

Capacity building activities in the field of Biosafety: Australian Submission

In Australia's view, the most efficient way to develop effective national policies and regulations for trade in living (genetically) modified organisms (LMOs) is to build them into a country's existing regulatory framework. This avoids costly duplication and the need to set up of a whole new regulatory infrastructure. Capacity building in the field of biosafety should therefore be considered in the context of countries' broader regulatory policy and infrastructure capacity.

Australia has helped a number of developing countries to build infrastructure to safely manage LMOs by assisting with the development of their quarantine policy, capacity to manage sanitary and phytosanitary issues, risk assessment capacity and environmental impact assessment capacity. We focus on the Asia-Pacific region and have supported a number of regional and sub-regional meetings and other initiatives in this regard (see attachment 1). There is ample scope for including a biosafety component in such activities.

Australia has also undertaken a range of activities in the Asia-Pacific region to directly address biosafety issues. For example:

- A regulatory expert from the Department of Agriculture, Fisheries and Forestry, Australia (AFFA) gave:
 - a presentation to the Pacific Plant Protection Organisation (PPPO) Executive Committee meeting on GMO developments and regulatory approaches (August 1999);
 - a presentation on GMO developments and regulatory approaches at a SPREP Invasive Species workshop (September 1999); and
 - in-house presentations on biosafety issues as part of training programs provided to a number of countries including China and Korea.
- The Australian Environment Ministry, Environment Australia, identified Biosafety capacity building as area of cooperation in an agreement recently concluded with China's State Environment Protection Administration.
- In December 1999, Australia fully funded a regional workshop on Biosafety in Fiji, organised by the South Pacific Commission (SPC) in collaboration with the South Pacific Regional Environment Program (SPREP) which, for the first time, brought together key government decision makers from South Pacific Island agriculture, quarantine environment and conservation departments to discuss GMO risks and benefits and appropriate regulatory approaches. A report from this workshop is attached (attachment 2). Our feedback was that the workshop was very helpful to the Pacific Island Countries that attended. It clearly underlined the usefulness of collaboration at the national level between regulatory practitioners and policy makers. SPREP plans to hold a further regional workshop on Biosafety in collaboration with SPC later this year, which would (among other things) explain additional risk assessment and other procedures generated under the Biosafety Protocol. Australia expects to provide technical assistance to the workshop.

- Australia has also contributed to work within the Agricultural Technical Cooperation Experts Group of APEC, which has been developing a program of cooperation in research, development and extension of agricultural biotechnology. The main focus of this work is on information exchange and capacity building in developing economies aimed at facilitating the uptake of biotechnology and influencing the development of national processes and procedures for evaluating biotechnology products. The main focus of the expert group's biotechnology work program in 2000 is on:
 - Completing a “best practice” guide to risk communication relating to agricultural biotechnology;
 - Compiling a series of case studies on issues related to intellectual property rights, including plant variety protection, for transgenic crops of specific regional interest;
 - Reporting on risk assessment and risk management procedures to facilitate improved regional coordination and efficient use of risk assessment resources;
 - Increasing collaboration with the IPPC Secretariat in developing standards/guidelines for biosafety risk assessment (in cooperation with the ACTEG sub-group on Animal and Plant Quarantine and Pest Management);
 - Convening the fourth biotechnology workshop focusing on capacity building and public information in the context of agricultural biotechnology.

Recommendations

On the basis of our experience in capacity building activities in the Asia Pacific region, and in view of the significant amount of activity occurring in this field, Australia recommends that:

- capacity building efforts focus, where possible, on ways to incorporate biosafety regulation into countries' existing and regulatory arrangements, including strengthening those arrangements where necessary;
- collaboration between quarantine/regulatory officials and environmental policy makers be encouraged; and
- the Secretariat, in addition to seeking and consolidating information from national governments, contact relevant regional and international organisations (such as the FAO, UNEP, the OECD, SPREP, SPC) for a report on their capacity building activities in the area of biosafety.

PHYTOSANITARY CAPACITY BUILDING AND TRAINING ACTIVITIES UNDERTAKEN BY AUSTRALIA

It is Australian policy to assist developing countries where possible to develop effective quarantine policy and infrastructure and the ability to manage sanitary and phytosanitary issues in general. Australia also fulfils its responsibilities in this area under various international agreements, including the *World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures* and the *International Plant Protection Convention*.

Australia has contributed to regional and sub-regional initiatives to build capacity in risk analysis with financial support from the Department of Agriculture, Fisheries and Forestry – Australia, including the Australian Quarantine and Inspection Service (AQIS), the Department of Foreign Affairs and Trade, and the *Australian Agency for International Development* (AusAID) through its APEC Support Fund and other bilateral programs.

Below is a summary of the activities that Australia has been involved in to assist other countries in this area. The summary is set out as follows:

- (1) Australian Quarantine and Inspection Service (AQIS) Head Office In-House Training;**
- (2) Capacity Building activities undertaken by AQIS Training Services;**
- (3) Northern Australia Quarantine Strategy (NAQS);**
- (4) Australian Training in non-APEC International Fora; and**
- (5) Australian involvement in APEC Activities**

(1) AUSTRALIAN QUARANTINE AND INSPECTION SERVICE (AQIS) HEAD OFFICE IN-HOUSE TRAINING

AQIS is responsive to requests for training programs to help developing countries comply with international standards. It also hosts short-term visits from counterpart agencies that wish to familiarise themselves, for example, with Australian quarantine, standards or export certification agreements, or quality management systems.

In 1997 two **Chinese** animal and plant quarantine officials undertook training with AQIS on quarantine decision making and import risk analysis. In 1997/98 two **Korean** plant quarantine officials undertook training in areas including pest and disease identification and disinfection treatments for fresh fruit and vegetables and grains. Other general assistance included: a training program for the Chief of the **Samoan** quarantine service and two **Korean** weed officers; and risk assessment training to officers from **Fiji, Samoa, Myanmar** and **Malaysia**. In May 1999, AQIS participated in providing training to a 16 member delegation from **China** as part of a APEC training program. In August AQIS provided two weeks training for four SAIQ officials from **China**.

(2) CAPACITY BUILDING ACTIVITIES UNDERTAKEN BY AQIS TRAINING SERVICES

The following are recent training-related activities undertaken by AQIS Training Services, Sydney, Australia:

- Training of Quarantine Officers in the Kingdom of Tonga, the Federated States of Micronesia (FSM), the Republic of Palau, the Marshall Islands and Cook Islands;
- Preparation of plant and animal quarantine legislation and pesticides legislation for Tonga; review of existing plant and animal quarantine regulations and preparation of new draft regulations for FSM; and preparation of draft combined animal and plant quarantine regulations for the Republics of Palau and the Marshall Islands;
- Preparation of Quarantine Operations Manuals for many Pacific Island countries, including the FSM, Republic of Palau and the Marshall Islands.
 - AQIS workshopped legislation and operational manuals over five days.
- Provision of technical assistance to the Ministry of Agriculture and Forestry in the Kingdom of Tonga to aid in the preparation of Animals (Importation) Regulations, a bill for a new Pesticides Act, new Pesticides Regulations, a bill for an Agricultural Commodities Exports Act and a set of Agricultural Commodities Exports (General) Regulations;
- Responses to requests for training and technical assistance from the Galapagos Islands (quarantine legislation), Ethiopia (quarantine training in Australia), Iran (quarantine training), Israel (assistance with technical support in post-entry plant quarantine), New Caledonia (quarantine training for newly appointed Chief Quarantine Officer), Papua New Guinea, Solomon Islands and Vanuatu (quarantine attachment training in Australia) and Samoa (training of Chief Quarantine Officer).
 - As a result of the above the following has also been provided/organised:
 - (i) technical advice and draft legislation models to the Galapagos Islands;
 - (ii) a 2-3 month training program for two officers from Ethiopia on general quarantine activities and specific activities related to quarantine policy and post-entry quarantine of cereals and pulse crops;
 - (iii) information and meeting of costs for a range of quarantine training opportunities for Iran;
 - (iv) a Nursery Stock Manual detailing post-entry plant quarantine operational activities for Israel. Details and costing of a one month training program at the Plant Quarantine, Knoxfield, Victoria were also provided to assist in the preparation of a funding application to a donor body;

- (v) on-the-job training in the form of a 25 week Certificate IV in Quarantine and Exports to the new Chief Quarantine officer for New Caledonia. This course had been especially tailored to meet the needs of the client and included time in a fruit fly free area, Central Office, Canberra and in Cairns viewing the implementation of the Northern Australian Quarantine Strategy (NAQS). The Officer's costs were met by his own government;
 - (vi) a training program in Brisbane for four Quarantine Officers (2PNG, 1 Solomon Islands and 1 Vanuatuan). Funding for the training was obtained from the Secretariat of the Pacific Community and the European Union;
 - (vii) an introductory quarantine workshop of one weeks duration in Rarotonga, Cook Islands to train 6 experienced and 6 new Quarantine Officers (December 1999).
- management of the Tonga Quarantine Project funded by AusAID (continuing). This Project is in its 9th year and nearing completion. Under the Project the competencies of quarantine officers have been documented and a syllabus for a training program of around 400 hours duration has been prepared. 15 of the 27 training modules for the course, which will be fully competency-based and largely conducted on-the-job, have been written.
 - provision of in country competency based training to officers of the Tongan Quarantine Service (continuing). Training has included the conduct of 3 day “Train the Trainer” course, a 3 day course in “Training Workplace Assessors” and a 2 day course in “Recognition of Prior Learning”. Other training has included clearance of air and sea cargo, ship and yacht inspection, aircraft clearances, mail clearance, inspection of export and import fresh produce, fumigation, correct preparation and use of export documentation, use of the Quarantine and Exports Operational Manuals and understanding Legislation.
 - A review in 1997 of the Quarantine Service of the Pacific island Republic of Kiribati at the request of the Australia international aid agency, AusAID. Under this consultancy AQIS spent approximately three weeks in Tarawa and Christmas Islands within the Republic. AQIS assessed the current capacity of the Service to fulfil its local and international obligations and made recommendations accordingly. AQIS also developed a proposal for a five year project to upgrade the Service to world’s best practice. The project called for infrastructure development, institutional strengthening, provision of equipment, development of legislation and provision of in-country and out of country training.

(3) NORTHERN AUSTRALIA QUARANTINE STRATEGY (NAQS)

Australia, through AQIS’s NAQS program, provides assistance with training of quarantine personnel in both **Indonesia** and **Papua New Guinea** as part of our obligations as a member of the Tripartite Committee on Agricultural Health and Quarantine (TCAHQ) and as a signatory to Memorandums of Understanding with both of these countries.

Collaborative activities carried out by NAQS with **PNG** and **Indonesia** include the exchange of technical information on animal and plant health status and quarantine methodology and the conduct of joint surveillance and monitoring activities in the **Torres Strait, Papua New Guinea** and **Indonesia**.

NAQS has provided resources and training to assist with the development of diagnostic facilities and pest and disease surveillance and monitoring activities in **Indonesia** and **PNG**. NAQS also funds visits to Australia by **Indonesian** and **PNG** veterinary and plant health scientists to participate in diagnostic training and surveillance activities.

(4) AUSTRALIAN TRAINING IN INTERNATIONAL FORA

AQIS resource officials ran the International Course for Masterclass in New Technologies for Plant Quarantine Management held in Malaysia 5-7 October 1998. This was jointly organised by the Crawford Fund for International Agricultural Research and Department of Agriculture Malaysia for participants from **8 Asian countries**.

AQIS ran a risk analysis training session, amongst other things, at the Pacific Plant Protection Organisation and South Pacific Commission SPS workshop that was run in Fiji, February 15-19 1998, for **22 Pacific Island Countries**.

AQIS was also involved in the following:

- an APEC workshop on Pest Risk Analysis, held in Cairns 15 – 18 June 1999;
- an APEC Training course for China for 1999-2000, involving 15 trainees;
- an AusAID/China Structural Adjustment Course for 1999-2003.

(5) AUSTRALIAN INVOLVEMENT IN APEC ACTIVITIES

Australia has supported regional and sub-regional initiatives in capacity building in risk analysis with financial support from the Department of Agriculture, Fisheries and Forestry – Australia, including AQIS, the Department of Foreign Affairs and Trade, and AusAID through its APEC Support Fund. Some recent initiatives include:

- Electronic Data Interchange pilot project on electronic health certificate message - **Thailand** and **Malaysia**;
- quarantine administrative training program - **China** (to improve the skills capacities of Chinese officials to deal with the standardisation of quarantine issues and to better analyse and develop policy regulations);
- as a new member (AFFA/AQIS) of the Network of Aquaculture Centres in Asia-Pacific (NACA), participation (through funding provided by AusAID) in development of technical guidelines on quarantine and health certification, and the establishment of information systems, for the responsible movement of live aquatic animals in **Asia**. This document will include chapters on import risk analysis, disease zoning, health certification and quarantine.

- Establishment of area freedom status for quarantine pests - **Philippines** (to enhance Philippines' capacity to provide PRA needed to underpin market access negotiations for their agricultural commodities, specifically in relation to their request for export of mangoes to Australia, AQIS/Office of Animal and Plant Health);
- quarantine technical assistance - **Thailand** - (an Australian plant quarantine expert was placed in Thailand to assist Thai officials with the compilation of scientific information necessary for their request for Australian market access for fresh durian fruit. This also provided Thai officials with the opportunity to observe the technical issues of how to monitor, record and report disease and pest risks, and will help Thailand develop its domestic quarantine processes and meet its international obligations);
- training in import or quarantine risk analysis - **China, Indonesia, Malaysia, PNG, Philippines, Thailand, Vietnam**. Workshops on sanitary and phytosanitary risk analysis April 1999 - AQIS/Office of Animal and Plant Health);
- preparation of a project proposal for funding from AusAID to conduct a survey for mango pulp weevil in **Guimaras Island** in the Philippines in February-April 1999 (AQIS/Office of Animal and Plant Health);
- Specialist training course on detection techniques using molecular biology held in Indonesia. The course was organised by the Crawford Foundation and supported by AusAID, AQIS and the governments of participating countries.

REPORT OF WORKSHOP

BIOSAFETY WORKSHOP

**TRANS-BORDER MOVEMENT OF
GENETICALLY MODIFIED ORGANISMS (GMOS)**

Nadi, Fiji Islands, 15 – 17 December 1999

SECRETARIAT OF THE PACIFIC COMMUNITY

BIOSAFETY WORKSHOP

**TRANS-BORDER MOVEMENT OF
GENETICALLY MODIFIED ORGANISMS (GMOs)**

Nadi, Fiji Islands, 15 – 17 December 1999

REPORT

Suva, Fiji Islands
1999

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1. INTRODUCTION

The Trans-border Movement of Genetically Modified Organisms (GMOs) Workshop was held in Nadi, Fiji Islands, from 15 - 17 December, 1999 at the Tokatoka Resort Hotel. The meeting was officially opened by Honourable Dr Ganesh Chand, Minister for National Planning, Local Government, Housing and Environment, Fiji Islands.

At the first working session, it was decided that a rotating Chairperson was appropriate so that each day a different sub-region would be Chair. Day one Chairperson: Mr Elijah Philemon, Chief Quarantine Officer (Plants), Papua New Guinea, representing Melanesia. Day two Chairperson: Mr Eteuati Siitia, Chief Quarantine Officer, Samoa, representing Polynesia. Day three Chairperson: Mr John Wichep, Quarantine Co-ordinator, Federated States of Micronesia, representing Micronesia.

A draft report was presented on the 17 December, and, with revision, was accepted by the meeting.

The meeting was formally closed at 1500 on Friday 17 December 1999.

2. PROGRAMME

Wednesday 15 December

Introduction

Welcome and dedication

Dr Jimmie Rodgers, Deputy Director General, SPC, Fiji Islands

Official Opening

Honourable Dr Ganesh Chand, Minister for National Planning, Local Government, Housing and Environment, Fiji Islands

The Biosafety Protocol

Mr Andrea Volentras, SPREP, Samoa

Morning tea

Country reports: State of preparedness in the Pacific for managing LMOs to reduce risks to agriculture, environment, animal and human health

Lunch

Nature, risks, benefits and management of live genetically modified organisms

Construction of live genetically modified organisms (LMOs)

Dr John Watson, Division of Plant Industry, CSIRO, Australia

Risks to biological diversity, agriculture, animal and human health

Dr Jacqui Wright, SPC Suva, Fiji

Afternoon tea

Benefits of live genetically modified organisms (LMOs)

Dr John Watson, Division of Plant Industry, CSIRO, Australia

Risk management issues for work with living modified organisms

Dr Deborah Maguire, Genetic Manipulation Advisory Committee, Australia

Thursday 16 December

Regulation of live GMOs

Biosafety and the Convention on Biological Diversity

Ms Lyndel Sutton, Environment Australia

Status of other regional and international biosafety regulatory activities

Mr Paul Trushell, Agriculture, Fisheries & Forestry, Australia

PPPO recommendations on the regulation of the importation of genetically modified organisms (GMOs)

Dr Mick Lloyd, Secretariat Pacific Plant Protection Organisation, Fiji Islands

Morning Tea

Development of policy and practice for the regulation of live genetically modified organisms (LMOs) in the Pacific Islands

Mr Sione Foliaki, Chief Quarantine Officer, Tonga

Plenary Discussion

Options for strengthening national regulatory systems to ensure the development of cost effective systems for assessing and managing the potential risks from living genetically modified organisms

Lunch

Working Groups to discuss, make recommendations, set priorities and formulate actions on live GMOs for the Pacific region

Afternoon tea

Working Groups to prepare recommendations, priorities and actions for presentation to plenary on Friday 17 December

Working group rapporteurs and Secretariat to prepare draft report from 1900 hours

Friday 17 December

Priorities and actions for live GMOs in the Pacific region

Informal consideration and discussion by participants of draft recommendations, priorities and actions on live GMOs in the Pacific region

Morning tea

Presentation of recommendations, priorities actions by Working Groups to plenary session for discussion and, if necessary, modification.

Lunch

Secretariat to prepare draft recommendations and priorities for distribution to participants

Consideration, modification and endorsement by plenary of Pacific priorities, recommendations and actions on live GMOs

Closure

3. SUMMARY OF PROCEEDINGS

Welcome and dedication

1. Dr Jimmie Rodgers, Deputy Director General of the Secretariat of the Pacific Community, Suva, Fiji Islands welcomed the participants on behalf of SPC and opened in prayer.

Official opening

2. The Trans-border Movement of Genetically Modified Organisms (GMOs) Workshop was held in Nadi, Fiji Islands, from 15 - 17 December, 1999 at the Tokatoka Resort Hotel. The meeting was officially opened by Honourable Dr Ganesh Chand, Minister for National Planning, Local Government, Housing and Environment, Fiji Islands. He emphasised the need for Pacific Island nations to be aware of modern biotechnology in order to utilise the benefits of GMOs whilst safeguarding against the associated risks. He highlighted the need for understanding of modern technology or run the risk of becoming “guinea pigs” or dumping grounds for technology rejected elsewhere.

Election of a chairperson

3. The meeting decided that the Chairperson should rotate each day between subregions. On day one, Mr Elijah Philemon, Chief Quarantine Officer (Plants), Papua New Guinea, representing Melanesia was Chairperson. On day two, Mr Eteuati Siitia, Chief Quarantine Officer, Samoa, representing Polynesia was elected and on the third day, Mr John Wichep, Quarantine Co-ordinator, Federated States of Micronesia, representing Micronesia was elected.

Adoption of programme and hours of work

4. The meeting adopted the provisional programme and hours of work.

Keynote address: The Biosafety Protocol

5. Mr A. Volentras (South Pacific Regional Environment Programme, Apia, Samoa) introduced the Biosafety Protocol within the context of the CBD. He outlined the involvement of the Pacific in the development of the Biosafety Protocol. (Annex A)

Country reports: State of preparedness in the pacific for managing LMOs to reduce risks to agriculture, environment, animal and human health

6. Country reports were presented by the delegates from Cook Islands, Federated States of Micronesia, Fiji Islands, Kiribati, Nauru, Niue, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu. (Annex B)

The nature, risks, benefits and management of live genetically modified organisms

7. Dr J. Watson detailed the methods used to create GMO's. (Annex C.1)
8. Dr J. Wright outlined some of the risks that are being discussed in international forums. (Annex C.2)
9. Dr J. Watson outlined methods for improving food production and the benefits of GMO technology. Genetic engineering objectives: add a new characteristic; modify an existing characteristic. e.g. potato leaf roll virus. He gave numerous examples of genetically modified organisms developed for a number of reasons (e.g. agronomic qualities). (Annex C.3)
10. Dr D. Maguire spoke about risk management for deliberate releases of GMOs. She mentioned the types of issues that the Genetic Manipulation Advisory Committee (GMAC) considers when doing risk analysis. Several examples of management of field releases were given. (Annex C.4)

Regulation of live GMOs

11. Ms L. Sutton presented important clauses in the Convention of Biological Diversity that relate to Genetically Modified Organisms. She highlighted threats to the environment from GMO releases including long term risks. Benefits to countries providing genetic resources were discussed. Article 19.3 of the CBD is one specifically considering the need for a Biosafety Protocol. Article 19.4 specifies (irrespective of a Biosafety protocol) onus on countries to share information on LMOs and the right of countries to establish stringent regimes for import of LMOs. (Annex D.1)
12. Mr P. Trushell identified international fora dealing with Biosafety including: UNEP/CBD biosafety Protocol negotiations; WTO Seattle Ministerial – Biotechnology Committee Proposal ; Codex Alimentarius – standards committee; Office of International Epizootics (World Animal Health Organisation) – technology application committee; Interim Commission on Phytosanitary Measures (under the 1997 IPPC) – GMO Working group; FAO undertaking on Access to Genetic Resources; CBD SBSTTA, IUCN and other Alien Invasive Species activities; APEC and other regional organisations, including Pacific Plant Protection Organisation; Asia Pacific Plant Protection Commission. (Annex D.2)
13. Dr M. Lloyd explained the role and function of the Pacific Plant Protection Organisation (PPPO) particularly in the international arena. Dr Lloyd discussed the outcomes of the Executive Committee of the PPPO in September 1999 where an import risk analysis procedure was developed for GMOs and PPPO recommendations for regulating GMOs circulated to Ministries of Agriculture, Health and Environment in 26 member countries. (Annex D.3)
14. Mr S. Foliaki gave an overview of IRA in Tonga and their viewpoint on GMO importation and related it to other Pacific Island challenges and problems. (Annex D.4)

Plenary session - Discussions on options for strengthening national regulatory systems to ensure the development of cost effective systems for assessing and managing the potential risks from living genetically modified organisms

15. Paul Trushell presented a paper for discussion regarding options open to Pacific Island countries to strengthen regulatory systems, and Australia's position. (Annex E)

Working groups to discuss, make recommendations, set priorities and formulate actions on live GMOs for the Pacific region

16. Four topics were identified for discussion by Working groups:

- Risks of Live GMOs and their Assessment;
- National/regional access to benefits of live GMOs;
- The regulation of live GMOs;
- The management of live GMOs.

Presentation of recommendations, priorities and actions by working groups to plenary session for discussion and, if necessary, modification

17. Recommendations arising from the four working groups were consolidated by the Report Drafting Committee for presentation to the Plenary.

Consideration, modification and endorsement by plenary of Pacific priorities, recommendations and actions on live GMOs

19. The meeting adopted the report and amended recommendations listed in Section 4.

Closure

22. The meeting was closed by the Chairperson, Mr J. Wichep, Micronesia.

4. RECOMMENDATIONS

The following recommendations and associated actions that were adopted by the meeting were developed by PIC delegates during working group and plenary sessions without the participation of resource persons, observers and the Secretariat¹:

1. ENSURE REGIONAL AND FACILITATE NATIONAL CO-ORDINATION OF POLICY AND DISTRIBUTION OF RESPONSIBILITIES
 - 1.1. Formalize and/or enhance a communication/consultative link between relevant agencies for the assessment, sanctioning and monitoring of GMO-related projects, particularly for integration of Environmental Impact Assessments (EIAs) and Import Risk Analyses (IRAs).
 - 1.2. Develop a memorandum of understanding (MOU) on standardized guidelines for access to benefits and benefit-sharing of GMOs for common usage by PICTs.
 - 1.3. Establish national co-ordinating bodies to co-ordinate policies/activities related to GMOs.
 - 1.4. Develop and implement EIA procedures for live GMOs.
 - 1.5. Establish an Advisory Group to assist PICTs in:
 - 1.5.1. management of GMOs;
 - 1.5.2. accessing information on GMOs;
 - 1.5.3. accessing existing databases on GMOs.
2. REVIEW AND, WHERE APPROPRIATE, STRENGTHEN EXISTING NATIONAL LEGISLATION WITH A VIEW TO INCORPORATING PROVISIONS FOR REGULATING AND MANAGING GMOs.
 - 2.1. Review/amend existing legislation to include the regulation and labelling of GMOs and GMO products.
 - 2.2. Develop appropriate legislation for the national management of GMOs.
3. DEVELOP INFORMATION SYSTEMS TO PROVIDE ACCESS AND SHARING OF CURRENT INFORMATION ON GMOs TO ENHANCE TRANSPARENCY
 - 3.1. Review existing GMO databases and make these accessible to PICTs.
 - 3.2. Regional organisations or agencies to make information on GMOs easily accessible to member countries (PICTs).
 - 3.3. Facilitate the assessment of benefits of live GMOs.

¹ In plenary discussions it was agreed that these recommendations were directed to SPC and SPREP and, where applicable, national governments.

4. BUILD REGIONAL AND NATIONAL CAPACITY TO ENSURE GOOD MANAGEMENT AND REGULATION OF TRANS-BOUNDARY AND IN-COUNTRY MOVEMENT OF GMOs
 - 4.1. Carry out a regional/in-country assessment on preparedness for managing GMOs and capacity to perform risk analysis.
 - 4.2. Evaluate PICs Quarantine mechanisms (and/or mechanisms for their implementation) to determine their capacity to undertake GMO Import Risk Analysis.
 - 4.3. Draft a regional model for regulation of GMOs (importation, import risk analysis, screening, monitoring, etc.).
 - 4.4. Provide specialised training on:
 - 4.4.1. Import Risk Analysis;
 - 4.4.2. GMO Risk Analysis;
 - 4.4.3. Appropriate management of GMO's and develop a curriculum to be included into regional tertiary institutions.
 - 4.5. Each PIC to strengthen existing, relevant policies and procedures (i.e. Quarantine Import Risk Assessment to include live GMOs).
 - 4.6. Facilitate the drafting of a GMO emergency response plan for the eradication of GMOs that accidentally become pests/invasive species/pollutants or cause other environmental damage.
 - 4.7. Regional organisations to assist in infrastructure and institutional development for the regulation and management of GMO's.
5. INCORPORATE GMO INFORMATION IN EXISTING NATIONAL AND REGIONAL PUBLIC AWARENESS PROGRAMMES
 - 5.1. Conduct public awareness activities on risks and benefits of GMOs.
 - 5.2. Develop information packages for appropriate target groups in PICs.
 - 5.3. Increase GMO awareness and implications in trade for the private and public sectors.

THE BIOSAFETY PROTOCOL

Andrea Volentras,
South Pacific Regional Environment Programme, Samoa

The presentation paper seeks to update PICs on the outstanding Biosafety Protocol issues in preparation for the First extraordinary meeting (resumed session) of the Conference of the Parties to the Convention on Biological Diversity to be held in Montreal, 24-28 January 2000.

It will focus on the outstanding essential core and core issues as identified in paragraph 52 of UNEP document- UNEP/CBD/ExCOP/1/L.2/Rev.1 noting that these issues formed the basis of the informal discussions held in Vienna 15-19 September 1999.

In updating PICs, the paper will look at *inter alia*:- the different suggestions proposed by the differing negotiating blocks to achieve consensus on the outstanding issues and offer a rationale for the various approaches taken by them. The paper will also refer to PICs participation to date in the negotiations and SPREP assistance to PICs.

The presentation sets the discussion in context by referring back to two articles in the Convention on Biological Diversity which refer to biosafety in relation to LMOs:-

Article 8(g) which requires Parties, as far as possible and as appropriate, to establish or maintain means to regulate, manage or control risks associated with the use and release of LMO's resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health.

and

Article 19(3) where parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Focusing on Article 8(g), the paper notes the international initiatives to assist in capacity building through the GEF/UNEP Pilot Biosafety Enabling Activities Project. The paper also refers to regional initiatives to recognising the need to implement Article 8(g)-for example and SPREPs role in initiative. The paper also refers to efforts to regulate biotechnology at the national level and SPREPs role in that process in Papua New Guinea.

The presentation notes that a survey of the state-of-play in the Pacific indicates a serious lack of capacity in terms of administrative structures, resource personnel who can act as competent national authorities and national focal points, the lack of people with the necessary scientific expertise to conduct risk assessment/re-conduct risk assessment in the light of new scientific assessment, policies, guidelines and legislation. With no biosafety

systems in place to regulate LMOs and limited capacity to regulate trade in biosafety, noting in particular how ecologically fragile the PICs are, the paper underlines the importance of capacity building and the inclusion of a strong provision in the Protocol on capacity building.

Turning toward Article 19(3), the presentation briefly traces the work of the various Biosafety Working Groups and PICs role in that process. The paper examines issues that are significant to PICs. These are the scope of the Protocol; the Advance Informed Agreement Procedure; the Relationship with Other International Agreements as well as the remaining core issues that have been identified for resolution.

The ultimate objective of the paper is to be a capacity building exercise in itself. Information about biosafety generally and documents in preparation for Montreal will be disseminated. The negotiating positions will be highlighted in the hope that PICs will hit the ground running when they arrive in Montreal.

COUNTRY REPORTS

Cook Islands

Law

Signed and ratified CBD 93,94

95 – Environment Act only for one island (Rarotonga). In the Environment Act there is provision for Environmental Impact Assessment (e.g. 96 proposal for alpaca quarantine station)

Environment Act does not cover GMOs.

There is legislation regarding importation of animals and plants. Antiquated, 1972.

Under review. Under this legislation, organisms are mentioned but not GMOs, but is considered to cover GMOs.

Constraints

Limited capacity to carry out risk assessments (rely on exporting countries).

Need to have capacity to verify information provided.

Lack of co-ordination amongst government agencies.

Island councils have power but limited knowledge

Cook Islands does not have the capacity to deal with these things, so take precautionary measures.

Other

GMOs – products are accepted...consumers are commenting on this.

Need co-operation from private sector.

Federated States of Micronesia

Law

No regulatory framework to deal with GMOs, can't put any legislation together until protocol is finalised. They might not accede to the Bios Protocol but will work with the region to help FSM prepare for acceding.

New quarantine act for animals. GMOs need to be put into the act.

Environment and protection act, 1981. Empowered the agency to cover the environment and to review the projects to be carried out in Ponape state on air land or water.

GMOs have not been covered

Constraints

Co-ordination between island states

Capacity building especially in RA

Awareness – GMOs are a new issue.

Fiji

Law

Reviewed sustainable development bill under parliament scrutiny. Provision of setup policy for introduction of alien species. Direct implementation of National biodiversity strategy action plan (still to be endorsed by cabinet) Provision for EIA in sustainable development bill. In this bill, there is no definition of organism, species or GMOs.

Section 37 subsection 2 part D – GMOs (that could destroy native species) have to go through administrator (in charge of EIA).

Food Export and Marketing Act, to be developed when Fiji joined WTO
 FAO carried out review. Suggested a unified Plant and Animal Quarantine, Fruit Export and Marketing Legislation based on WTO/SPS Agreement and the principles of IPPC, OIE and Codex Alimentarius Commission

Plant and Animal Quarantine Act -Cabinet paper to be submitted to review legislation (attached SPS agreement). To make them aware of the provision in SPS agreement for technical assistance.

Food safety Bill (ministry of health)

Pure food act (new act prepared incorporated Codex Alimentarius principles)(Does not mention GMOs)

Constraints

Not a lot of awareness in public or government.

Need for awareness, expert advice and technical assistance.

Greatest weakness Risk Assessment.

Kiribati

Law

Environment Act just endorsed by government last week. All departments to comply with this Act including quarantine. Preparedness – not yet.

Projects need to go through EIA before approval.

Issues, labels, permits and certification.

Capacity for EIA

Quarantine- determines import of agricultural products which is supported by legislation
 Quarantine and biological protocols.

Constraints

Limited public awareness.

Depend on outside laboratories e.g. biocontrol agents. Encourages IPM.

Unavailability of facilities and experts

Financial constraints

Other

Recovery of costs for governments – to importers

Living organisms introduced so far are screened by overseas laboratories...suggesting the same thing occur for GMOs

Nauru

Law

Ecology bill passed 2 months ago

Quarantine bill in the Act passed few weeks ago.

Other

Health inspector under Director of medical services and public health, acts as a quarantine officer.

Niue

Law

No policy in place, just existing protocols in quarantine.

Last stages of environment bill (by end of this year). Don't want to take precautionary approach. (They had quarantine station for alpacas).

1984 Quarantine Act

Strong position for deal with EIAs and GMOs in new environment bill

Now EIAs are not mandatory on any parties at present

Constraints

GMOs are a new issue in Niue, not a lot of awareness. Awareness needs to be promoted.

Rely mainly on importation

Need to regulate to protect people

Risk assessment needs to occur

Other

Niue will support regional move to control GMO imports in the Pacific

Niue doesn't have – domestic co-ordination of services (environment, health and agriculture and lands etc.), human resources, infrastructure and facilities to be vigilant in managing GMO threats

Do have –multi-departmental bodies with small technical teams, just haven't had opportunity to co-ordinate

Papua New Guinea

Law

Environment Act

Quarantine Act and Plant Disease Control Act

Must do Risk Assessment under regulations of the Q Act

Members of international community and must comply with standards

92 and ratified March 93 – CBD

Member of CITES and WTO – so obligations are large.

New Environment Act (combines various acts) have yet to go before parliament

Microorganisms are largely ignored, not just in PNG but in the region

Constraints

Need information (e.g. lists of GMOs)

PNG – limited in its ability to do EIA for GMOs

Other

RA process and procedures and then Risk management

Systems approach to PRA

Samoa

Law

Land Act – provides for EIA.

Fragmented legislation in country.

Legislation – 1959

General prohibition of import of plants, animals and fish likely to cause harm to plants, animals etc

Legal officer trying to expand the legislation to fit in new issues

Awaiting cabinet on application for IPPC

Legal officer working on GMO issues

Constraints

Capacity building a high priority for Samoa
Awareness is low in Samoa

Other

Samoa took an active role in Biosafety under CBD.
Cautious of introduction of any new technologies.
Currently National Biodiversity strategy action plan to deal with CBD issues
GMOs should be made known to small island countries
Access and benefits-sharing is being discussed with the minister
Quarantine is now a division rather than a section. Have own assistant director
1st year that the government has allowed a legal post in quarantine section

Solomon IsLaw

Need for capacity building
Agriculture and Livestock Ordinance
Disease of Livestock Ordinance
Agricultural Quarantine Act 1982
Amendment and associated order of the Principle Act (Agricultural Quarantine Act 1982)
came into force in 1986
Pure Food Act 1996
Biodiversity Act
National Disaster Act
Quarantine carries out some of the responsibilities of the Biodiversity Act and Pure Food
Act
No response plans for GMO incursion
Nothing in National Disaster Act for exotic organisms

Constraints

Great need for co-ordination of Acts
No facilities and technical ability to carry out post entry quarantine on micro-organisms –
rely heavily on outside sources

Other

Work closely with Research and Vet Sections as well as Medical and Dept Forests and
Conservation

TongaLaw

Animal importation Act and plant quarantine act cover similar situations (e.g. potential
risk) but nothing specific for GMOs

Constraints

Public awareness lacking
Need technical assistance in IRA and management
Ensure that PICTs are not testing sites for GMOs
Issue is new in Tonga.
Lack of capacity and co-ordination between departments
Lack of staff numbers

Other

There is paranoia in Tonga about GMOs

IRA and management processes for GMO is similar process for non-GMO

TuvaluLaw

No environment legislation

Tuvalu has not ratified CBD

Quarantine regulations under Plant Act

Trying to incorporate the Animal and Plant act into one

Constraints

Lack of awareness

Lack of co-ordination between ministries/departments

Other

Tuvalu is limited in agriculture

Main interests – prevent harmful diseases

VanuatuLaw

No specific legislation for GMO

Legislative controls exist with respect to specific subjects e.g. imports of plants and animals and their products

Animal importation and quarantine act 1988 – animals and biological products refers to “organisms”

Plant protection act 1997 – exclusion and effective management of plant pests; exportation

Defines “plant pests”

Defines “risks”

Public health act 1984 – wider provision than environmental health.

Food control act 1993 – regulates and control of manufacture and importation of food, packaging.

Wildlife protection regulation 1962 – biodiversity

Vanuatu is a signatory to CITES

International trade of flora and fauna act 1989?

Vanuatu does not have a position on GMO

Waiting for outcomes of Biosafety Protocol

Constraints

Dependency on imported goods – lack of knowledge on contents of those goods

Prohibition of food with deleterious substances threatening human health etc..

Lack of technical expertise, lack of enforcement, lack of funding dependent on aid, no environmental legislation, but has been drafted and is being circulated.

ANNEX C.1

Note. Paper not available at time of first draft.

RISKS TO BIOLOGICAL DIVERSITY, AGRICULTURE, ANIMAL AND HUMAN HEALTH

Dr Jacqui Wright,
SPC Suva, Fiji

Many risks associated with GMOs and GMO products are already acknowledged to be the same as risks associated with non-GMOs and their products

Threats to the Environment:

- Escape and spread of introduced genes into wild populations
Observed? 4
- Herbicide resistant crops could become weeds in subsequent crops
Observed? 8
- Increased use of herbicide will result in weed resistance
Observed? 4
- Increased use of herbicides will have ecological impacts
- Observed? 4
- Widespread use of GMO crops could threaten crop genetic diversity by simplifying cropping systems and promoting genetic erosion
- Observed? 8
- Pests will develop resistance to crops with Bt toxin (or other toxins in GMOs)
- Observed? 4
- Massive use of Bt toxin (or other anti-pest product) in crops may unleash negative interactions affecting ecological processes and non-target organisms
- Observed? 4
- Existing species may be displaced from the ecosystem by GMO organisms
- Observed? 4

Threats to human, animal and plant health:

- The spread of diseases across species barriers
Observed? 8
- Vector-mediated horizontal gene transfer and recombination might create new pathogens
Observed? 4
- The use of plasmid vectors with drug resistance markers could allow the persistence of modified organisms in patients treated with antibiotics or in the natural environment which is the primary source of new antibiotics
Observed? 8
- The production of novel proteins that could be new allergens and toxins.
Observed? 4

- The introduced gene may act differently when working within its new host
Observed? 8
- The original genetic structure of the host will be disrupted
Observed? 8
- The new combination of host and introduced genes will have unpredictable effects
Observed? 8
- Health risks associated with the persistence of a herbicide resistance mechanism that protects the transgenic plant without degrading the herbicide.
Observed? 8

ANNEX C.3

Note. Paper not available at time of first draft.

RISK MANAGEMENT ISSUES FOR WORK WITH LIVING MODIFIED ORGANISMS (LMOs)

Dr Deborah Maguire,
Genetic Manipulation Advisory Committee, Australia

General principles

Risks associated with use of LMOs are generally assessed and managed on a case-by-case basis until familiarity with the organism has been acquired.

In determining the measures necessary to manage potential effects associated with an LMO, the likelihood of an effect occurring and the acceptability of the effect must both be taken into account. For example, for a release of an LMO into the environment, it will often be the case that an adverse effect, such as gene transfer from the LMO to a weedy relative, cannot be prevented, but only made less likely. If such gene transfer were to have consequences that were unacceptable, risk management would involve preventing the release from taking place at all.

With respect to risks to biodiversity, particular attention will need to be paid to risk assessment and risk management in cases where LMOs are being used in the centre of origin of the parent organism, because of the possible effects on related species that are present.

Risk management for contained work with LMOs

Contained work is work that is conducted in facilities which are designed to prevent escape of the LMO into the open environment. The main concerns for contained work are:

- to ensure that the LMO remains confined to the facility (that is, contained), and
- to minimise hazards to the people carrying out the work.

These aims can be achieved using physical containment, biological containment, or a combination of both. Physical containment involves the use of specially designed facilities and procedures. The level of hazard associated with a specific LMO determines the level of physical containment that the work requires. Biological containment involves the use of particular strains of the organism which have a reduced ability to survive or reproduce in the open environment.

Risk management for deliberate release work

Deliberate release work involves release of LMOs into the environment for field trials or for unrestricted release. In contrast to contained work, the emphasis in risk assessment and risk management for release work is on the potential risks to the environment.

The risks associated with release of an LMO into the environment depend on the properties of the LMO, the nature of the receiving environment, the interaction between the LMO and the environment, and the intended use of the LMO. An LMO that is considered to pose no risks in one region could potentially be hazardous to the environment in another region which has a different climate and ecology.

In assessing the risks that release of an LMO might pose, relevant issues to be considered include:

- the species to be released;
- the ecology of the parent organism;
- the genetic modification and its effect;
- the location of the release;
- the experimental procedures to be used during the release;
- the monitoring procedures to be used after the release.

For a plant, particular attention would be paid to:

- mechanisms of reproduction;
- the potential for pollen dispersal;
- weediness characteristics of the parental plant and effects of the genetic modification on these;
- ability of the modified plant to cross with other species in the environment at the release site;
- potential for dispersal of seed;
- effects of the modification on fitness;
- any other ecological effects of the genetic modification (e.g. effects on soil biota, effects on non-target pest species, toxicity to animals);
- the possibility of seed dormancy leading to emergence of volunteer plants.

For field trials of genetically modified plants, risk management measures generally include precautions to minimise the potential for the LMO or its genetic material to disseminate from the trial site or to remain in the environment after the release. Examples of such measures are:

- physical isolation of the LMO from other plants with which it might hybridise;
- ensuring that the LMO will not flower at the same time as other plants with which it might hybridise;
- use of 'buffer rows' of non-modified plants that act as a trap for pollen carried from the LMO by insects;
- removing or bagging the flowers of the LMO;
- use of sterile plants;
- controlling the dispersal of seeds from the LMO;
- removing the LMOs from the site after the trial;
- monitoring the site after the trial to ensure removal of volunteer plants.

In most cases, the trial will be monitored to ensure that any adverse effects are detected and to provide information relevant to the safety of future work. When sufficient data have been collected during contained work and field trials to indicate that an LMO will not pose unacceptable risks to the environment, unrestricted or general release of the LMO may be considered.

The Convention about Life on Earth

THE CONVENTION ON BIOLOGICAL DIVERSITY

WHAT IS BIOLOGICAL DIVERSITY?

The term "biological diversity" is commonly used to describe the number and variety of living organisms on the planet. It is defined in terms of genes, species, and ecosystems which are the outcome of over 3,000 million years of evolution. The human species depends on biological diversity for its own survival. Thus, the term can be considered a synonym for "life on Earth".

To date, an estimated 1.7 million species have been identified. The exact number of the Earth's existing species, however, is still unknown. Estimates vary from a low of 5 million to a high of 100 million.

WHY CONSERVE BIOLOGICAL DIVERSITY?

Species extinction is a natural part of the evolutionary process. Due to human activities, however, species and ecosystems are more threatened today than ever before in recorded history. The losses are taking place in tropical forests -- where 50 - 90 per cent of identified species live -- as well as in rivers and lakes, deserts and temperate forests, and on mountains and islands. The most recent estimates predict that, at current rates of deforestation, some two to eight per cent of the Earth's species will disappear over the next 25 years.

While these extinctions are an environmental tragedy, they also have profound implications for economic and social development. At least 40 per cent of the world's economy and 80 per cent of the needs of the poor are derived from biological resources. In addition, the richer the diversity of life, the greater the opportunity for medical discoveries, economic development, and adaptive responses to such new challenges as climate change.

The variety of life is our insurance policy. Our own lives and livelihood depend on it.

WHY HAVE A CONVENTION?

The conservation of biological diversity and the sustainable use of its components is not a new item on the diplomatic agenda. It was highlighted in June 1972 at the United Nations Conference on the Human Environment, held in Stockholm. In 1973, the very first session of the Governing Council for the new UN Environment Programme (UNEP) identified the "conservation of nature, wildlife and genetic resources as a priority area".

The international community's growing concern over the unprecedented loss of biological diversity inspired negotiations for a legally binding instrument aimed at reversing this alarming trend. The negotiations were also strongly influenced by the growing recognition throughout the world of the need for a fair and equitable sharing of the benefits arising from the use of genetic resources.

THE OBJECTIVES OF THE CONVENTION

The Convention's objectives are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources".

The Convention is thus the first global, comprehensive agreement to address all aspects of biological diversity: genetic resources, species, and ecosystems. It recognises -- for the first time -- that the conservation of biological diversity is "a common concern of humankind" and an integral part of the development process.

THE CONVENTION'S NOVEL APPROACH

The conservation of biological diversity has ceased to be viewed merely in terms of protecting threatened species or ecosystems. It has emerged as a fundamental part of the move towards sustainable development.

Thus the Convention introduces a novel approach aimed at reconciling the need for conservation with the concern for development. It is also based on considerations of equity and shared responsibility.

To achieve its objectives, the Convention -- in accordance with the spirit of the Rio Declaration on Environment and Development -- promotes a renewed partnership among countries. Its provisions on scientific and technical cooperation, access to financial and genetic resources, and the transfer of ecologically sound technologies form the foundations of this partnership.

Indeed, for the first time in the context of biodiversity conservation, an international legal instrument spells out the rights and obligations of its Parties concerning scientific, technical and technological cooperation. To this end, the Convention provides for a financial "mechanism" and a subsidiary body on scientific, technical and technological advice.

For all these reasons, the Convention on Biological Diversity is one of the most significant recent developments in international law, international relations, and the fields of environment and development. It is an affirmation in favour of life itself in all its myriad forms.

This leaflet was written by the United Nations Environment Programme's Information Unit for Conventions.

STATUS OF OTHER REGIONAL AND INTERNATIONAL BIOSAFETY REGULATORY ACTIVITIES

Paul Trushell
Agriculture, Fisheries and Forestry, Australia

International For a dealing with Biosafety:

- The UNEP/CBD Biosafety Protocol negotiations
- WTO Seattle Ministerial - Biotechnology Committee Proposal
- Codex Alimentarius - standards committee
- Office of International Epizootics (World Animal Healthy Organisation) - technology application committee
- International Commission on Phytosanitary Measures (under the 1997 IPPC) - GMO Working Group
- FAO Undertaking on Access to Genetic Resources
- CBD SBSTTA, IUCN, and other Alien Invasive Species activities
 - APEC and other regional organisations, including Pacific Plant Protection Organisation

**Pacific Plant Protection Organisation
Executive Committee Meeting
Nadi, Fiji Islands
September 6 - 8, 1999**

**INTERNATIONAL SANITARY AND PHYTOSANITARY REGULATION OF
GENETICALLY MODIFIED ORGANISMS (GMOs)²**

Issues

The potential risks from trading in genetically modified organisms (GMOs) are similar to those presently assessed and managed for non-GMO living organisms by quarantine services:

- such as the need to also assess and manage human health and safety, and the potential animal and plant pests and environmental impacts;
- as well there is the similar need for a case by case approach to risk analysis.

The process used for risk analysis of all the likely consequences of import (plant, animal, human health and the environment) are also similar, therefore it is not necessary to establish entirely separate agencies to assess genetic modification in addition to those agencies already in existence for assessing and managing countries' human, plant, animal and environmental health status.

- It is essential that regulatory services, such as quarantine (which are generally within agriculture departments), health and environment departments and other regulatory agencies, where they exist, interact to develop appropriate domestic regulatory arrangements for assessing and managing the potential risks from trading in GMOs;
- Where regulatory 'gaps' are evident, the existing agencies should receive any additional resources available for addressing GMO issues to fill these 'gaps'.

In terms of how GMOs can be regulated internationally, the importer notification model should be the preferred administrative process for assessing the potential risk posed from trade in GMOs. This model is aligned to the import permit process that most countries in the Pacific utilise for other living organisms that pose a risk to animal, plant and human life and health and the natural environment. The advantages of an importer based system are:

- It reflects existing systems for managing risks associated with imports of living organisms;
- It recognises that national governments have principal responsibility for protecting their own biological diversity;
- It provides full control to importing Parties to decide what information they want and how they can best apply national procedures appropriate to their own circumstances;

² Please note that living modified organism (LMO) is the terminology used in the Biosafety Protocol, however the meeting brief and explanatory paper (not the attachments) will refer to genetically modified organism (GMO) to alleviate confusion. LMO is being used under the Biosafety Protocol to make it clear that non-viable GMOs (i.e. non propagable) are not covered in the scope of the treaty.

- It ensures that importing Parties have legal reach over the notifier;
- It places the responsibility for notification on those who are most familiar with the requirements of the importing Party, and best placed to obtain the required information;
- Recognising that, in reality, exporters, importers, Parties of export and developers all have a role in providing information that may be sought by the Party of import;
- It avoids problems with co-mingling and the uncertainty of exporters as to what the requirements of destination countries may be (or indeed what the destination country is);
- All potential product approvals (e.g. for GMOs approved for general release) can be obtained well before an actual transaction is initiated, as the importer will be able to ensure that all possible components of the import have been approved - or that the import is certified as containing only approved GMOs;
- Removes the need to define precisely the application of the AIA procedures as each importing Party will define what it wishes to apply AIA to;
- It enables notifiers (importers) to seek recourse through domestic administrative law for an importing Party's failure to respond, rather than having to resort to cumbersome and potentially expensive international compliance procedures;
- It does not require exporting Parties to enforce decisions of other Parties - which the exporting may not even agree with.

Considerations

What are the risks and benefits for the Pacific region if they adopt a managed risk approach to trading in GMOs?

GMO risk analysis is multifaceted and crosses discipline boundaries, involving human, animal, plant health and other environmental issues, that will require inputs from a range of technical sources:

- How can countries ensure they are able to efficiently and effectively fulfil their regulatory responsibilities, with the relatively high level of resources that will be required, so countries can realise the full benefits of access to biotechnology?

Quarantine pest risks for non-GMO organisms, are already assessed and managed by national plant protection organisations on a day-to-day basis, therefore the existing technical expertise in this area could be strengthened to handle GMOs at a national level.

- However import permit and export certification systems will involve approval from a range of agencies where the issues to be considered are additional to phytosanitary risk.

What are the administrative arrangements in place in countries for assessing and managing non-GMO products, and do they have the resources to coordinate agencies and build on existing regulatory systems to assess and manage the potential risks from GMOs in an effective manner?

The current draft legal Biosafety Protocol presently being negotiated by parties to the Convention on Biological Diversity (CBD) contains elements that would cause administrative burden for regulatory agencies:

- Most input from countries and negotiating groups has come from environmental and trade agencies, without much input from agencies that will fulfil the administrative, legal and risk analysis obligations under the Protocol;
- Interagency cooperation on this protocol and regional cooperation is essential to ensure the Protocol does not impose undue administrative and regulatory burdens on governments;
- Are quarantine services involved in this debate in the Pacific region?

Recommendations

- 1) In order to effectively assess and manage risks from importing GMOs, additional technical resources would be required to build on the existing quarantine and other regulatory systems that use the well tried and tested "importer notification" process:
 - The capabilities and resources available for quarantine purposes should be increased to handle the extra responsibilities for assessing and managing pest risks from GMOs, rather than new agencies being created;
 - SPC should facilitate an analysis by countries of their specific technical expertise and other resources available to conduct GMO activities, and determine their capacity building and training requirements, so the resource implications of establishing effective regulatory systems in the region can be properly assessed;
 - SPC is an appropriate agency for undertaking IRAs on GMOs where expertise is lacking in a particular country. Therefore consideration should be given to allocating resources to this area in SPC.
- 2) The Secretariat of the Pacific Community (SPC) and the Pacific Plant Protection Organisation (PPPO) should build a GMO element into the current regionally adopted pest risk analysis process and could incorporate GMO risk analysis and regulatory development into on-going IRA training activities already planned for 1999 and 2000.
- 3) SPC to ensure that the region's Quarantine and other regulatory services are adequately represented in the development of regional policy approaches to the development of the Biosafety Protocol that are put forward in international negotiations.
- 4) SPC/PPPO be nominated as the most appropriate organisation to represent the interests of PICTs in regional and international developments on biosafety issues affecting IRA and quarantine services:
 - PPPO could also become the conduit for disseminating information on biotechnology developments and GMO regulation issues to members.

ANNEX D.4**DEVELOPMENT OF POLICY AND PRACTICE FOR THE REGULATION OF
LIVE GENETICALLY MODIFIED ORGANISMS (LMOs) IN THE PACIFIC
ISLANDS**

Sione Foliaki, Quarantine & Quality Management Division,
Ministry of Agriculture & Forestry, Tonga.

- Pacific Island Countries have the sovereign right to make import decisions to protect their own agriculture, environment, human and animal health.
- National governments have principal responsibility for protecting their own biological diversity
- The assessment process/ procedures of the potential risks and benefits posed by trading in LMOs should be similar to those currently assessed and managed for non-LMOs by national quarantine/ regulatory authorities.
 - International Standards and Guidelines (FAO- IPPC/OIE/ CODEX, WTO-SPS & CBD)
 - ISPM #2 – standards on how to conduct PRA/IRA
 - Market Access vs. Technical Barrier to Trade (TBT)
- The obligations to ensure safe trade in LMOs required collaboration between the existing national quarantine service and other concerned government authorities, importers, exporters with the assistance of the regional organizations (SPC-Animal Health Service & Plant Protection Service, Pacific Plant Protection Organization & SPREP etc).
- National Quarantine/Regulatory authorities should have in-place a transparent & scientific-based Import Risk Analysis (IRA/PRA) or modified the existing IRA in accordance with the updated international standards /guidelines.
- National government should have a National emergency response plan (ERP) in case of GMOs uncontrolled 'escape' or incorporate living GMOs into their National Disaster Management Plans.
- Application for Import LMO's always say "Yes, But....." _Set and develop science-base import conditions or requirements.
- Remember to weigh the Pros.. and Cons.. of the benefits of genetically modified living organisms.
- Pacific Island Nations should consider as essential requirement that the importer/exporter commission a mutual agreed organization to conduct Biotechnology researches (i.e the University of the South Pacific, CSIRO etc.) to provide data needed for IRA of the GMOs at no cost to PICs.

- Access to all available information to assist in conducting IRA.
 - CAB, GPPIS etc...
 - Scientific Publications
 - WEB sites, AQIS, USDA-APHIS, NZMAF etc..

PICs should be proud that their Quarantine Services are the real quarantine & regulatory authorities in the world.... Keep up the reputation.

**COST EFFECTIVE REGULATIONS FOR ASSESSING AND MANAGING THE
POTENTIAL RISKS FROM LIVING GENETICALLY MODIFIED
ORGANISMS (LMOs/GMOs)**

Paul Trushell, Agriculture, Fisheries & Forestry, Australia

Australia recognises and understands the concerns that developing countries have over their capacity to make informed decisions on applications to import living modified organisms (LMOs). The advanced informed agreement process (AIA; import permit application and risk analysis processes) that Australia has promoted during the Biosafety Protocol negotiation process, ensures safe trade in LMOs, and involves a range of obligations on importers, exporters and government authorities. This mix of obligations assists to ensure that importing government authorities have adequate information to make an informed decision on import applications.

Australia's overarching policy approach to the negotiations of the Biosafety Protocol is based on the following:

- the Biosafety Protocol should focus on the conservation and sustainable use of biological diversity,
- living modified organisms (LMOs) are not inherently dangerous but, like other living organisms, particular LMOs may pose risks to biological diversity in particular environments,
- countries have the sovereign right to make import decisions, and in the case of Parties to the Convention on Biological Diversity (CBD), an international obligation, to protect their own biological diversity, including through the regulation of imports, and,
- the Biosafety Protocol procedures for notifying intent to trade in an LMO and the subsequent risk analysis process, should allow parties to adequately protect their biological diversity, however they should not inhibit countries from having access to the significant environmental, economic and social benefits that may be gained from LMOs resulting from modern biotechnology.

AIA under the present draft text of the Biosafety Protocol, is what is viewed as exporter notification. This exporter notification approach has its conceptual roots in the prior informed consent procedures developed for hazardous wastes and hazardous chemicals in the *Basel Convention on the Transboundary Movement of Hazardous Wastes and Their Disposal* and the *Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC)* respectively. Both of these instruments place the balance of responsibility for notification (import permit application) and control of export on the exporter and exporting Party. They both deal with a strictly defined and limited set of substances which are internationally recognised to be hazardous and requiring special handling and control.

Australia does not believe that transboundary movement in LMOs should be governed by rules similar to those in place for a small and clearly defined list of hazardous wastes and hazardous chemicals. LMOs are not inherently hazardous and those LMOs that may

pose a risk in one environment, may not pose a risk in other environments. There is a clear need for case by case risk analysis on first imports of LMOs.

Australia continues to believe that the only rational structure for AIA for LMOs is to build on existing mechanisms governing imports of all living organisms: ie quarantine regimes. This should not be viewed as either an importer or exporter based system, as the import permit and risk analysis processes proposed by Australia involve responsibilities on importers, exporters and importing and exporting governments.

The advantages of the Australian proposal for a system of LMO import permit and risk analysis processes is:

- it reflects existing systems for managing risks associated with imports of living organisms,
- it recognises that national governments have principal responsibility for protecting their own biological diversity,
- it provides full control to importing Parties to decide what information they want and how they can best apply national procedures appropriate to their own circumstances,
- it ensures that importing Parties have legal reach over the import permit applicant,
- it places the responsibility for notification on those who are most familiar with the requirements of the importing Party, and best placed to obtain the required information,
- **recognising that, in reality, exporters, importers, Parties of export and developers all have a role in providing information that may be sought by the Party of import (see part 2 of this paper),**
- it avoids problems with co-mingling and the uncertainty of exporters as to what the requirements of destination countries may be (or indeed what the destination country is),
- all potential product approvals (eg for LMOs approved for general release) can be obtained well before an actual transaction is initiated, as the importer will be able to ensure that all possible components of the import have been approved - or that the import is certified as containing only approved LMOs,
- and thus removes the need to define precisely the application of the AIA procedure as each importing Party will define what it wishes to apply AIA to, and,
- it enables notifiers (importers) to seek recourse through domestic administrative law for an importing Party's failure to respond, rather than having to resort to cumbersome and potentially expensive international compliance procedures

We continue to support obligations on all Parties to share all relevant information (subject to confidentiality) directly or through the Biosafety Clearing House mechanism, including of LMOs approved for general release and regulatory actions taken. Australia is assisting a number of countries in the area of capacity building for institutional capacity and technical expertise so they can undertake rigorous risk analysis procedures. We will continue these efforts, and believe that the most effective and efficient to assist with capacity building to deal with LMOs is to build onto this existing work.

The attached flowchart to this paper seeks to set out the responsibilities of exporters, importers and governments under the import permit process and risk analysis processes that Australia has recommended should be adopted in the Biosafety Protocol.

Session 4 - The responsibilities of importers, exporters and government authorities under Australia's proposed system of LMO import permits and risk analysis processes under the Biosafety Protocol

The import permit process

An importer, or an entity within the legal jurisdiction of the importing government, submits an LMO import application to the importing government authority. The import application would request the importer to provide as much information as possible as required under Annex 1 of the draft text of the Biosafety Protocol. The importing government authority verifies the information provided, where possible (Clearing House, exporting government etc.), and advises the importer (if they have not already established this prior to the import permit application) either that;

1. a risk analysis for the proposed import has already been undertaken, and that either, the import can proceed without risk management conditions, with risk management conditions attached or is not allowed entry as the risk analysis has determined that the risks from importation cannot be managed. In the case that the import can proceed, the importer is provided with an import permit (and tracking number) setting out the risk management conditions,

or

2. the application is for the first import of the LMO. The importing party authority advises the importer that a full risk analysis process will be undertaken as set out in Annex 2 of the draft text of the Biosafety Protocol.

Initiating the risk analysis information exchange process

If the importing government authority has advised the applicant that a full risk analysis procedure will be undertaken, they advise the applicant to prepare a detailed dossier of information – specifying what additional information is required beyond that provided in the import application. As noted in Annex II of the draft text of the Protocol, the information required for risk analysis purposes will vary in content and volume, depending on the LMO under assessment, its intended use and the receiving environment.

The Importer/exporter decisionmaking

The importer and exporter liaise to make a decision whether to proceed with the proposed transboundary movement of the LMO, if risk management options are already determined, or whether they

will commit resources to the preparation of an information dossier as requested by the importing government authority.

Preparation of the dossier of information for the importing government authority

Importer prepares the dossier of information required for the full risk analysis process. This can involve:

1. Seeking the required information from exporter (which may in some circumstances be the same legal entity as the importer).
2. If necessary, the importer or exporter seeks information from the researcher and/or commercialiser who developed GMO.
3. The importer or exporter can also request information from the exporting government authority.
4. Most technical market access negotiations need to be undertaken at a government to government level. This is relevant where the import is seen to be in the national interest to the exporting and/or importing country, and there is a clear need for government involvement in information exchange to speed up the risk analysis process. Also this role for government authorities can overcome public concerns that the information provided by the commercial interest is not adequate.
5. Utilising the clearing house mechanism and other risk analysis databases.

Exchange of risk analysis information

- Exporter, developer and exporting government authority provides required information to importer or directly to the importing government authority, where possible.
- Importer finalises the risk analysis dossier of information.

Information for the full risk analysis

- Importer submits dossier of information to importing government authority so the risk analysis process can be undertaken; within the proposed timeframes under the draft text of the Biosafety Protocol.
- Please note that the importing government authority is not bound to allow the importation to proceed, if they do not have adequate

information to determine the risks and whether these risks can be managed to ensure an adequate level of protection to biological diversity. This is where the importing country can apply leverage to ensure adequate information is provided to ensure informed decisionmaking on import applications for LMOs.

Risk assessment and management analysis commences

- Importing government authority assesses whether they have the institutional capacity or skills base to undertake the risk assessment; if not, they can request assistance from the exporting government authority.
- Importing government authority commences import risk analysis, as set out in Annex II of the draft legal text of the Biosafety Protocol, by identifying the potential risks and whether any identified risks can be managed, or whether the risks are too high to ensure an adequate level of protection to biological diversity.
- If the exporting government authority prepares a risk assessment for the importing party, the importing party must verify and validate this information and advise the exporting party whether the data provided is adequate to make an informed decision on the proposed import.

Risk communication undertaken

- Importing government authority advises applicant of the outcomes of the risk assessment and management analysis, and either disallows the import, provides an import permit (allowing import with or without conditions) and advises whether an import permit will be required for subsequent imports of the LMO.
- Importing government authority advises the exporting party government of any pre entry risk management requirements that the exporting party must fulfil for the exports to proceed.
- The importing government authority also advises the clearing house and other relevant information exchange mechanisms that the risk analysis has been undertaken for that particular LMO, and what the risk management requirements are for that LMO.

Consideration of, and/or appeal against, the decision

- The exporting government authority assesses the risk analysis outcomes and whether any export party risk management requirements can be met.
- The importer and exporter determine whether they will proceed with the proposed import of the LMO, and liaise with the exporting government authority on how to meet any export party risk management requirements.
- The importer, exporter, exporting government authority, or any other party affected by the risk analysis decision, can appeal to

the importing party authority to reassess the decision, although this would only occur if the affected party could demonstrate that the risk analysis process did not consider certain factors or information that could have affected the outcome.

Reassessment of the risk management conditions

- Over time the importing government authority has the right to reassess the outcomes of the risk analysis for any LMO, if they determine a need, or if requested by any interested party, although this requirement would only apply when new information is provided on the risks and benefits from trading in the LMO.

ACRONYMS AND ABBREVIATIONS

ACIAR	Australian Centre for International Agricultural Research
AQIS	Australian Quarantine Inspection Service
CABI	Commonwealth Agricultural Bureau International
CBD	Convention on Biological Diversity
CSIRO	Commonwealth Scientific and Industrial Research Organisation
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FORSEC	Forum Secretariat
FSM	Federated States of Micronesia
GATT	General Agreement on Tariffs and Trade
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organism
GPPIS	Global Plant Protection Information System
ICPM	Interim Commission on Phytosanitary Measures
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
IRA	Import Risk Assessment
NPPS	National Plant Protection Service
NZ MAF	New Zealand Ministry of Agriculture and Forestry
NZODA	New Zealand Overseas Development Agency
OGTR	Interim Office of the Gene Technology Regulator
OIE	International Organisation for Animal Health
PHALPS	Regional Conference of Permanent Heads of Agriculture and Livestock Production Services
PICT	Pacific Island Country or Territory
PPPO	Pacific Plant Protection Organisation
PPS	Plant Protection Service
PRA	Pest Risk Assessment
RPPO	Regional Plant Protection Organisation
RTMPP	Regional Technical Meeting on Plant Protection
SPC	Secretariat of the Pacific Community
SPREP	South Pacific Regional Environmental Programme
SPS	Sanitary and Phytosanitary Measures
UNEP	United Nations Environment Programme
USDA	United States Department of Agriculture
USP	University of the South Pacific
WTO	World Trade Organisation

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