material transfer agreements;</p>	<p>Accredited postgraduate level short courses, distance education courses online</p>
<p><b>Competent Authority</b></p>	<p>Regulators need ability to review applications and conduct risk assessments; professional administrators able to process paperwork</p>	<p>Fulfillment of CBD obligations; Implementing existing and new regulations; Initiate in-country training programs; Documentation for LMO shipments</p>	<p>General theoretical biotechnology and biosafety issues; Training on AIA procedures; risk analysis; Decision-making processes; Risk prevention strategies; biosafety emergency management procedures; addressing socio-economic considerations in risk and benefit analyses;</p>	<p>Fully accredited degree-granting undergraduate and postgraduate level programs leading with a major in biosafety or a related topic; International Postgraduate Diploma in Biosafety by Distance Learning</p>
<p><b>Monitoring, Quarantine (Biosecurity) Enforcement and Customs Officers</b></p>	<p>Ability to detect LMOs and monitor field release trials</p>	<p>Carrying out day to day Biosecurity (quarantine) border inspection services</p>	<p>Identification and detection of LMOs; monitoring protocols; emergency procedures for</p>	<p>"Hands on" Ad hoc customized training appropriate to their environment or</p>

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			unintentional environmental releases; Inspection systems for LMO shipments	regional needs
<b>General Public, NGOs, Civil Society</b>	Biotechnology awareness raising	Consumers of LMO products; participants in decision-making	What is biotechnology; What are the biosafety risks;	Public broadcasts (radio, TV), press, internet, open dialogue forums; public lectures by local and / or visiting experts
<b>Media/ Press</b>	Understanding of the technological issues so they can communicate them to lay public	Providing information to various stakeholders through print, Internet and multimedia formats	Producing locally relevant multimedia programs on biosafety issues; formal classes in risk communication	Internet, regional training workshops targeted specifically at media personnel
<b>Staff working on Biosafety Clearing House web site</b>	Mastering the computer skills needed to maintain BCH web links	Establish a national BCH link to the central BCH- publish information online	IT and software push,-pull mechanisms, website creation; web site and data base design and maintenance	ad hoc regional workshops; in-country site visits by expert consultants with skills to customize training
<b>Middle School Primary Level and Secondary Students</b>	Preparation in sciences that is sufficient to undertake higher level degree coursework	Future biosafety regulators, researchers, policy-makers and consumers of LMO products	What is biotechnology; ethical issues surrounding biotechnology	Incorporating modularized units on biotechnology that can be incorporated into traditional or existing science curricula
<b>Undergraduate Tertiary Students</b>	Preparation in sciences that is sufficient to undertake higher level degree coursework	Professionals in biosafety related jobs; some will undertake specialized postgraduate studies	Lab courses in molecular biology; theoretical issues about biotechnology including socio-economic issues, risk assessment classes	Accredited degree-granting programs (face-to-face) in lab skills, supplemented by distance learning theoretical courses; internships and secondments with research institutions
<b>COM-FSM</b>	Sufficient	Scientific advisors;	International	Membership to

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<b>Faculty and Staff doing Scientific Research</b>	knowledge that is currently updated to teach students and conduct collaborative research	biotech research and development; technical cooperation; technology transfer; collaborative partnerships in technology transfer; biotech product development relevant for local environmental conditions	Postgraduate Diploma in Biosafety by Distance Learning	professional networks or associations; conference attendance; postgraduate level degree or diploma granting programs
<b>Teachers (primary and secondary level), especially science and agriculture vocational teachers and extension agents</b>	Need sufficient understanding in order to be able to prepare their students to undertake	Translate informational materials into local languages; develop curricula and unique instructional materials targeted at different age levels	Science classes aimed specifically at teachers on biotechnology and biosafety issues that also address socio-economic considerations	Ad hoc accredited summer or vacation training programs in regional and local teacher training institutions that award postgraduate or continuing education credits
<b>Farmers</b>	Decision-making that will affect their livelihoods and ability to improve living standards	Adopters of the technologies; purchase seeds, grow the crops;	Cost/benefits of using biotech crops specific to their environment / climate / growing conditions; agronomic practices using biotech	Ad hoc workshops, "hands on" short courses aimed at utilizing a certain technology
<b>Public Health Practitioners</b>	Understanding of biotechnology and potential biohazards	Testing LMOs for allergenicity & toxicity; public health communication	Food safety analysis procedures; treatment in emergency situations that involve biohazards	Regional or local Ad hoc courses, ideally for continuing education credits
<b>Private Biotechnology Business Sector; company owners or potential partners</b>	Require enough information & skills to prepare applications for LMO import requests	Biotechnology product development, safe handling of LMOs	Business opportunities and collaborations available for technology transfer and partnerships; Adequate	Ad hoc workshops tailored to the requirements of the ex- and importing countries

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			packaging, labeling and transport of LMO shipments	
<b>Regional partners and UN agencies</b>	To understand the country-driven needs as well as challenges and obstacles faced internally	Developing standards, tools and support materials (e.g. guidelines, publications)	Foundations in biotechnology and biosafety, overview of constraints in target countries	International negotiations; task force specialized meetings on particular issues or topics

An analysis of the listed indicative requirements demonstrates that there is a manifest need to also develop a package of country-driven strategies that involve vocational, community and continuing educational programs.

**Part 23. Existing Biosafety and Risk Analysis Expertise within FSM**

Under this FSM NBF project, a database was created with detailed information about and contacts for local experts living within the FSM. The focus was on people who have skills particularly related to Biosafety, biological diversity of the local ecosystems, biosecurity and other fields of expertise that may be necessary to conduct risk analysis on LMO import applications. Database entries were based on responses to a questionnaire sent to government, academia and relevant organizations. Experts on environmental law, sustainable agricultural, plant protection, environmental economics, food safety, security and nutrition, plant variety and breeding research, aquaculture, environmental impact assessment, risk management, general capacity building and training, and socio-economic analysis are included. With approval of the FSM government, at least a few names from this FSM Roster of Experts (the ones who have appropriate Doctorate degree qualifications and publications) should be submitted to the Biosafety Clearing House.

Although there are resident people with some of the necessary Biosafety risk assessment and management qualifications, the majority of them are expatriates, either employed as consultants, working or interning for NGO's or teaching and researching within the College of Micronesia-FSM. There is only one person who has embarked on a postgraduate program specifically majoring in the field of *Biosafety*.

In planning for sustainable human resource development and capacity-building, there are no guarantees that even indigenous experts will not get married, pass away, change jobs, move abroad, or completely change fields. Nonetheless, there is an inclination within FSM to prioritize capacity-building opportunities for Micronesian citizens. It is recommended that this trend continue for Biosafety Capacity-Building; with attention to assisting young people just embarking on their careers to obtain scholarships.

The FSM National Coordination Committee (NCC) for the UNEP/GEF Biosafety Enabling Activities Project has gained considerable knowledge about Biosafety issues, although not necessarily scientific expertise on the specific technical issues involved. It is recommended that those NCC members who choose to continue to serve as members of the new

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Technical Advisory Committee (TAC) under this FSM NBF be assisted in obtaining additional training. The addition of new members who are already experts in relevant fields related to conducting scientific risk assessments is strongly advocated. Socio-Economic impact assessment is also a crucial element and should be incorporated into any training curricula.

**Part 24. Priority Needs for Biosafety Capacity-Building in the FSM**

**Key Elements Requiring Concrete Action- Systemic Development**

Apply a holistic approach by integrating biosafety strategies into relevant sectoral sustainable development policies and strategies towards the achievement of Millennium Development Goals

Mainstream biosafety into National and State development planning

Coordinate donor assistance- identify financial resources that can support Cartagena protocol ratification and biosafety capacity-building implementation (GEF, multilateral, bilateral, other international and national sources, business sector, other stakeholders)

Identify and maximize bilateral partnership & regional cooperation initiatives for biosafety capacity-building

Take a long-term perspective in the design and implementation of biosafety projects

Include socio-economic and cultural considerations in the design and implementation of all related projects

Allocate national and state budget funds for biosafety activities

Develop time-lines and sequences of actions needed for biosafety capacity-building to achieve objectives

Apportion funding to support dedicated and specific FSM risk assessment research

Strengthen biotechnology/ biosafety research capacities

**Part 25. Institutional Strengthening Requirements**

Currently, FSM requires much institutional strengthening to comply with obligations under the Cartagena Protocol. Capacity building to overcome institutional weaknesses must be given top priority. As the designated Competent Authority, the FSM Department of Economic Affairs (DEA) needs to honestly evaluate and address current shortcomings in carrying out their "strategic functions." The term "strategic functions" refers to cross-cutting managerial functions that influence traditional environmental and project management such as: strategic planning (including priority-setting), human and financial resources management, travel follow-up, inter-departmental policy dialogue, collaborative partners' utilization and communications. Financial resources and staff time are wasted in the absence of focused institutional strengthening. Failings in performance of strategic functions act as structural barriers that hinder progress towards different objectives. Honest, critical self-analysis is not only needed for Biosafety implementation, but also for compliance with other environmental treaties and projects. A first step would be to identify bottlenecks within the DEA in an intentionally positive facilitated dialogue, then to develop supportive initiatives that could help to overcome targeted challenges.

Other institutional strengthening physical and structural requirements range from diagnostic labs and equipment for conducting LMO identification and detection investigations, to containment research buildings and/or disposal facilities for Quarantine and Customs

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services to isolate suspected LMO or products illegally entering the country. Biosecurity surveillance, disposal and environmental monitoring require vehicles, boats, and ongoing purchases of fuel, all of which have budget implications.

Information exchange and data management is crucial to effective implementation of the Cartagena Protocol at the national level. The ubiquitous spread of Information and Communication Technology (ICT) infrastructure varies amongst the different islands and FSM states, with outer island having less reliable connections and telecommunications. Since the islands are so spread out and FSM borders are so permeable, any island could potentially be an LMO port of entry, not just official airports and docks that have regular Quarantine officers of Customs inspectors. All of the state's major capital islands will need dependable power and Internet connections plus the ability to continually maintain and pay the fees involved, in order to report to and access the Biosafety Clearing House and other information about biotechnology risks or applications. This implies expense not just for computer hardware and software, and consumable supplies, but also for appropriate ICT training, that will support Biosafety decision-making. This implies each state will have access to online bioinformatics tools, roster of expert's database and decision-trees for risk assessment. Computer equipment and training can serve a multitude of purposes and may be available under other types of grants and funding schemes.

**Part 26. Human Resources Development**

The need for science-based Biosafety risk assessment conducted according to internationally accepted standards will require strategic planning to develop scientific and technical professionals to fill both the short-term and long-term human resource needs for FSM. The Convention on Biological Diversity (CBD) Secretariat has stated that "*Short-term ad hoc courses and workshops alone are not sufficient to train the cadre of biosafety professionals and specialists required for the effective implementation of the Protocol.*" That means some people will need to commit to longer-term Biosafety specific training, probably up to the Masters Degree level.

Some of the advantages and disadvantages of short-term vs. long-term approaches are summarized in the table below.

Capacity Building Strategy	Advantages	Disadvantages
<b>ad hoc / informal training</b>	Meets specific needs more immediately; May have low operational costs; Intensive; Can focus on vocational / job-related skills	Does not respond to long-term needs; Does not build in-depth, integrated and higher level skills; Does not offer academic and/or professional accreditation; Relies mostly on outside expertise; Trainees may not be sufficiently trained for carrying out their biosafety regulatory responsibilities on the basis of short courses
<b>Long-term training</b>	Can be tailored to meet long-term needs; Allows pooling of regional intellectual	Increased operational costs / expensive for students & course providers; On-going professional commitments

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assets (expertise); Develops high degree of breadth, specialization and competencies; Can offer degree-based academic and professional qualifications	limiting participation; Scholarship / fellowship may be required to support trainees; High rate of staff turnover compromising course delivery
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IF FSM chooses to strengthen national capacity to conduct in-country Agricultural and Aquaculture Biotechnology research beyond just doing import risk assessment, effort will involve training to the graduate level in the life sciences. In order to position biotechnology in a balanced perspective within the framework of existing national research agendas and priorities, it will also be crucial to train responsible policy advisors in social science field so they are able to research and obtain the most up-to-date information, and to ensure balanced and neutral presentations to government officials.

For starters, the disciplines of biological sciences, agriculture, and social sciences all need vast enhancement in the primary and secondary school curriculum. The FSM-wide minimum standardized curriculum needs to include environmental and sustainability education. Pre-service and working teachers need to understand the technical issues so they can teach about DNA, genetics, biotechnology, and to also facilitate student discussions of the ethical issues involved. K-12 science preparation will be crucial for students who intend to major in biology, microbiology, biotechnology, environmental resource management or any related fields and who plan to go on eventually to obtain postgraduate degrees.

The College of Micronesia-FSM campuses only currently award Associate (two year) degrees, as well as a third-year teaching certificate. Therefore, students must choose between leaving their islands to go abroad for further training, or to be sufficiently motivated and computer literate enough to engage in online distance education at home. Most young FSM students choose to go abroad to finish Bachelors, or even Masters Degrees.

For the time being, some of the environmental and or food safety risk assessment expertise necessary may need to be hired from abroad, until a cadre of competent Biosafety risk assessors can be trained in FSM up to the postgraduate level. This is most likely to be done initially utilizing distance education opportunities for working professionals, such as those offered by UNIDO as part of their E-Biosafety MSc program through the University of Malaya in Kuala Lumpur. Ultimately, hopefully, a regional Biosafety Masters degree program will be established at either the University of Guam, University of the South Pacific or one of the University of Hawaii campuses. The only program internationally that currently offers a PhD in *Biosafety/ Biosecurity* is the University of Canterbury in New Zealand. If FSM students wish to pursue a postgraduate degree-granting Biosafety program abroad, they will be assisted in obtaining scholarships and financial assistance tied to an obligation to return to FSM to share their knowledge and expertise for a define period of time. The choice of which program a student would like to enroll in will be that of the individual, not of the Government.

The Cartagena Protocol has specific requirements for the safe handling, packaging, identification and transportation of LMOs. Therefore, a short-term workshop explaining this information will be required for Customs, Quarantine, and staff members working at the ports.

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The Department of Foreign Affairs will need briefing to fulfill the functions of the Focal Point and to know exactly to whom information needs to be disseminated. As the Competent National Authority, responsible for performing the administrative functions required by the Cartagena Protocol, the support staff of the FSM Department of Economic Affairs will need training and information on what the obligations are as a member party, so work can get processed within the allotted timeframes. Delegations who attend the COP-MOP negotiations will need very specific balanced briefings (pros and cons) on the issues that are likely to be discussed.

The FSM law and policy-maker communities will need to discuss legal issues of relevance to FSM regarding confidentiality, intellectual property rights for plant breeders, material transfer agreements, patents, and Biosafety accident liability and redress. This could be organized within a two-day workshop, debate and discussion format that would include delegates from all four states as well as the National Government.

Monitoring for any contained use or field releases will fall under the jurisdiction of the states in collaboration with the environmental NGOs or the Municipalities. Monitoring the borders is a responsibility of the Quarantine Services (national) and Customs officers. All of these people will need at least some introduction to biotechnology and biosafety issues, depending on their responsibilities and level of prerequisite knowledge.

Public disclosure of biosafety hazards requires special skills in risk communication. This sort of training could best be addressed in an undergraduate level class at the College of Micronesia campuses, perhaps related to journalism or multimedia design. The Public Information Officers at Palikir and in the states should also receive a course in risk communication that combines biosafety issues along with other emergency management concerns.

### **Part 27. Regional & International Collaborations for Improving Capacity**

Regional capacity development and networking will be essential tools for Biosafety risk management, because small Pacific Island countries with limited personnel and expertise will need to share resources across borders. The Pacific Island regional organizations tend to be useful in helping to identify training experts and funding opportunities. Scientific, technical and institutional collaboration at sub-regional, regional and international levels is generally more cost-effective. Technology transfer from private industry or donor partners for research on genetic materials in FSM could also have a clause that training of FSM citizens be a part of the agreement.

The South Pacific Regional Environment Programme (SPREP) has been one of the lead agencies in the past in assisting FSM to build capacity to handle obligations for other environmental treaties. Given their experiences in coordinating regional initiatives, including some of the early UNEP NBF Project training and Biosafety Clearing House capacity-building, it is expected that FSM will continue to rely on SPREP to organize workshops and provide some programs and training incentives.

The Secretariat of the Pacific Community (SPC) maintains and is now expanding their Northern Pacific presence. The regional office maintained by SPC in Kolonia, Pohnpei has

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hosted the UNEP/GEF NBF Project Office as well as the Micronesian Island Biotechnology and Biosafety Information Center (MIBBIC).

### POINTS TO CONSIDER

The following points are based on the above observations:

- Choices need to be made between creating new curricula and networks or capitalizing on existing ones
- How and under what conditions can FSM gain from the involvement with existing biosafety training networks and/or single academic institutions offering training?
- What are the sources and means to secure funding for trainee-related costs?
- What are appropriate strategies to create a critical mass of FSM-based trainers? How can FSM best utilize a Train-the-Trainers model that will be sustainable in the long-term?

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**SECTION SIX: PUBLIC AWARENESS, EDUCATION AND PARTICIPATION**

**Part 28. Mechanisms for Public Awareness and Participation**

All members of civil society are consumers of modern biotechnology products including food, animal feed, cotton clothing and other modified products, so, logically, all people residing in FSM are stakeholders in LMO decision-making. However, in order for the general public, especially indigenous FSM citizens, to play a genuine role in informed decision-making, they first need to be educated and informed about modern biotechnology, and the Biosafety concerns that could possibly impact their island environments, livelihoods and health.

By and large, there is very little opposition to the import of genetically modified (GM) food in the FSM, and no outcry to initiate labeling policies, beyond the food labeling policies which the National Government already created and is now attempting to enforce.

**Part 29. Best practices/Lessons Learned- Activities during NBF Development**

Visual aids- little booklets, displays of LMO food  
Translation  
Short & sweet  
Go out and meet public- be accessible in lay language

**Part 30. Future plans for Public Awareness, Education & Outreach**

Establish a mechanism to inform all stakeholders (in indigenous languages)  
World Food Day, Environmental Events such as Earth Day, Agricultural Fairs

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## **SECTION SEVEN: Implementation Plan**

### **Part 31. Adoption of NBF, Implementation and Regulations**

The Final Draft of the FSM National Biosafety Framework (NBF) will be adopted by the National Government Federated States of Micronesia prior to submission to the United Nations Environment Program (UNEP) in 2007. The Draft Bill will be submitted to FSM Congress for consideration. As a draft, it is subject to regular revision and updates. As an interim measure, the Competent Authority may develop regulations to supplement this framework at any time after it has been submitted to UNEP. Implementation of the NBF, particularly the institutional and human capacity building and awareness-raising components, will require seeking further funding from the Global Environmental Facility (GEF), as well as bi-lateral, regional and multi-national partner agencies.

### **Part 32. Mainstreaming Biosafety into Relevant Sectoral Planning**

Biosafety is not an issue that stands alone, but is multidisciplinary by its nature. In the future, the impacts of modern biotechnology and Biosafety concerns will be integrated into environmental law, land use and resource management policy and planning, planning for protected area (conservation) networks and climate change.

Particularly, Biosafety will be mainstreamed into developing future legislation, strategies and guidelines for science and technology education, agriculture, the environment, fisheries, aquaculture, near-shore marine resources, food safety, food security, human health concerns, biofuels energy planning, income-generating private sector development activities and bioterrorism.

### **Part 33. State Biosafety Committees**

The states of Kosrae, Pohnpei, Chuuk and Yap may set up their own State Biosafety Committees to review requests and applications provided to them by the National Government Competent Authority specific to imports, requests to transit, or environmental releases that could impact their state biological diversity and human health. Although, ultimate decisions will be made at the National Government according to the procedures outlined in this National Biosafety Framework, the remarks and comments of the stakeholders and State Biosafety Committees will be taken into full consideration in decision-making.

### **Part 34. Public Outreach & Education Timeline & Implementation Plan**

#### **GENERAL PUBLIC EDUCATION STRATEGIES**

#### **GENERAL PUBLIC AWARENESS-RAISING TIMELINE 2007**

Write balanced articles for the *Kasehlehlia Press* and *Serehd Newsletter*

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Get permission from Nova in US to broadcast "Harvest of Fear" video on cable TV in all four FSM states

Continue public outreach Stakeholders Awareness and AIA Decision-Making meetings in the states of Chuuk and Yap

Hold Draft NBF approval and finalization workshop on Pohnpei

**2008**

- ◆ Create FSM Biosafety Web Site with link to the Biosafety Clearing House
- ◆ Take Power Point Presentation (Mommy, There's a Gene in My Food) out and give it to seventh and eighth graders at the elementary schools around Pohnpei Island
- ◆ Develop interactive "hands on" assignments for secondary and tertiary (undergraduate) school students on biotechnology and Biosafety
- ◆ Give Biosafety talk and have display booth at World Food Day
- ◆ Give Biosafety talk and have display booth at Earth Day (April)

**Part 35. Biosafety Capacity Building Timeline & Implementation Plan**

**BIOSAFETY CAPACITY BUILDING TIMELINE**  
**Institutional Strengthening**

**2007**

Harmonize legislation and laws for biotechnology, Biosafety, biosecurity and bioterrorism (including genetic resource conservation, intellectual property, and access and benefit sharing considerations)

Do a briefing for members of FSM Congress, Cabinet and Sustainable Development Council on Biosafety issues, the Cartagena Protocol and Draft Biosafety Bill

Adopt FSM National Biosafety Framework and National legislative and regulatory framework and proposed administrative system

Insure telecommunications infrastructure is adequate for full participation by states

Encourage at least one or two additional FSM people (preferably at least one FSM citizen from Kosrae, Chuuk or Yap) to commence the MSc E-Biosafety distance education UNIDO program at Universiti of Malaya

Participate in International and Asia/ Pacific Island regional discussions on Biosafety Capacity building

Develop Biotechnology Science Education Course for K-12 Teachers for COM-FSM Curriculum Committee Approval

**2008**

Write, get support and approval for a thorough *FSM Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety*

Establish a national node for the Biosafety Clearing House (BCH)

Organize an FSM- wide *Biosafety Risk Assessment* Workshop

Organize a workshop on Biosafety Risks specifically targeted at Emergency Preparedness personnel from the National Government and four states.

Plan emergency measures to handle unintentional movements and measures to prevent illegal transboundary movement

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Organize a workshop for attorneys and environmental stakeholders on genetic resources management material transfer agreements/ intellectual property of agrobiotechnology;  
Develop policies for the handling of confidential information  
Request that an FSM student be placed in an internship position at USDA facility in Hilo  
Begin teaching or promoting Biotechnology Teachers Training Course for K-12 teachers

### 2009

- ◆ Improve documentation systems for shipments of LMOs
- ◆ Create a reasonable budget for costs associated with opening reference laboratories to analyze samples and monitor the release of living modified organisms into the environment (COM-FSM?)
- ◆ Draft proposal and seek funding for improving laboratories
- ◆ Provide high quality information on capacity-building, projects, lessons learned, etc. to the BCH
- ◆ Investigate possibilities for promoting technology transfer agreements with private biotechnology businesses and seed companies under favorable terms for FSM

### 2010

- ◆ Conduct first scheduled review of National Biosafety Framework and capacity building progress for Cartagena Protocol implementation

### ACTIVE OR PLANNED NATIONAL PROJECTS FOR CAPACITY BUILDING RELATED TO THE SAFE USE OF BIOTECHNOLOGY Human Resource Development and Training Strategies

- ◆ Create general public awareness about biosafety technical and scientific issues through seminars and short-term training to ensure systematic participation by stakeholders & civil society
- ◆ Strengthen financial capacities to access grants, technology transfer and technical assistance
- ◆ Create core group of in-country technical experts through long-term training and attachments of personnel to specialized institutions located abroad (a "learning by doing" approach)
- ◆ Utilize biosafety training opportunities offered internationally and on the Internet
- ◆ Consider development of a "Train the Trainer" program in technical aspects of biosafety, mobilizing existing experts and ensuring their effective utilization
- ◆ Offer a course of practical training in the identification, detection and analysis of living modified organisms
- ◆ Risk assessment and decision-making under the Protocol
- ◆ Risk management including Emergency management
- ◆ Training in database design, data management, web site design and interoperability for insuring full participation to provide and receive information from the BCH

### AGRICULTURAL BIOTECHNOLOGY & PLANT PROPAGATION

For the most part, FSM is and will continue to be a food and agriculture importing country. Without ruling out the possibility of developing some transgenic plant crops for local agriculture in the future specifically for the specific climatic conditions, pests, and diseases

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experienced by local farmers, the main thrust will be import decisions on LMO seeds and crops, which will be taken by the Competent Authority as outlined in this NBF.

Currently, the COM-FSM, Kosrae Campus will continue to offer a one-year certificate under its Agriculture program teaching tissue culture and micropropagation techniques, and requiring lab-based internships at the Micronesian Plant Propagation Research Center. If funding allows, more permanent and paid positions will be offered to lab employees. Additionally, under the implementation phase, it is hoped to have a construction upgrade and to totally rebuild the containment facility at this lab, as well as to expand the grow-out facility. Staff at the Kosrae MPPRC lab, and quarantine personnel in all four FSM states will need training in GMO detection, as well as the tools to do the inspections at the border, when suspected mislabeling is suspected.

The COM-FSM National Campus on Pohnpei is also hoping to upgrade their lab facilities, in order to be able to conduct relevant biotechnology research on abiotic stress tolerance for the outer atolls related to climate change impacts.

Partnerships with the USDA Agricultural Research Services new Pacific facility in Hilo, Hawaii will be explored for potential cooperation.

BIOFUELS

FOOD SAFETY (GM FOOD)

MARINE BIOTECHNOLOGY

PHARMING (PHARMACEUTICALS AND NUTRACEUTICALS)

**Part 36. Biosafety Clearing House Node (database and web site)**

Personnel working under the FSM National Government Competent Authority will create a FSM-specific Biosafety Clearing House Internet web portal, and will provide (push) information to the Geneva, Switzerland Biosafety Clearing House portal maintained by the Secretariat of the Convention on Biological Diversity. It will be updated at the minimum of once per month, to contain current up-to-date information about the status of any LMO import applications requested, permissions granted, capacity building and public education opportunities, and other relevant information. This Internet web site will also provide links to the Cartagena Protocol documents, to Pacific regional Biosafety initiatives, and to research on modern agricultural and marine biotechnology related to tropical islands, as well as the most current information on risks and risk assessment methodologies. Contact information will be provided to allow someone to directly connect by email to persons responsible for Biosafety within the states of Kosrae, Pohnpei, Chuuk and Yap.

**Part 37. Plan for Regularly Scheduled Reviews and Revisions**

The Final FSM National Biosafety Framework and any resultant Biotechnology and Biosafety bills passed by legislature will be reviewed every three years in the light of new innovations in modern biotechnology as well as changing circumstances within the nation and global

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community. This assessment of FSM Biosafety regulations, AIA procedures, monitoring and enforcement compliance and their continued sufficiency will take place in the years 2010, 2013, 2016, 2019, 2021, 2024 and so forth. The National Government has the responsibility for assigning a reviewer, who will report directly to the President's Council on Environmental Management and Sustainable Development (SD Council) and will work under the Competent Authority, as the direct supervisor of all work outputs. The SD Council will also establish a coordinating mechanism for overseeing and reviewing progress towards Biosafety capacity-building. While periodic internal review is mandatory under this NBF, the SD Council can also assign responsibility and contract services of an independent, external reviewer.

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**SECTION EIGHT: Glossary and Terms**

**Part 38. Acronyms**

<b>AIA</b>	Advanced Informed Agreement
<b>BA</b>	Bachelor of Arts Degree
<b>BS</b>	Bachelor of Sciences Degree
<b>BCH</b>	Biosafety Clearing House
<b>BSAC</b>	Biosafety Scientific Advisory Committee
<b>BSAP</b>	Biodiversity Strategies and Action Plan (states)
<b>CA</b>	Competent Authority
<b>CBD</b>	(United Nations) Convention on Biological Diversity
<b>COFA</b>	Compact of Free Association (between the FSM and the United States)
<b>COM-FSM</b>	College of Micronesia-FSM
<b>COP-MOP</b>	Conference of the Parties, serving as Members of the Parties to the Cartagena Protocol
<b>CPB</b>	Cartagena Protocol on Biosafety
<b>CRES</b>	Cooperative Research and Extension Services (COM-FSM Land Grant)
<b>CSP</b>	Conservation Society of Pohnpei
<b>DEA</b>	Department of Economic Affairs (FSM National Government)
<b>DSAP</b>	Development of Sustainable Agriculture in the Pacific (SPC)
<b>EPA</b>	Environmental Protection Agency (states of Yap, Chuuk and Pohnpei)
<b>FAO</b>	Food and Agriculture Organization of the United Nations
<b>FSM</b>	Federated States of Micronesia
<b>GE</b>	Genetic Engineering
<b>GEF</b>	Global Environmental Facility
<b>GM</b>	Genetically Modified or Genetic Modification
<b>GMO</b>	Genetically Modified Organism (s)
<b>HESA</b>	Health, Education and Social Affairs (FSM National Government)
<b>IFCP</b>	Island Food Community of Pohnpei
<b>KCSO</b>	Kosrae Conservation and Safety Organization
<b>KIRMA</b>	Kosrae Island Resource Management Authority
<b>LMO</b>	Living Modified Organism (s)

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<b>MA</b>	Master of Arts Degree
<b>MIBBIC</b>	Micronesian Islands Biotechnology and Biosafety Information Center, Pohnpei
<b>MPPRC</b>	Micronesian Plant Propagation Research Center, Kosrae
<b>MSc</b>	Master of Sciences Degree
<b>NBF</b>	National Biosafety Framework
<b>NBR</b>	National Biosafety Regulator
<b>NBSAP</b>	National Biodiversity Strategies and Action Plan
<b>NCC</b>	National Coordination Committee for Biosafety (Biosafety Advisory Committee: 2003- 2007)
<b>NEA</b>	National Executing Agency
<b>NFP</b>	National Focal Point
<b>NGO</b>	Non-Government Organization
<b>NPC</b>	National Project Coordinator for Biosafety (alternately, <b>NBC</b> = National Biosafety Coordinator)
<b>PhD</b>	Doctor of Philosophy Degree
<b>PRA</b>	Participatory Rural Appraisal
<b>SAC</b>	Scientific Advisory Committee (same as Technical Advisory Committee or TAC)
<b>SD</b>	Sustainable Development
<b>SFP</b>	State Focal Point
<b>SPC</b>	Secretariat of the Pacific Community
<b>SPREP</b>	South Pacific Regional Environment Programme, Apia, Samoa
<b>TNC</b>	The Nature Conservancy (Micronesia Office)
<b>UHH</b>	University of Hawai'i at Hilo
<b>UHM</b>	University of Hawai'i at Manoa in Honolulu
<b>UM</b>	Universiti of Malaya, Kuala Lumpur, Malaysia
<b>UNDP</b>	United Nations Development Programme
<b>UNEP</b>	United Nations Environment Programme
<b>UNESCO</b>	United Nations Education, Scientific and Cultural Organization
<b>UNIDO</b>	United Nations Industrial Development Program
<b>UOG</b>	University of Guam
<b>USDA</b>	United States Department of Agriculture
<b>USP</b>	University of the South Pacific



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YINS

Yap Institute for Natural Science

**Part 39. Technical Terms with Definitions**

- "Advanced Informed Agreement (AIA)"* means the consent obtained before any activity is undertaken based upon full disclosure of all relevant matters;
- "Animal"* means any mammal (other than human), bird, insect, amphibian, reptile, fish, mollusk or other member of the animal kingdom, whether alive or dead, and includes the egg, embryo, ova or semen and any organic animal tissue from which another animal could be produced;
- "Applicant"* means a person or legal entity or country submitting an application notification or petition pursuant to the provisions of this Act;
- "Biosafety"* means the safe use and applications of biologically based technology;
- "Biosafety Clearing House"* means the information exchange mechanism established under Article 20 of the Cartagena Protocol;
- "Biosecurity"* means the control by legal and administrative means of pests and diseases affecting animals, plants and their products, in order to avoid adverse effects on the economy, environment and health of FSM;
- "Cartagena Protocol"* means the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity adopted at Montreal in January 2000;
- "Competent Authority"* means the entity responsible for the implementation of this Act, i.e. the FSM National Government, Secretary of Economic Affairs;
- "Contained Use"* means any operation or activity, undertaken within a closed facility, installation of other physical structure, which involved LMOs that are controlled by specific approved measures that effectively limit their contact with, and their impact on, the external environment and the general population;
- "Deliberate Release"* means any intentional introduction into the environment, including any production or use that is not in contained use; this includes approved field releases for research experiments, or commercialization;
- "Document"* means any mode of communicating information in a retrievable form capable of being copied, including electronically;

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"*Environment*" includes -

- (a) the ecosystem and its constituent parts, including people and communities;
- (b) all natural and physical resources;
- (c) the qualities and characteristics of locations, places and areas.

"*Export*" means the intentional transboundary movement from the FSM into another country;

"*Exporter*" means any legal or natural person who exports or seeks to export goods or products;

"*Genetic material*" means any material of plant, animal, microbial or other origin containing functional units of heredity;

"*Import*" means the intentional transboundary movement of goods into the area of national jurisdiction of FSM from the area of national jurisdiction of another country;

"*Importer*" means any legal or natural person who imports or seeks to import goods;

"*Intentional introduction into the environment*" means any deliberate use of LMOs subject to this Act that is not contained use, but does not include LMOs imported for direct use for food or feed or for processing;

"*In transit*", means the goods are not imported but pass through to another area, whether by the same or another conveyance, during which time they remain enclosed, are not split up, are not combined with other goods, and do not have their packaging changed;

"*Living modified organisms*" (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. It includes genetically modified microorganisms, plants and animals.

"*Living organism*" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, bacteria, fungi, viruses and viroids.

"*Microbe*" means any organism or biotic entity of microscopic proportions, whether unicellular, multi-cellular or sub-cellular in common form;

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- "Modern biotechnology"* means the application of:  
in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or  
fusion of cells beyond the taxonomic family,  
that overcomes natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;
- "National Biosafety Regulator"* means the person appointed by the FSM National government to serve as coordinator of implementation activities under this Act;
- "National Focal Point"* means the Secretary of Economic Affairs; the entity designated to be responsible on behalf of FSM for liaison with the Secretariat of the Cartagena Protocol;
- "Notification"* means providing information to and where appropriate, the lodging or depositing of samples for testing with the Competent Authority;
- "Organism"* means a biotic entity capable of reproduction or replication;
- "Person"* includes both natural and legal entities; this includes: corporations, businesses, universities and research institutes;
- "Placing on the market"* means supplying or making available to third parties LMOs or products thereof on a commercial basis;
- "Plant"* includes seeds, germplasm, or any other part of the plant;
- "Receiving country"* means a country which is the intended destination of an article or goods proposed to be exported;
- "Regulations"* means regulations, orders and any other subsidiary legislation made under this Act;
- "Release"* means the introduction of agriculture-related LMOs for field trials or commercial use
- "Risk"* means the magnitude and likelihood of an adverse effect occurring;
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"*Risk assessment*" means the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic conditions and cultural values of the FSM; this includes the evaluation of secondary and long-term effects;

"*Risks to human health*" means the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of biological diversity.

"*Secretariat of the Cartagena Protocol*" means the Secretariat established by Article 31 of the Cartagena Protocol;

"*State Focal Point (STP)*" means the office or person named by the Governor of Chuuk, Kosrae, Pohnpei or Yap to coordinate Biosafety implementation within that state.

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**ANNEX I**