Convention on Biological Diversity

An Information Package for Pacific Island Countries

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FOREWORD

The Convention on Biological Diversity (CBD) is a landmark international agreement providing a framework that outlines action needed on all major issues for the conservation and sustainable use of biological diversity, and for the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The importance of the Convention to Pacific island countries is illustrated by its high level of membership in the region. At the time of going to print, 13 Pacific island states are party to this agreement. These Parties are: Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga and Vanuatu.

The sheer size, scope and number of issues dealt with by the Convention have created special problems for Small Island Developing States (SIDS), including those in the Pacific region. These are largely due to the limited capacity the Pacific states have to effectively work on the Convention's implementation at the local, national, regional and international levels.

One of the problems is the difficulty in accessing useful information regarding implementation of the Convention's numerous articles. Many of these provisions contain new issues for the region, such as biosafety and access to genetic resources. In response to this problem, SPREP has produced this CBD Information Package which provides information on the legal and institutional aspects of the Convention, as well as implementation of the articles and related issues of high priority to Pacific island countries. It is intended that this first edition of the CBD Information Package will be followed by further information packages that will form an updated series of information on implementing the Convention in the Pacific islands region. The CBD Information Package is being produced both in hard copy and electronic form to maximise access to the information. It is SPREP's hope that the CBD Information Package will prove useful to government and non-government agencies involved in biodiversity initiatives in the Pacific region. Feedback on the design, content and usefulness of the CBD Information Package is warmly welcomed.

I wish to acknowledge our partners in this work, the Foundation for International Environmental Law and Development (FIELD) and the World Wide Fund for Nature-South Pacific Programme (WWF-SPP). Each partner has brought technical and financial resources to bear on this project and have built a constructive working relationship of benefit to the region that is extending well beyond the initial project.

Finally, on behalf of FIELD, WWF-SPP, I wish to acknowledge the United Kingdom's Department of the Environment's Darwin Initiative for funding the project.

I wish us all well in our continuing efforts to conserve, maintain, sustain and enhance what we have in terms of both our biodiversity and cultural heritage for the benefit of current and future generations.

Tamari'i Tutangata
Director
South Pacific Regional Environment Programme

INTRODUCTION

Content of this information package

This information package has been compiled by the Foundation for International Environmental Law and Development (FIELD), in collaboration with the South Pacific Regional Environment Programme (SPREP) and the World Wide Fund for Nature-South Pacific Programme (WWF-SPP) as part of a UK Darwin Initiative project.

The package is intended to provide an introduction to certain legal and institutional issues arising under the Convention on Biological Diversity (CBD) for Pacific island countries. In addition to an overview of the rights and obligations of Contracting Parties to the Convention, the package contains more detailed chapters addressing the Convention's provisions on access to genetic resources and benefit sharing; on intellectual property rights; and on genetically modified organisms and biosafety. Finally it addresses on a preliminary basis issues related to coordinating national implementation of the Convention.

The information contained in these chapters is intended to provide a basic understanding of the relevant provisions of the Convention, and an overview of some of the considerations to be taken into account in its implementation. As far as possible, available information and experiences to date from the Pacific islands region itself have been incorporated into the package. In relation to certain issues, more detailed information and examples have been provided in annexes to the information package. Some of the annexes have been compiled by FIELD. Others have been adapted, or reproduced, with permission, from other sources. All material and examples in the various chapters and in the annexes are provided for illustrative purposes only, and their inclusion does not imply any endorsement of approaches or views reflected therein.

Finally, at the end of each chapter there is a list of sources and selected references, as well as a list of useful worldwide web sites. At the end of the package, an overall bibliography and list of websites is provided. Overall, it is hoped that the package constitutes a starting point for consideration of the complex issues associated with implementation of these aspects of the Convention.

The information package is being distributed in hard copy to governments and to a number of NGOs in the Pacific islands region. In addition, it is being made available in electronic form on the SPREP website and on the list server for National Biodiversity Strategy and Action Plan coordinators maintained by WWF-SPP.

Suggestions for the further improvement of the information contained here are welcomed. As far as possible, this information package is up-to-date as of June 2000, and includes developments at the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity held in Nairobi in May 2000.

Project methodology

In April 1997, the UK Department of the Environment Darwin Initiative scheme awarded a grant for a collaborative project between FIELD and SPREP aimed at building legal and institutional capacity for implementation of the Convention on Biological Diversity in the South Pacific region. The project was designed to answer a need for information and capacity in the region relating to the Convention.

The work plan for the project was developed as follows. In the first phase, FIELD, in collaboration with SPREP, produced a series of draft working papers addressing certain legal and institutional issues related to implementation of specific aspects of the Convention identified as priorities for Pacific island countries. These draft working papers formed

the basis of a one-week workshop held in Nadi, Fiji in March/April 1998. (Further information on the workshop is given below). Participants at the workshop were asked to comment on the drafts and to provide additional relevant information to be incorporated into the information package. The draft materials have subsequently been updated and supplemented in light of the workshop discussions, and the comments and information from participants and others. The information package contains chapters and annexes addressing the following issues:

(1) An introductory overview of the Convention on Biological Diversity;
(2) Access to genetic resources and benefit sharing, including the rights and interests of local and indigenous communities;
(3) Intellectual property rights;
(4) Genetically modified organisms and biosafety; and
(5) The relationship between the Convention and other international (and regional) agreements and institutions and the coordination of existing national legal and institutional arrangements relevant to the achievement of the Convention's objectives.

These issues were selected on the basis of consultations by SPREP in advance of the Nadi Workshop.

Nadi Workshop and Nadi Statement

As noted above, the Nadi workshop, held in March/April 1998, addressed legal and institutional issues related to implementation of the Convention in Pacific island developing states. The workshop was convened by SPREP in partnership with the WWF-South Pacific Programme and FIELD. It was intended to serve as a forum for national decision-makers to exchange information on experiences to date in implementing the Convention, including in relation to developing National Biodiversity Strategies and Action Plans (NBSAPs), and to discuss particular difficulties in implementation of the Convention in Pacific island countries. Some 50 participants from 13 governments, as well as regional NGOs and intergovernmental organisations, attended the workshop. A copy of the workshop report and list of participants, as well as the *Nadi Statement* adopted at the end of the workshop, are included in this information package.

The *Nadi Statement* recommended activities for regional support for CBD implementation in Pacific island countries. Furthermore, it made certain recommendations to Pacific island country governments represented at the fourth meeting of the Conference to the Parties (COP 4) of the Convention on Biological Diversity, which was held in May 1998. Many of the *Nadi* recommendations were reflected in decisions adopted at COP 4. Other recommendations for regional support have begun to be taken up. For example in July 1999, SPREP, WWF-SPP and FIELD initiated a further Darwin Initiative project focusing on access to genetic resources and benefit sharing in the Pacific islands region. As part of that project, a regional workshop on access and benefit-sharing was held in Nadi, Fiji in March 2000. SPREP and WWF have also designed a programme to support the development and implementation of NBSAPs by Pacific island countries.

ACKNOWLEDGEMENTS

A large number of individuals and institutions have contributed to the development of the CBD Information Package for Pacific islands, and to the overall project.

At SPREP, Sue Miller (Biodiversity Officer) had primary responsibility for the project together with Clark Peteru, Legal Consultant, and SPREP's Legal Officers, Bernard Moutou and Andrea Volentras. At FIELD, Ruth Khalastchi and Ruth Mackenzie were responsible for production and coordination of the package with the assistance of Adrian Wells, Research Associate, Carolina Lasen Diaz, Staff Lawyer, and Margaret Enstone and Rachel Holmwood, Programme Assistants on the Biodiversity and Marine Resources Programme. Cedric Schuster, Biodiversity Officer at WWF-SPP, has provided critical input to a number of elements of the package, and he also co-organised the Nadi workshop.

The participants in the March 1998 Nadi Workshop provided critical input to the package through their comments on draft materials, through country and NGO reports, as well as through workshop discussions.

At the beginning of the project, an informal advisory committee was constituted to comment on the draft papers as they were developed. The advisers were: Ben Boer, Australian Centre for Environmental Law; Nina Eejima, formerly Attorney General's Office, Federated States of Micronesia; Lyle Glowka, formerly IUCN Environmental Law Centre; Kosi Latu, Commonwealth Secretariat; Mere Pulea, University of the South Pacific; and Mick Naimegi Raga from Papua New Guinea. The advisers provided a range of valuable information and comments over the life of the project.

In the period after the Nadi workshop, a large number of individuals also kindly provided helpful comments, information and materials, including: William Aalbersberg, University of the South Pacific (USP); Augustine Njamshi Bantar, Bioresources Development and Conservation Programme, Cameroon; David Downes, Centre for International Environmental Law (CIEL); Sue Edwards, Institute for Sustainable Development; Sam Johnston, CBD Secretariat; Sarah Laird; Manuel Ruiz Muller; Kent Nnadozie, Bioresources Development and Conservation Programme; Vivian Rambarath, Institute of Marine Affairs, Trinidad; Carole Stephens, Natural Resources Conservation Authority, Jamaica; and Kerry ten Kate, Royal Botanical Gardens, Kew. Finally, over the course of the project, many legal interns and associates at FIELD contributed to the development of the package.

Any errors or misinterpretations, which may remain in the text, are of course the responsibility of the authors.

This project, and the production of the information package, was made possible through financial assistance from the UK Department of Environment, Transport and the Regions Darwin Initiative. In addition, the following agencies and institutions provided financial support for the Nadi Workshop: WWF-SPP; UK Department for International Development; Government of New Zealand; Government of Australia; and the Conservation, Food and Health Foundation. SPREP and FIELD are grateful to all the donors for supporting the project.

CONTENTS

I THE CONVENTION ON BIOLOGICAL DIVERSITY: AN OVERVIEW

This chapter provides a general introduction to the substantive provisions of the 1992 Convention on Biological Diversity. It assumes no prior knowledge of the Convention. It does not attempt to provide a comprehensive article by article account of the Convention. The chapters that follow provide more detailed information on certain aspects of the Convention.

1. INTRODUCTION

The Convention on Biological Diversity was one of the two international treaties signed at the UN Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992. It entered into force in December 1993, and now has 177 Parties, including 13 of the small island developing states (SIDS) of the Pacific islands region. These Parties are: Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga and Vanuatu. The Convention is a binding legal instrument that both imposes obligations and confers rights upon the States that become Parties to it. This chapter considers the obligations imposed upon all Parties to the Convention. It also examines the opportunities or potential benefits that the Convention offers to developing country Parties.

The Convention was negotiated in the light of growing international recognition of and concern over the loss of the world's biological diversity, as well as an increased awareness of the economic value of that diversity. It was also negotiated against a backdrop of existing international and regional agreements that deal with aspects of biodiversity conservation and sustainable use. The Convention is of significance to small island statesSIDS of the Pacific region, given their unique species diversity and the fragility of their ecosystems. As recognised in the Declaration by the Ministers of the Alliance of Small Island States (AOSIS) at the first meeting of the Conference of the Parties to the Convention in 1994, the fragility and degree of endemism of small islands' biological diversity warrants urgent conservation measures. Coastal and marine biodiversity are of particular significance.interest and concern to small island developing states.

Box 1: Objectives of the Convention on Biological Diversity

The Convention has three objectives (Article 1):

1 The conservation of biological diversity

2 The sustainable use of components of biological diversity

3 Fair and equitable sharing of the benefits arising out of the use of genetic resources, to be achieved by appropriate:
- access to genetic resources
- transfer of relevant technologies
- funding

1.1 What is biological diversity?

Unlike many earlier conservation treaties, the Convention on Biological Diversity does not simply address endangered species and habitats important for their conservation. Instead, it targets the whole spectrum of biological diversity on Earth, at the genetic, species and ecosystem levels. The Convention therefore defines biological diversity as:

> *the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes the diversity within species, between species and of ecosystems (Article 2).*

The scope of this definition and the breadth of the Convention's objectives clearly make its implementation challenging and complex.

The Convention applies to both terrestrial and marine biodiversity. It covers biodiversity within the national jurisdiction of Parties, as well as processes and activities carried out under the jurisdiction and control of Parties, regardless of where their effects occur. The Convention is therefore of great significance to the conservation and sustainable use of marine biological diversity, which has featured highly on its agenda to date. Of note is the Convention's Jakarta Mandate on Marine and Coastal Biological Diversity, adopted by the Conference of Parties to the Convention at its second meeting (COP 2) in 1995 (Decision II/10) and the programme of work on marine and coastal biological diversity adopted in 1998 (Decision IV/5).

1.2 The nature of the Convention

The Convention breaks new ground by taking a comprehensive, ecosystem approach to the conservation and sustainable use of biological diversity, and by explicitly coupling the conservation of biological diversity with rights to control access to genetic resources and to share benefits deriving from their utilisation. Thus it potentially offers important opportunities to biodiversity-rich developing countries to take action to control access to their biological resources.

The Convention represents a framework for future action in that:

- it adopts a "country-driven" approach, expressing overall goals and policies and imposing obligations in general terms, but leaving decision-making as to priorities, specific action and mechanisms for implementation largely to the national level; and
- it allows for further development of its provisions through decisions taken at regular meetings of the Parties and through the elaboration of further annexes and protocols.

The vital role of the various stakeholders involved in the conservation and sustainable use of biological diversity is recognised in the Preamble to the Convention, and is central to the effective implementation of many of its provisions. These stakeholders in-

clude indigenous and local communities, women, non-governmental organisations and the private sector.

2. OBLIGATIONS

The Convention places few precise and binding obligations upon Parties, but rather provides goals and guidelines. Most of the commitments of Parties under the Convention are qualified, and their implementation will depend upon the particular national circumstances and priorities of individual Parties and upon the resources available to them. Nevertheless, Parties to the Convention are obliged at least to address the issues covered by the Convention.

2.1 National strategies and plans

The implementation of the Convention requires the mobilisation of both information and resources at the national level. As a first step, the Convention requires Parties to develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity, or to adapt existing plans or programmes for this purpose (Article 6(a)). Furthermore, Article 6(b) stresses the importance of integrating the conservation and sustainable use of biodiversity into relevant setoral or cross-sectoral plans programmes and polices.

All Pacific Island States have some form of existing national plan, most commonly the National Environment Management Strategies (NEMS), which provides a starting point for this Convention's requirement. However, the broad scope of the Convention, the newer issues it addresses, e.g biosafety, and the opportunity for resources from the Global Environment Facility to assist strategy development, have largely resulted in Pacific Island Parties investing significant effort in developing new plans and strategies.

This may require a new national planning process, or a review of existing National Environmental Management Strategies (NEMS) or other national plans. For most Parties, developing a national biodiversity strategy will, for example, involve an extensive consultative process, stocktaking and assessmentidentifying of the th biological diversity which that Party has within its jurisdiction, including theand reviewng of existing legislation or administrative measures to ensure that these adequately address the issues dealt with in the Convention.

A review of COP guidance shows that, among others, the following elements should be incorporated into national biodiversity strategies and action plans (NBSAPs):

- Strategies for biodiversity conservation;
- Strategies for sustainable use of biological resources;
- Strategies for equitable sharing of benefits derived from the use of genetic resources;
- Strategies for the conservation and sustainable use of agricultural biodiversity;
- Strategies for bio-safety;
- Conservation and sustainable use of marine and coastal biodiversity

Among Furthermore, a national biodiversity plan is likely to:

- identify important biological diversity within the jurisdiction of the Party concerned;
- identify the measures that might be taken to conserve and sustainably use biological diversity;
- identify the obstacles, including financial and technological, to such measures being taken; and

- identify the various government departments or agencies which might have a role in biodiversity conservation, and allocate responsibilities amongst them.

National strategies and plans may contain indicators and targets against which countries can measure progress towards stated objectives. The Conference of the Parties (COP) to the Convention has urged Parties to identify indicators of biological diversity and, in relation to in-situ conservation, the COP has encouraged Parties to set measurable targets in order to achieve conservation and sustainable use objectives.

Measures for conservation and sustainable use may also take the form of policy goals, administrative or legislative action. A number of approaches might be considered in relation to legislative measures to implement the Convention, including:

- modifying existing environmental or sustainable development legislation;
- drafting laws specifically intended to implement the Convention; and
- integrating provisions aimed at implementing the Convention into sectoral and cross-sectoral legislative measures.

The Convention also requires Parties to integrate conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies, as well as into national decision-making (Article 6(b)). This is Implementation of Article 6(b) is clearly a more complex undertaking, requiring an assessment of the impacts of other sectors on biodiversity conservation and sustainable use. It will also require co-ordination among government departments or agencies. A national biodiversity planning process can provide a basis to assist with cross-sectoral coordination through identifying impacts and opportunities for integration (see further, chapter 5).

Financial support for the development of National Biodiversity Strategies and Action Plans is available through GEF "Enabling Activities". Given the importance of stakeholder involvement for the implementation of the Convention, it has been recommended that national planning processes provide plenty of scope for public consultation and participation. Guidance for the development of national strategies can be found in: Guidelines for Preparation of Biodiversity Country Studies prepared by the UN Environment Programme; National Biodiversity Planning: Guidelines Based on Early Country Experiences, prepared by the World Resources Institute, UNEP and IUCN; and UNDP Draft Guidelines for Countries Preparing National Biodiversity Strategies and Action Plans.

In some of the Pacific island countries, national biodiversity planning processes have already been completed or are underway. For example, the Marshall Islands are currently formulating a National Biodiversity Strategy and Action Plan (NBSAP) with funding from the Global Environment Facility (GEF). Other Pacific island countries receiving assistance from GEF (through UNDP) for the preparation of NBSAPs include Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Niue, Vanuatu, Papua New Guinea, Solomon Islands and Samoa.

UNDP and UNEP have established a Biodiversity Planning Support Programme, with funding from the GEF, to strengthen national capacity to prepare and implement NBSAPs (see Chapter 5, Box 4). SPREP and WWF-SPP are executing agencies for this programme in the Pacific islands region.

2.2 Identification and monitoring of biodiversity

Information provides the key for the implementation of the Convention. In contrast to a number of previous international or regional agreements on conservation, the Convention does not contain an internationally agreed list of species or habitats which are to be subject to special measures of protection. This is in line with the Convention's country-

driven approach. Instead, the Convention requires Parties to identify for themselves components of biological diversity important for conservation and sustainable use (Article 7). Samoa has, for example, performed two national biodiversity surveys, in 1991 and 1992, as well as a bird species survey. Other initiatives exist in the Pacific region for documenting the region's biological diversity. (For example, Dr. Art Whistler at the University of Hawaii has undertaken studies on tree and plant species for Pacific island countries such as Samoa, Tonga and the Cook Islands).

While it does not contain lists, the Convention, does indicate, in Annex I, the types of species and ecosystems that Parties might consider for particular attention (see Box 2). Annex I is likely to be a key element in the implementation of the Convention, as Parties identify which types of species and habitats they might target for special conservation efforts. Work is also underway within the Convention to elaborate Annex I in order to assist Parties.

In order to identify the components of biological diversity, Parties will require a set of information so as to identify national priorities, for example:

- which species and habitats are endangered;
- which factors might be indicative of the status of biological diversity;
- where are the areas of high diversity; and,
- which species or ecosystems have particular social, cultural or economic significance, and which are of actual or potential value.

Parties are also required to monitor important components of biological diversity, and to identify processes or activities likely to have adverse effects on biological diversity. The development of indicators may assist Parties in monitoring the status of biological diversity, and the effects of measures taken for its conservation and sustainable use. In order to implement the Convention effectively, Parties need to be in a position to collect, manage and use these types of data.

The Conference of the Parties has requested the Global Environment Facility to provide resources to developing countries to address the need for capacity-building for implementation of Article 7, taking into account the special needs of small island developing states.

Box 2: Annex I to the Convention on Biological Diversity

Indicative categories to guide Parties in the identification and monitoring of biological diversity are set out in Annex I to the Convention:

Ecosystems and habitats

- with high diversity, large numbers of endemic or threatened species, or wilderness;
- required by migratory species;
- of social, economic, cultural or scientific importance; and,
- representative, unique or associated with key evolutionary or other biological processes.

Species and communities

- threatened;
- wild relatives of domesticated or cultivated species;
- of medicinal, agricultural or other economic value;
- of social, scientific or cultural importance; and
- of importance for research into the conservation and sustainable use of biological resources, such as indicator species.

Described genomes or genes of social or economic importance

2.3 Biodiversity Conservation and sustainable use

2.3.1 In-situ conservation

The Convention addresses both in-situ and ex-situ conservation, but the emphasis is upon in-situ measures, i.e. within ecosystems and natural habitats or, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties. Article 8 sets out quite a comprehensive framework for in-situ conservation and part of a Party's national biodiversity planning process might usefully consider the extent to which it currently addresses the issues outlined in Article 8. The Convention calls on Parties, as far as possible and as appropriate, to take measures in a number of areas:

Protected areas

Parties are required to establish a system of protected areas or areas where special measures are required to conserve biological diversity. In the Pacific Island context, the most successful form of protected area initiative has been the development of community-based conservation areas (CAs). Such CAs are firmly grounded in local tenure systems and rely on the stewardship of local people over their resources to achieve conservation largely via sustainable use. Examples of protected areas that have been designated in the Pacific region include Big BayVatthe Conservation Area, in Vanuatu, and Uafato Uafato Conservation Area, in Samoa.

Guidelines should be developed for the selection, establishment and management of protected areas. The protection of such areas should be enhanced by the environmentally sound and sustainable development of adjacent areas. The concept of protected areas would cover both terrestrial, and marine and coastal areas. Clearly, marine protected areas may give rise to specific difficulties regarding establishment and management.

Designating protected areas, for example, national parks, national reserves or heritage sites, and effectively managing these areas, is a familiar approach to implementing conservation obligations in international or regional agreements and programmes. Thus, many of these types of measures have already been given some attention in the context of, for example, the Apia Convention, and for community-based CAs, in the South Pacific Biodiversity Conservation Programme.

Increasing attention is being given to how systems of protected areas can be established, while recognising economic and social imperatives, and respecting and preserving traditional or customary uses of land rights over those areas by local communities. The role of non-governmental organisations is particularly important in this regard. For example, the Siosiomaga Society in Samoa works with several villages on Savaii island to designate and undertake work in protected areass. This might include schemes such as eco-tourism, butterfly farming or selling palm seeds as a means of generating income and encouraging local communities to conserve their biological diversity.

Regulation and management of biological resources

Parties should regulate or manage important components of biological diversity whether within or outside of protected areas. Legislation or other regulatory measures for the protection of threatened species or populations should be introduced or maintained. Parties are to promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings (Article 8 (c), (d) and (k)).

Regulation and management of activities

Where Parties have identified activities which may be detrimental to biological diversity, such activities should be regulated or managed (Article 7(c), Article 8(l)).

Rehabilitation and restoration

Parties should develop plans and management strategies for the rehabilitation and restoration of degraded ecosystems and the recovery of threatened species (Article 8(f)).

Alien species

Parties should prevent the introduction of, and control or eradicate alien invasive species, which threaten ecosystems, habitats, or species (Article 8(h)).

Living modified organisms

Parties should establish or maintain means to regulate, manage or control the risks associated with the use and release of living (genetically) modified organisms (LMOs) resulting from biotechnology. Parties are, therefore, required to take action at the national level so that LMOs do not have adverse effects on biological diversity (Article 8(g)) (see further Chapter 4 and section 4.4 below on the Biosafety Protocolnegotiations).

Traditional knowledge, innovations and practices

The Convention recognises that local communities have a crucial role to play in the conservation of biological diversity, and acknowledges the significance of traditional knowledge and practices in conserving and sustainably using biodiversity. It calls on Parties to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities and to encourage their customary uses of biological resources compatible with the conservation and sustainable use of these resources (Article 8(j)). The fourth meeting of the Conference of the Parties (COP 4) established an ad hoc working group on Article 8(j) to consider the implementation of this provision (see further section 6.1 below and Chapters 2 and 3).

2.3.2 Ex-situ conservation

While prioritising in-situ conservation, the Convention recognises the contribution that ex-situ facilities and measures, such as gene banks, botanic gardens and zoos, can make to the conservation and sustainable use of biological diversity. It specifies that, where possible, facilities for ex-situ conservation should be established and maintained in the country of origin of the genetic resources concerned (Article 9).

The Convention does not, however, apply its provisions on access and benefit-sharing (see section 3.1 below) to ex-situ genetic resources collected prior to the entry into force of the Convention. This is of particular concern to developing countries, from which genetic resources have already been acquired and stored in ex-situ collections, often without consent, and without a mechanism to ensure benefit-sharing. The issue of the status of ex-situ plant genetic resources is currently being reviewed within the context of the work of the FAO. (See further Chapter 2 on Access to Genetic Resources and Benefit-sharing, and Annex 5).

2.3.3 Sustainable use

Although the term conservation has traditionally been understood to incorporate sustainable use of resources, the terms ‘conservation’ and ‘sustainable use’ appear side by side throughout the Convention. Furthermore, a specific Article of the Convention is devoted to sustainable use (Article 10). This reflects the concern of many developing countries when negotiating the Convention that sustainable resource use should be accorded explicit recognition in the Convention text. Sustainable use is defined in the Convention as:

> *the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.*

The practical implications of this definition in terms of management are difficult to assess. Article 10 does not suggest quantitative methods for establishing what constitutes sustainable use, but sets out five elements relevant to sustainable use:

- integration of conservation and sustainable use into national decision-making;
- adoption of measures relating to use which will minimise adverse impacts on biological diversity;
- protection and encouragement of customary uses of biological diversity;
- support for local populations to rehabilitate degraded areas; and
- cooperation between government and the private sector in developing methods for sustainable use.

The Conference of the Parties considered the concept of sustainable use at its fifth meeting in May 2000. The Secretariat has been requested to initiate relevant work on sustainable use and to assemble principles, operational guidelines, associated instruments and guidance specific to sectors and biomes. The COP invited Parties to assist developing countries in increasing their capacity to implement sustainable use programmes and policies through workshops, action plans, information dissemination and technology transfer.

2.3.4 Measures to promote conservation and sustainable use

The Convention makes explicit reference to a number of additional policy and procedural measures to promote conservation and sustainable use. For example, it requires Parties to adopt economically and socially sound incentives for the conservation and sustainable use of biological diversity (Article 11). Case studies on incentive measures are being gathered by the Convention Secretariat, and may provide material for further guidance from the Conference of the Parties. The Convention also recognises the importance of public education and awareness to the effective implementation of the Convention (Article 13). Parties are therefore required to promote understanding of the importance of, and the measures required for, conservation of biological diversity.

With regard to procedures, Parties are required to introduce appropriate environment impact assessment (EIA) requirements for projects likely to have significant adverse effects on biological diversity (Article 14). Legislation on EIA generally incorporates a number of elements including a threshold for determining when an EIA will be required (i.e., that the project is likely to have a significant adverse effect); procedural requirements for carrying out the EIA (e.g. imposing time limits, and requirements that provision be made for appropriate public consultation); and the requirement that the EIA be taken into account when determining whether to proceed with the proposed project. Effective environmental impact assessment is, again, likely to hinge on the availability of information concerning potentially affected biological diversity.

In addition, Parties are required to consult with other States on activities under their jurisdiction and control that may adversely affect the biodiversity of other States or of areas beyond national jurisdiction (Article 14).

2.4 National reporting

National reporting will be the principal mechanism for tracking the implementation of the Convention, and is fundamental to the Convention's continued development. Parties are required to make available to the Conference of the Parties (COP) periodic reports on measures they have taken to implement the Convention and the effectiveness of these measures (Article 26).

The first national reports of all Parties were due to be submitted to the COP, through the Convention Secretariat, by 1 January 1998. This deadline was extended to 31 Decem-

ber 1998 by the fourth meeting of the COP. The focus of the first national reports is on the actions taken by Parties to implement Article 6 of the Convention, in particular the development of national strategies and action plans. Many developing countries have obtained or requested financial assistance from the Global Environment Facility (GEF) for the preparation of their national strategies and action plans and their first national reports. COP 5 requested Parties to submit their next national reports by 15 May 2001 and recommended a report format. Parties were also invited to prepare detailed thematic reports on one or more of COP 6's main agenda items such as forest ecosystems, alien species and benefit-sharing (Decision V/19).

3. POTENTIAL BENEFITS

Recognising that the vast majority of the world's remaining biological diversity is found in the south, in return for undertaking conservation obligations, the Convention gives developing countries an opportunity to derive financial and technical benefits from their biological resources.

The Convention provides for scientific and technical co-operation to support the conservation and sustainable use of biological diversity, and a clearing house mechanism has been established to promote and facilitate such co-operation (Article 18). The provisions on scientific and technical co-operation provide a basis for capacity-building activities. For example, the Conference of the Parties has requested the financial mechanism to support a Global Taxonomy Initiative designed, among other things, to develop national, regional and subregional training programmes on taxonomy, and to strengthen reference collections in countries of origin.

In addition to general provisions on research and training (Article 12), the exchange of information (including, where feasible, repatriation of information) (Article 17), and scientific and technical co-operation, the Convention offers developing country Parties potential benefits in three ways:

- **Benefit-sharing** - access to the benefits resulting from the use of their genetic resources (Articles 15, 16 and 19);
- **Technology transfer** - access to and transfer of relevant technology, including biotechnology (Articles 16 and 19); and
- **Financial resources** - access to "new and additional" financial resources for eligible projects, and to bilateral assistance from developed country Parties for implementation of the Convention (Articles 20 and 21)

The extent to which these benefits actually materialise is likely to be a crucial factor in the success or failure of the Convention.

3.1 Access to genetic resources and benefit-sharing

Before the negotiation of the Convention on Biological Diversity, genetic resources were generally considered to be freely available, despite their enormous potential value. The approach taken in the Convention is, however, radically different.

Article 15 of the Convention reaffirms the sovereignty of Parties over their genetic resources, and recognises the authority of States to determine access to those resources. It is important to note that, while the Convention addresses sovereignty over resources, it does not address ownership as such (Glowka, 1994). Ownership remains to be determined at the national level, in accordance with national legislation or practice. Although the sovereign right of States over their genetic resources is emphasised, access for environmentally sound uses is to be facilitated.

Since genetic resources are no longer regarded as freely available, the Convention paves the way for new types of arrangements governing the relationship between providers and users of genetic resources. As envisaged in Article 15 of the Convention, there are three key elements to access to genetic resources:

- **prior informed consent**: the need to obtain the prior approval of the country of origin before obtaining access to resources;
- **mutually agreed terms**: the need to agree terms of access with the country of origin (and, potentially, with direct providers of genetic resources such as private owners or local communities); and
- **benefit-sharing**: the obligation to share, in a fair and equitable way, benefits arising from the use of genetic resources with the Party that provides those resources.

Each of these elements is dealt with in more detail in Chapter 2 on Access to Genetic Resources and Benefit-sharing, which considers some of the early national and regional efforts to implement Article 15.

Controlling access to resources is likely to provide the key to subsequent benefit-sharing. This is likely to involve establishing a procedure for regulating access and for granting (or denying) authorisation to potential users of resources. The practical implication of the Convention's provisions on access to genetic resources is that a potential bioprospector should seek authorisation from the government of the country of origin before it can seek and obtain such resources. Such authorisation might include minimum conditions as to the types of benefits required by the country of origin of the genetic resources. Benefits required might include: the depositing of voucher specimens with a national collection in the country of origin; the participation or training of national researchers; the transfer of screening equipment and technology; and, shares of any profits derived from the use of the resources, for example in pharmaceutical or agricultural applications.

It is generally agreed that benefit-sharing should extend not only to the government of the country of origin but also to local communities directly responsible for the conservation and sustainable use of the genetic resources in question. National legislation might require bioprospectors to agree terms with local communities for the use of resources. The agreement of terms between local communities and bioprospectors will be all the more crucial where bioprospectors are seeking to draw not only upon the resources themselves, but also upon the knowledge of local communities concerning the applications of those resources. Significant attention is being paid to this question under the Convention, focusing on ways to protect the knowledge of indigenous and local communities, and to ensure that any knowledge is used only with their prior informed consent and is appropriately compensated. This issue is addressed in more detail in chapter 3 on Intellectual Property Rights.

As outlined in chapter 2, some Pacific island countries have begun to take action to regulate access to genetic resources within their jurisdiction. In addition, in July 1999, SPREP, WWF-SPP and FIELD launched a new Darwin Initiative project on access to genetic resources and benefit-sharing in the Pacific islands region. The project intends to provide an opportunity for Pacific island countries to consider these issues in more depth at the regional level. A regional workshop on access to genetic resources and benefit-sharing was held in March 2000.

3.2 Access to and transfer of technologies

Under Article 16 of the Convention, Parties agree to provide and/or facilitate access to and the transfer to other Parties of:

- technologies relevant to the conservation of biological diversity;

- technologies relevant to the sustainable use of its components; or
- technologies that make use of genetic resources.

The provisions of the Convention on technology transfer are controversial and ambiguous. In particular, the relationship between technology transfer and intellectual property rights is extremely contentious.

Technology in the context of the Convention explicitly includes biotechnology. Technology transfer under the Convention incorporates both "traditional" technology transfer, in the sense that there is a recognition, as in the case of many multilateral environmental treaties, that developing country Parties will require the transfer of technologies to assist them to implement the Convention effectively. In addition, technologies which make use of genetic resources are subject to special provisions relating to the country of origin of the resources. The Convention makes it a specific requirement that all Parties create a legislative, administrative or policy framework with the aim that technology which makes use of genetic resources is transferred, on mutually agreed terms, to those providing those genetic resources, in particular to the developing country Parties (see Box 3). This obligation extends to technology protected by patents and other intellectual property rights. GEF funding (see section 3.3 below) may be available to assist with the costs of technology transfer, for example, where relevant technology is protected by an intellectual property right.

More generally, developing country Parties are to have access to technology under terms, which are fair and most favourable, including on concessional and preferential terms, where mutually agreed. Article 16 provides that where relevant technology is subject to an intellectual property right such as a patent, the transfer must be on terms, which recognise and are consistent with the adequate and effective protection of the property right. However, it also goes on to provide that Parties are to co-operate to ensure that intellectual property rights are supportive of and do not run counter to the objectives of the Convention. The practical effects of the apparent ambiguities in Article 16 are still unclear, and have been the subject of much discussion within the Conference of the Parties.

Box 3: Biotechnology and benefit-sharing (Article 19)

Biotechnology is defined in the Convention as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

The Convention foresees that countries of origin of genetic resources utilised in biotechnological application should share in the commercial and other benefits of those applications. Hence, all Parties are required to create a legislative, administrative or policy framework so that the providers of genetic resources, in particular developing country Parties, may:

- effectively participate in the biotechnological research which uses the genetic resources, and
- have priority access on a fair and equitable basis to the results and benefits arising from biotechnologies based on the genetic resources, on mutually agreed terms.

Some of these issues are addressed in more detail in Chapters 2 and 3 on Access to Genetic Resources and Intellectual Property Rights.

3.3 Financial resources – Global Environment Facility

All Parties to the Convention undertake to provide financial support and incentives for implementation of the Convention at the national level, in accordance with their capabilities. In addition, developed country Parties agree to make available to developing country Parties, new and additional financial resources to meet "the agreed full incremental costs" of implementing measures to fulfil their obligations under the Convention. The Convention establishes a financial mechanism to channel this assistance. De-

veloped country Parties may also provide resources related to the implementation of the Convention through bilateral channels, such as overseas development agencies. The Convention explicitly recognises that the extent to which developing country Parties will be able to implement their obligations under the Convention will depend on the developed country Parties fulfilling their obligations to provide resources. The Convention also acknowledges that economic and social development remains the overriding priority of developing countries.

In Article 20 on financial resources, the Convention explicitly recognises the special circumstances and needs of the small island developing states. Parties are to give due consideration to the dependence, distribution and location of biological diversity within developing countries, and in particular small island states.

Funding through the financial mechanism is to be provided on the basis of

- policy, strategy and programme priorities;
- eligibility criteria for access to and utilisation of financial resources; and
- an indicative list of incremental costs.

Guidance on these issues has been provided to the Global Environment Facility (GEF) (see below) by the COP. In addition, at each of its meetings to date, the COP has addressed further guidance to the GEF on national activities, which should be supported.

Global Environment Facility (GEF)

The Convention's financial mechanism is operated (formally still on an interim basis) by the Global Environment Facility. The GEF was established in 1991 as a joint initiative of the United Nations Environment Programme (UNEP), the United Nations Development Programme (UNDP) and the World Bank.

GEF resources are available for projects and activities in four focal areas:

- biodiversity;
- climate change;
- ozone depletion; and
- international waters.

These are outlined in the GEF Operational Strategy. In relation to biodiversity, the GEF functions under the authority and guidance of, and is accountable to, the Conference of the Parties to the Convention, and the Operational Strategy incorporates the guidance issued by the COP. In accordance with this guidance, the GEF Operational Strategy currently provides for three categories of activities:

- operational programmes encompassing long-term measures;
- enabling activities; and
- short-term response measures.

In relation to biodiversity, enabling activities prepare the foundation for the design and implementation of effective response measures required to achieve Convention objectives. As noted above, a number of small island states in the Pacific region have GEF enabling activities funding to assist with the development of national strategies, plans or programmes in accordance with Article 6 of the Convention, and the identification of components of biodiversity, and of activities and processes likely to have significant adverse effects pursuant to Article 7. In response to the emphasis that the COP has placed on capacity-building, the GEF adopted Guidelines for Additional Funding of Biodiversity Enabling Activities (expedited procedures) at its meeting in February 2000. This will be available for assessing capacity-building needs and defining country-specific priorities in relation to priority issues determined by the COP.

Governments may apply for GEF funds direct to any of the implementing agencies (to date UNDP has been most active in this regard in the Pacific region). The GEF Operational Strategy and other GEF documentation are available on the GEF website at http://www.gefweb.org.

4. INSTITUTIONAL ARRANGEMENTS

The Convention contains important institutional provisions that provide a mechanism for the further development of, and for monitoring the implementation of, the Convention through meetings, work programmes, reviews, and negotiations. The three key institutions are the Conference of the Parties (COP), the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), and the Secretariat. The Conference of the PartiesCOP 2 established an Ad Hoc Working Group on Biosafety to negotiate a protocol on the safe handling, transfer and use of living modified organisms. The Cartagena Protocol on Biosafety was adopted in January 2000 and opened for signature at COP 5 in May 2000. (see section 4.4 below and Chapter 4).

4.1 The Conference of the Parties

The governing body of the Convention is the Conference of the Parties (COP). Its function is to keep under review the implementation of the Convention and to steer its development. To date, there have been five meetings of the COP, the last meeting having taken place from 15 to 26 May 2000 in Nairobi, Kenya. Meetings of the COP are open to all Parties to the Convention, as well as to observers from non-Parties, intergovernmental organisations and non-governmental organisations. The next meeting of the COP will be held in 2002 in the Hague, Netherlands.

The broad scope of the Convention has meant that the COP has been required to deal with a large agenda. The COP has initiated work in a number of areas to elaborate or clarify aspects of the Convention, and has taken numerous procedural and substantive decisions, clarifying the scope of the Convention and the relationships between the Convention and other relevant institutions. At COP 5 it was decided that meetings of the COP should take place every two years.

Other important functions of the COP include adoption of the budget for the Convention, the consideration of national reports, the adoption of protocols or annexes, and the development of guidance to the financial mechanism.

4.2 Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)

Article 25 of the Convention establishes a Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to provide the COP with advice and recommendations on scientific, technical and technological aspects of the implementation of the Convention. SBSTTA is open to all Parties of the Convention. Specific functions of SBSTTA include:

- providing scientific and technical assessments of the status of biological diversity;
- preparing scientific and technical assessments of the measures taken to implement the Convention;
- identifying innovative, efficient and state of the art technologies and know how, and advising on how to promote their development;
- providing advice on scientific programmes and international co-operation in research and development; and
- generally responding to scientific, technical, and technological and methodological questions asked by the COP.

To date, SBSTTA has held five meetings. After COP 5, SBSTTA will meet every year.

4.3 The Secretariat and the Clearing House Mechanism

The Secretariat provides administrative support to the COP, SBSTTA and other Convention bodies. It represents the day-to-day focal point of the Convention, organises and services all meetings under the Convention and provides background documentation for those meetings. The Secretariat plays a significant role in co-ordinating the work carried out under the Convention with that of other relevant institutions and conventions, and represents the Convention at meetings of other relevant bodies.

The Parties to the Convention have established a Trust Fund to meet the costs of administering the Convention, including the costs of the Secretariat. The Trust Fund is administered by UNEP. All Parties contribute to the budget of the Convention. The financial rules governing contributions to the Trust Fund have yet to be been finally agreed upon by the Parties but, in practice, contributions are weighted in accordance with the UN scale of assessments. Contributions of Parties to the Trust Fund for the 2001/2002 biennium were determined in Decision V/22 of the COP.

The Secretariat administers the Convention's Clearing House Mechanism, established under Article 18(3) as a principal means of scientific and technical cooperation http://www.biodiv.org/chm/.

4.4 The 2000 Cartagena Protocol on Biosafety

Advances in biotechnology now mean that genes carrying specific characteristics (such as pest resistance) can be isolated and transferred between species, even between plant and animal species. Organisms created in this way are referred to as 'genetically modified organisms' or 'genetically engineered organisms', and in the Convention, as 'living modified organisms'. However, while the potential benefits of biotechnology are manifest, at the same time much uncertainty remains about its potential adverse impacts on biodiversity through, for example, possible impacts on non-target species.

Article 19 required the Conference of the Parties to the Convention to consider the need for a Protocol setting out appropriate procedures for the safe transfer, handling and use of living (genetically) modified organisms (LMOs). At its meeting in 1995, the Conference of the Parties decided to establish an Ad Hoc Working Group on Biosafety to elaborate a protocol on biosafety (i.e. safety in biotechnology). This working group was due to complete its negotiations in February 1999. An Extraordinary Meeting of the COP was held in Cartagena, Colombia in February 1999 to adopt the Protocol on Biosafety. However, the Parties failed to reach agreement on the text of the Protocol. Resumed negotiations in Montreal led to the adoption of the Biosafety Protocol in January 2000, and the Protocol was opened for signature in May 2000.

The focus of the Protocol is on the transboundary movement of LMOs, resulting from modern biotechnology, which may have an adverse impact on the conservation and sustainable use of biological diversity. The core elements of the Protocol are an advanced informed agreement procedure for transboundary transfers of LMOs, risk assessment and risk management. For further information on LMOs and the Biosafety Protocol, see Chapter 4.

4.5 Financial mechanism

The financial mechanism is a key component of the Convention's institutional structure. It has been considered briefly above at section 3.3.

4.6 Participation in Convention meetings

In order to promote broad participation, developing country Parties are able to obtain financial assistance to meet their costs of participating in the meetings of the Conference of the Parties, SBSTTA and the Biosafety Working Group, as well as regional preparatory meetings. This assistance is funded through voluntary contributions by the Parties. Priority is given to least developed countries and small island developing states. However, so far, this assistance has been severely limited, such that funding has not been available to support the attendance of delegates from all developing country Parties at meetings organised under the auspices of the Convention.

Consistent with the United Nations practice, the Convention recognises the following regional groupings: African Group, Asian Group, Central and Eastern European Group, Latin America and the Caribbean Group, and Western Europe and Other Group. Pacific islands countries are part of the Asian Group.

5. LINKAGES AND COOPERATION WITH OTHER INSTITUTIONS

The scope of the Convention means that its effective implementation will require co-operation and co-ordination with a wide range of other conventions, institutions and processes. These include the traditional biodiversity-related conventions, such as the Convention on International Trade in Endangered Species (CITES), Ramsar Convention on Wetlands of International Importance and the World Heritage Convention; other environmental conventions such as those addressing climate change and desertification; and, more broadly, international agreements and instruments dealing with issues such as trade and intellectual property rights. A number of existing regional agreements will also be of relevance to implementation of the Convention: these include the 1976 Apia Convention, the Noumea (SPREP) Convention, and the agreement establishing the Forum Fisheries Agency.

Coordination will also be a key to national level implementation, in order to:

- achieve synergies between measures taken to implement more than one Convention (e.g. the various biodiversity-related or conservation agreements; or the Biodiversity and Climate Change Conventions); and
- integrate biodiversity considerations into other sectors, as required under Article 6(b) of the Convention.

These issues are considered in more detail in chapter 5 on National level Co-ordination of Implementation of the Convention.

6. INTERNATIONAL DEVELOPMENTS

The fifth meeting of the COP took place in Nairobi, Kenya, from 15 to 26 May 2000. This section briefly highlights some of the issues that were considered, and some of the decisions taken at COP 5.

6.1 Traditional knowledge of indigenous and local communities

Article 8(j) of the Convention is important to all three of the Convention's objectives. The Convention recognises the important role of indigenous and local communities in the conservation and sustainable use of biological diversity. It also recognises the entitlement of indigenous and local communities to receive a share of the commercial or other benefits derived by others from their ideas and innovations, or from genetic resources under their control or stewardship. Indigenous and local communities participate actively in the deliberations of the Conference of the Parties to the Convention.

COP 3 initiated an intersessional process to consider ways and means to implement the provisions of the Convention on indigenous and local communities. As part of this process a Workshop on Traditional Knowledge was convened in November 1997 in Madrid, Spain. COP 4 decided to establish an ad hoc, open-ended intersessional working group to address the implementation of Article 8(j) and related provisions of the Convention. The working group's mandate is, amongst other matters, to advise on how best to ensure the protection of the knowledge, innovations and practices of indigenous and local communities, and to advise the COP on how to implement Article 8(j) at the national level. The first meeting of the Ad Hoc Working Group on Article 8(j) was held in March, 2000 in Seville, Spain. The working group developed a programme of work based on the elements and recommendations made at the Madrid meeting in November 1997 (Decision IV/9).

In Decision V/16, COP 5 prioritised and endorsed the working group's work programme. The first phase of the work programme will address participatory mechanisms, status and trends, benefit-sharing, exchange and dissemination of information, monitoring and legal elements. Tasks in the second phase include participatory mechanisms, traditional cultural practices for conservation and sustainable use, exchange and dissemination of information, and monitoring elements. Decision V/16 further extended the working group's mandate to address progress in implementation and increased participation of indigenous and local communities in the thematic work programmes. The Ad Hoc Open-ended Inter-sessional Working Group on Article 8(j) and Related Provisions will report again to COP 6.

6.2 Thematic work programmes

COP 5 also considered its future work programmes in four ecosystems addressed by the Parties so far:

6.2.1 Marine and coastal biological diversity

COP 2 addressed the issue of marine and coastal biological diversity at its meeting in Jakarta in 1995. The COP mandated further work on the issue, and the development of a three year work programme. Specifically, a meeting of experts was mandated to assist the Secretariat in drawing up a draft programme of work, in accordance with priorities identified by the COP (Decision II/10). The meeting of experts was not held until March 1997, in Indonesia. It produced a draft work programme that was discussed by the SBSTTA at its meeting in September 1997. The draft work programme was further discussed at COP 4, which eventually adopted a work programme for the implementation of the Jakarta Mandate on marine and coastal biological diversity. COP 4 made specific reference to the unique and fragile marine and coastal environment of small island states, and strongly recommended to Parties, relevant organisations and donor agents that the special needs of such states be a focus for implementing each of the elements of the work programme (Decision IV/5).

Five programme areas were identified:

- integrated marine and coastal area management;
- marine and coastal protected areas;
- sustainable use of coastal and marine living resources (including coral reefs);
- mariculture; and
- alien species.

In Decision V/3, COP 5 urged the Secretariat and SBSTTA to complete the implementation of the work programme on Marine and Coastal biodiversity. The COP specifically addressed the issues of coral bleaching and requested the Secretariat to develop and implement a specific work plan on coral bleaching. On marine and coastal living

resources, Decision V/3 requests the Secretariat to gather and disseminate information on local and indigenous communities' management approaches. COP 5 also established ad hoc technical expert groups on marine and coastal protected areas, and on mariculture.

6.2.2 Forest biological diversity

The issue of forest biological diversity has been among the most controversial on the agenda of the COP. Much debate has focused on whether the Convention should take action on forests, or whether this should be left to the institutions established under the Commission on Sustainable Development. COP 4 adopted a work programme on forest biodiversity (Decision IV/7) whose main elements are:

- holistic and inter-sectoral ecosystem approaches
- comprehensive analysis of impacts of forest-management practices on biological diversity
- methodologies to elaborate and implement criteria and indicators for forest biodiversity
- further research and technological priorities

COP 5 urged implementation of the work programme and considered expanding its focus from research to practical action at COP 6. The COP requested SBSTTA to report to COP 6 on the impact of climate change on forest biodiversity, and to consider the causes and effects of forest fires and the impact of harvesting non-timber forest products. It also urged Parties to consider the proposals for action of the Intergovernmental Panel on Forests (IPF) and Intergovernmental Forum on Forests (IFF) and established an ad hoc technical expert group to assist SBSTTA in its work on forest biological diversity (Decision V/4). Forest biodiversity will be one of the priority issues at COP 6.

6.2.3 Agricultural biological diversity

Agricultural biological diversity was considered in detail at SBSTTA 2 and at COP 3. COP 3 adopted a decision for a multi-year programme of work on agricultural biological diversity, in co-operation with the Food and Agriculture Organisation. Progress made in elaborating this programme was reviewed at COP 4, which recommended further activities to speed up implementation of the work programme (Decision IV/6). COP 5 reviewed implementation of phase I of the programme of work and adopted a multi-year work programme. In particular, Decision V/5 establishes an international initiative to monitor the decline of pollinators and promote their conservation and sustainable use. Integration of Genetic Use Restriction Technologies (GURTs, often referred to as 'terminator technology') into each element of the work programme is also urged. The COP further requested the Secretariat to prepare a report on GURTs' potential impacts on indigenous and local communities, and on farmers' rights.

6.2.4 Inland water biodiversity

Inland water (freshwater) biological diversity was the ecosystem focus of COP 4. SBSTTA 3 adopted a set of recommendations on inland water biological diversity with proposals for further work under SBSTTA. COP 4 adopted a work programme on the biological diversity of inland water ecosystems. The COP requested SBSTTA to co-operate immediately with small island states to develop regional guidelines on assessment methodologies for inland water biological diversity.

COP 5 endorsed the joint work plan with the Ramsar Convention and urged implementation of capacity-building measures for assessments, monitoring of implementation, information-gathering and dissemination.

6.3 Review of operations of the Convention

It has been widely acknowledged that progress to date by the Conference of the Parties has been slow, and that this was in part due to the COP's heavy agenda. It was thus

considered necessary to undertake a review of the operations of the Convention. Having done so, COP 4 decided that an open-ended inter-sessional meeting should be held before the next COP specifically to discuss what arrangements could be made to improve the workings of the meetings of the COP. This meeting was held in June 1999. Among other things, the inter-sessional meeting recognised that regional level activities have an important role to play in preparing for Convention meetings, and called on Parties to facilitate such regional level activities, in particular for small island developing states. The inter-sessional meeting also recommended the development of a strategic plan, and discussed how to improve the implementation of the Convention. In addition to discussing the operations of the Convention, the meeting also served as a forum for an initial preparatory discussion on the issue of access to genetic resources and benefit-sharing. The recommendations of the inter-sessional meeting were considered by COP 5, where it was decided that there will be another open-ended inter-sessional meeting before COP 6.

COP 5 decided that a Strategic Plan for the Convention should be prepared. This will be considered and adopted at COP 6. The Strategic Plan will initially cover the period 2002-2010 and will provide strategic and operational guidance for the implementation of the longer-term work programmes (Decision V/20).

6.4 Review of effectiveness of the financial mechanism

In accordance with Article 21(3) of the Convention, COP 4 reviewed the effectiveness of the financial mechanism to date. COP 4 identified a number of actions to be taken by the Global Environment Facility (GEF) to improve its effectiveness, including making project preparation simpler, more transparent and more country-driven. The GEF reported on such activities to COP 5, which also determined the objectives, methodology, criteria and procedures for the second review of the effectiveness of the financial mechanism. The review will be conducted by an independent evaluator, on the basis of information submitted by the Parties.

6.5 National reports

COP 4 addressed the content and timing of second national reports. It requested the Secretariat to further elaborate a note it had prepared for COP 3 on the form and intervals of national reports. It also requested SBSTTA to consider the note and to provide COP 5 with advice on the intervals and form of future national reports (Decision IV/14). COP 5 endorsed a recommended format for future national reports and requested Parties to submit their next reports by 15 May 2001 (Decision V/19).

6.6 Access to Genetic Resources and Benefit-sharing

COP 4 decided to establish a panel of experts to develop a common understanding of basic concepts, and to explore all options for access and benefit-sharing on mutually agreed terms, including guiding principles, guidelines and codes of best practice for access and benefit-sharing arrangements (Decision IV/8). The first meeting of the Expert Panel on access to genetic resources and benefit-sharing took place from 4-8 October 1999 in Costa Rica. The Panel's final report addresses a range of issues for further consideration by COP 5 (see Chapter 2).

COP 5 decided to reconvene the Experts Panel for a further meeting to address outstanding issues. The Panel will submit its report to a new Ad Hoc Open-ended Working Group on Access and Benefit-sharing, which has the mandate to develop guidelines and other approaches for submission to the COP.

COP 4 also requested the financial mechanism of the Convention to provide funding for, among other activities, formulating access and benefit-sharing mechanisms at the national, sub-regional and regional levels. Decision V/13 on further guidance to the GEF, adopted at COP 5, also recommended that the GEF should support projects addressing access to genetic resources and benefit-sharing.

6.7 Alien species

COP 5 adopted interim guiding principles for the prevention, introduction and mitigation of impacts of alien species, and urged Parties to apply them. The COP further urged Parties to give priority to the development and implementation of alien invasive species strategies and action plans. It is envisaged that COP 6 will consider options for the implementation of Article 8(h) on the Conservation of Alien Species, including the possibility of further developing the guidelines, an international instrument, and other options (Decision V/8).

6.8 Sustainable use

Sustainable use (Article 10) was one of the priority issues for review at COP 5. The COP invited Parties to increase their capacity to implement sustainable use practices, programmes and policies at regional, national and local levels, especially in pursuit of poverty alleviation, through workshops, priority action plans, information dissemination and technology transfer. The Secretariat was requested to initiate relevant work on sustainable use and to assemble principles, operational guidelines and associated instruments (Decision V/24).

COP 5 also specifically addressed the question of sustainable tourism (Decision V/25).

6.9 Public education and awareness

COP 4 decided that public education and awareness should be an integral component of all sectoral and thematic items under the COP's programme of work. It called for relevant organisations to undertake a number of activities to promote such education and awareness. The COP will review progress on these activities at its seventh meeting at the latest (Decision IV/10). COP 5 requested the Secretariat to advance and identify priority activities for the global initiative on biodiversity education and public awareness.

7. FUTURE PROGRAMME OF WORK OF THE COP

COP 4 adopted a programme of work to be addressed at the fifth, sixth and seventh COP meetings. According to this, the issues to be addressed in depth at the next two COP meetings are:

COP 6	forest ecosystems
	alien species
	benefit-sharing
COP 7	mountain ecosystems
	protected areas
	transfer of technology and technology cooperation

Sources of Information

There are many sources of information about the Convention. These include printed materials and world-wide web-sites.The principal source of information about the Convention is the Convention Secretariat, which is located in Montreal, and the Conven-

tion's Clearing House Mechanism (administered by the Secretariat). The Secretariat can be contacted at:

World Trade Centre
Suite 300
393 Saint-Jacques Street
Montreal
Quebec
Canada H2Y 1N9
Tel: 1 514 288 2220
Fax: 1 514 288 6588
e-mail: chm@biodiv.org

The Secretariat's web-site is at http://www.biodiv.org, and includes information on upcoming meetings (including official documentation), as well as background information and links to other useful sources. It is also linked to the Convention's Clearing House Mechanism (http://www.biodiv.org/chm), which is envisaged as a mechanism for information exchange and scientific and technical co-operation among the Parties. National reports of Parties are also being made available on the web-site. In addition, the CHM website provides a link to a searchable database of all COP decisions to date.

A basic (and by no means comprehensive) list of sources and references is provided at the end of this Chapter. This also includes a preliminary list of other useful web-sites.

The Secretariat has prepared a Draft Handbook on the Convention. This contains the text of the Convention and the 2000 Cartagena Protocol on Biosafety, all decisions adopted by the COP to date, and a reference guide to COP decisions. The Handbook was distributed at COP 5 in a draft form and is also available on the CBD website. It will be updated shortly with COP 5 Decisions.

Sources and Selected References

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Global Environment Facility

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National Planning

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Biosafety

UNEP International Technical Guidelines for Safety in Biotechnology, UNEP, 1996.

South Pacific Islands Region

Report of the Global Conference on the Sustainable Development of Small Island Developing States, Bridgetown, Barbados, 25 April - 6 May 1994, UNEP, 1994.

Declaration by the Ministers of the Alliance of Small Island States (AOSIS) at the First Conference of the Parties to the United Nations Convention on Biological Diversity, Nassau, The Bahamas, 8 December 1994, UNEP, 1994.

Action Plan for Managing the Environment of the South Pacific Region, 1997–2000.

Action Strategy for Nature Conservation in the Pacific Islands Region, 1999 - 2002.

Report of the Biodiversity and Climate Change Forum for Small Island Developing States, Foundation for International Environmental Law and Development (FIELD), 1994.

Yamin, F., Small Island Developing States and the Convention on Biological Diversity: Obligations and Opportunities, FIELD, 1994.

Useful Websites

International Organisations/Agreements

http://www.biodiv.org	Convention on Biological Diversity
http://www.fao.org	UN Food and Agriculture Organization
http://www.gefweb.org	Global Environment Facility
http://www.iucn.org	IUCN-World Conservation Union
http://www.unep.ch	UN Environment Programme: for Basel Convention on Transboundary Movement of Hazardous Wastes; Biodiversity Convention; CITES; Bonn Convention on Migratory Species; Montreal Protocol; Climate Change Convention; Desertification Convention
http://www.unesco.org/whc	UNESCO World Heritage Convention
http://www.unicc.org/unctad	UNCTAD
http://www.wcmc.org.uk	World Conservation Monitoring Centre
http://www.wipo.int	World Intellectual Property Organization
http://www.wto.org	World Trade Organization
http://www.undp.org.fj	UNDP, Suva Office
http://www.undp.org.ws	UNDP, Apia Office
http://www.undp.org.pg	UNDP, Papua New Guinea
http://www.undp.org/bpsp	UNDP, Biodiversity Planning Support Programme

Regional Organisations

http://www.forumsec.org.fj	Pacific Islands Forum Secretariat
http://www.spc.org.nc	Secretariat of the Pacific Community
http://www.sidsnet.org	Small Island Developing States Network (SIDSnet) internet site
http://www.sprep.org.ws	South Pacific Regional Environment Programme (SPREP)

Regional NGOs

http://www.pcrc.org.fj	Pacific Concerns Resource Centre
http://www.wwfpacific.org.fj	WWF South Pacific Programme

Other NGOs and information sources

http://www.iisd.ca/linkages	Information on recent negotiations under the Commission on Sustainable Development; Framework Convention on Climate Change; Convention on Biological Diversity; Desertification Convention; FAO.
http://www.panda.org	World Wide Fund for Nature
http://www.twnside.org.sg	Third World Network
http://www.bcnet.org	Biodiversity Conservation Network

2 ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

This chapter provides an overview of the provisions of the Convention on Biological Diversity on access to genetic resources and the sharing of benefits arising from their use. It draws on early national and regional efforts to implement Article 15 and related provisions, and outlines some of the substantive and institutional considerations in the development of a regional or national framework for access to genetic resources and benefit-sharing.

Further information relevant to this Chapter is contained in Annexes 1-6.

1. INTRODUCTION

Biodiversity prospecting or "bioprospecting" is the systematic collection, extraction and screening of samples of biological resources for potential use in pharmaceutical, agricultural and other industrial applications. Bioprospecting creates possibilities to develop new products for global markets. urgent conservation measures. Coastal and marine biodiversity are of particular significance.interest and concern to small island developing states.

The rich terrestrial, coastal and marine biodiversity of the Pacific region has already attracted bioprospectors looking for new sources of biochemical compounds, genes, proteins, micro-organisms and other products from nature. In a few cases, partnership agreements between the source country and the users of the biological resources have been negotiated, either for research purposes or for use in product development. Such agreements, known as access agreements or Material Transfer Agreements (MTAs) set out the terms under which any transfer of biological resources is to take place, including making provisions for the source country to share in any benefits derived from the utilisation of the resource.

An example of a bioprospecting arrangement in the Pacific region is the agreement between the University of the South Pacific (USP) and the Strathclyde Institute of Drug Research (SIDR), in Scotland, United Kingdom, to provide samples of biological resources collected from the Verata Tikina Community in Fiji (see Box 1 below).

In many cases, however, biological resources have been removed from the source country without that country's knowledge and consent. In some cases, this has been followed by the commercialisation of products derived from the resources collected.

The Convention on Biological Diversity introduced a new international approach to regulating access to biological resources by specifically linking access to genetic resources with the sharing of benefits arising from their utilisation. This approach is based on the principle that states have sovereignty over their genetic resources and, as a result, have the right to control access to those resources and to receive a fair share of the benefits derived from their use. So far, only a few countries and regions have taken steps to implement the Convention's provision on access to genetic resources and benefit-sharing. However, a growing number of countries are now taking steps to address this issue.

Regulating access to genetic resources could assist Pacific island countries to ensure that they receive a fair share of any benefits derived from products developed using those resources. The provisions on access to genetic resources and benefit-sharing in the Convention on Biological Diversity address this situation. These are contained principally in Articles 15, 16 and 19 of the Convention.

Box 1: Example of a bioprospecting agreement

A bioprospecting agreement between the University of the South Pacific (USP) and the Strathclyde Institute of Drug Research (SIDR) covers the collection and extraction of samples of biological resources from the Verata Tikina Community in Fiji. The Verata Community is not a partner in the USP/SIDR agreement, but access and benefit-sharing is provided through a separate agreement between USP and the Community. The samples are screened by USP and the extracts licensed to SIDR for use by commercial entities involved in drug development under separate agreements between SIDR and the commercial entity. The samples are merely licensed to SIDR. USP can request the return of unused samples after the licensing period of one year.

Under the same USP/SIDR agreement USP is to receive 60 per cent of the funds obtained from the licensing of samples. USP is to pass this financial benefit on to the Verata Community. All the costs to USP of collecting and processing the extracts are met by funds from the Biodiversity Conservation Network (BCN) – a United States Agency for International Development-funded project.

The arrangement foresees the possibility of further negotiations on royalties should commercial products be developed. However, the Verata Community has no say as to whether or not a product can be developed commercially. The terms of the USP/SIDR agreement are consistent with the terms SIDR agrees with the commercial entities it contracts with, including a right of commercial development.

Further information on the SIDR/USP/Verata bioprospecting arrangement can be found in Annex 2.

Source: Personal communication, Aalsberberg, W.G., University of the South Pacific, Fiji.

Concerns about the development and commercialisation of products derived from biological resources taken from the Pacific region led to a Regional Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, held in April 1995 in Suva, Fiji. The participants in this consultation called for a moratorium on bioprospecting in the Pacific. They also urged indigenous peoples not to cooperate in bioprospecting activities until appropriate protection mechanisms were in place.

Box 2: Kava

Because of its relaxant and therapeutic properties, pharmaceutical and health food companies have for some time turned their attention to the potentially valuable products which they can develop using the Kava plant (Piper mythesticum). Today, Kava is widely used in Germany where a high quality extract was first pioneered by German researchers. Kava is also sold and used in other European countries and the United States.

Two issues have been of concern to Kava's source-countries in the Pacific.

1. Intellectual property claims by multi-national companies
   A number of multi-national companies in Europe and the US have taken out patents on Kava extracts and active compounds and have also trademarked (see Chapter 3) a number of terms similar to Kava. However, it does not appear that any benefits have been received by Pacific Island countries directly from the commercialisation of products derived from Kava.

2. The development of overseas Kava plantations
   In his opening speech to the first Expert Group consultation on the Production and Marketing of Kava in the Pacific Islands, held in Suva from 3-5 March 1997, the Permanent Secretary for Rural Infrastructure, Fiji, noted the real threat to the Pacific Islands kava industry of new entrants to the market from non-traditional kava-growing countries. He highlighted some recent developments of particular concern, including the establishment of commercial kava plantations in Hawaii, reports of attempts by European and American interests to grow kava on a large scale in South-East Asia, Mexico and Latin America, and a report that Australian interests have obtained permission to import Kava cultivars to grow it on a large scale in Australia.

Partially to address this situation the Suva Expert Group recommended, among other things, that the Forum Secretariat and the South Pacific Commission should address the intellectual property rights (IPR) issue of Kava, including by use of trademarks (see further Chapter 3 on Intellectual Property Rights and Biological Diversity).

At a symposium on kava, organised by the Forum Secretariat from 26-28 October 1998, participants once again discussed the use of IPRs to protect and promote the kava industry. It was recommended that genetic fingerprinting be used as a method to identify and distinguish Kava genotypes. Genetic finger printing was suggested as a way of establishing the origin of any given sample of kava so that authenticity for the purposes of geographical indication could be established. Hence each Pacific island, or community within an island, could market its unique blend of kava.

Source: Forum Secretariat, in co-operation with the Secretariat of the Pacific Community, the University of the South Pacific and the Centre for Development of Industry (Brussels), Kava Symposium, 26-28 October 1998, Suva, Fiji.

2. THE CONVENTION ON BIOLOGICAL DIVERSITY: BACKGROUND AND RELEVANT PROVISIONS

Article 15 on access to genetic resources, supplemented principally by provisions of Articles 16 (Technology transfer) and 19 (Handling of biotechnology), provide a basis to regulate access to genetic resources. National measures implementing those provisions will also need to be consistent with other relevant obligations in the Convention, such as those found in Article 8(j) (traditional knowledge, innovations and practices); Article 10(b) (measures to avoid or minimise impacts on biological diversity from the use of biological resources); and Article 10(c) (protect and encourage customary use).

Box 3: Defining "genetic resources"

Article 2 of the Convention provides a definition of genetic resources:

Genetic resources means genetic material of actual or potential value.

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

The prevailing view is that the term 'functional units of heredity' spans whole organisms, parts of organisms or biochemical extracts of tissue samples containing DNA and RNA. In other words, the Convention's provisions on access and benefit-sharing pertain to activities which make use of organisms' genetic attributes, including applications making use of genes or of metabolic compounds. 'Non-genetic' uses, such as timber extraction or ecotourism, are not regarded as falling within the Convention's definition.

Early examples of access legislation have attempted to resolve this ambiguity. For example, the Andean Pact's Common System on Access to Genetic Resources (see Annex 1) governs access to genetic resources contained in biological resources but not the movement of biological resources for other purposes.

Source: K. ten Kate, and S. A. Laird, The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing, Earthscan, 1999.

2.1 Scope of application

The Convention's provisions on access to genetic resources do not apply to:

- human genetic resources: while technically these would appear to be within the Convention's definition of "*genetic resources*", at its second meeting the Conference of the Parties confirmed that human genetic resources are not covered by Article 15;
- genetic resources located beyond the limits of national jurisdiction, such as in the high seas; and
- *ex-situ* genetic resources collected before the Convention entered into force (Article 15(3)): this means that, subject to national regulation and the policy of the *ex-situ* collection itself, a user may obtain access to genetic resources in ex-situ collections (e.g., gene banks and botanical gardens) without the obligation to share any benefits with the country of origin of those resources (see Box 9);

Marine genetic resources subject to a country's national jurisdiction, i.e., internal waters, territorial seas and the exclusive economic zone are subject to the principles and obligations of the Convention, provided these are consistent with the rights and obligations of States under the law of the sea (Article 22).

2.2 Historical Context

The Convention defines a new relationship between the users and the providers of genetic resources. Prior to its adoption, there was no international legal instrument that specifically linked access to genetic resources with the right to share in the benefits derived from the use of such resources. As a consequence, developing countries generally did not receive many, if any, of the economic benefits derived from products developed by companies using genetic resources originating from developing countries.

It was this situation which led many developing countries to argue, during the negotiation of the Convention, for a more equitable system that would redefine the benefit flows from the use of genetic resources. They also argued that the principle that States have sovereignty over their natural resources should apply equally to genetic resources.

2.3 Relationship with technology transfer and intellectual property rights

The Convention requires the Parties to provide and/or facilitate access to technologies and "know-how" that are relevant to the conservation and sustainable use of biological diversity, or which make use of genetic resources. In addition, Article 19 requires Parties to ensure the participation of the provider of genetic resources in biotechnological research activities utilising those resources (see Section 3.3 below). Controlling access to genetic resources through benefit-sharing arrangements provides one vehicle for implementing the Convention's requirements on access to and transfer of technologies (Article 16).

Chapter 3 on Intellectual Property Rights (IPRs) considers, among other issues, the role of IPRs in promoting the sharing of benefits arising out of the use of genetic resources.

2.4 Sovereignty over natural resources

The principle that States have the sovereign right to exploit their own natural resources is expressed both in the Preamble and Article 3 of the Convention. The reference to natural resources includes genetic resources. Article 15(1) provides:

Recognising the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Article 15 thus recognises that national governments have the authority to determine access to genetic resources, which is to be subject to national legislation. Despite the reaffirmation of a State's right to exercise jurisdiction over its genetic resources, Article 15 does not address the issue of ownership of those resources (Glowka, 1994) i.e. whether they are, or can be, owned by the private sector, indigenous peoples or the national government. This matter will need to be determined by national law.

3. CORE ELEMENTS OF ARTICLE 15

This section looks in more detail at the Convention's provisions on access to genetic resources and benefit-sharing. Section 4 outlines issues to be considered in the national implementation of these provisions.

The Convention sets out a number of key elements for access to genetic resources. These include the requirements to:

- obtain the prior informed consent of the Party providing the resources;
- negotiate a fair agreement on mutually agreed terms;
- agree on the sharing of the benefits arising from the use of the resources, including the participation of the provider in scientific research utilising the resources; and
- seek to ensure that the resources will be put to environmentally sound uses.

3.1 Prior informed consent (PIC)

The Convention makes access conditional on the prior informed consent (PIC) of the Party providing the genetic resources, unless that Party determines otherwise. The Convention makes PIC the rule by providing that any access will be subject to PIC "unless otherwise determined by that Party" (Article 15(5)). Although there is no legal obligation on Parties to establish a PIC procedure, the establishment of such a procedure is likely to assist countries to control access to genetic resources and to negotiate the terms of a fair benefit-sharing arrangement.

PIC is generally identified as meaning the following:

- 'prior' - an entity seeking access to genetic resources will need to obtain the consent of the providing Party before collecting or otherwise receiving any genetic resources, in accordance with the established procedure;
- 'informed' - based on truthful information provided by the applicant concerning, for example, the nature of the proposed bioprospecting activities and the potential uses of the genetic resources sought. The information must be sufficient for the designated national authority to understand the implications and to decide whether to grant or deny authorisation; and
- 'consent' - with the explicit agreement of the providing Party's designated national authority (see section 4.6), and, depending on national access laws, other stakeholders.

The designation of a national authority empowered to inform access-seekers of PIC procedures might help to 'facilitate' access for environmentally sound uses (Article 15.2).

3.2 Mutually agreed terms (MATs)

The Convention specifies that any access to genetic resources, where granted, should be on "mutually agreed terms" (MATs). Implicit in this requirement is the expectation of a negotiation, perhaps as part of a PIC procedure, between the user of the genetic resources resources (e.g., an individual, company or research institution), and the designated national authority of the provider State and/or other stakeholders (e.g., a research institution, a community or a private landowner), as recognised by the provider State's laws. The negotiations may then lead to the conclusion of an access agreement. The agreement would define the terms and conditions of the access arrangement, including how any benefits are to be shared.

3.3 Benefit-sharing

The fair and equitable sharing of benefits derived from the utilisation of genetic resources is one of the three objectives stipulated in Article 1 of the Convention. Specific measures to achieve benefit-sharing are expected to be formulated at the national level. Article 15 provides that:

> *[E]ach Contracting Party shall take legislative, administrative or policy measures... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources... (Emphasis added).*

Thus the benefits to be shared, pursuant to Article 15, are:

- research and development results; and
- commercial or other benefits derived from the utilisation of the genetic resources provided.

In addition, the Convention refers to other potential benefits to be shared with the country of origin of genetic resources, such as:

- participation in all scientific research (Article 15(6)) and biotechnological research activities (Article 19(1)) which are based on the genetic resources;
- access to and transfer of technology using genetic resources (Article 16(3)); and
- priority access to the results and benefits arising from biotechnological use of the genetic resources (Article 19(2)).

The Convention encourages the involvement of the providers of genetic resources in any research undertaken using the genetic resources (Articles 15(6), 18 and 19). The intention here is to build the scientific research capacity of the providing State through, for example, undertaking joint research programmes and projects with the user.

The Convention also requires the Parties to "provide and/or facilitate access for and transfer to" other Parties of technologies that:

- are relevant to the conservation and sustainable use of biological diversity; or
- make use of genetic resources.

Any such access or transfer of technology to developing countries is to be provided and/or facilitated "under fair and most favourable terms... where mutually agreed".

3.4 Environmentally sound uses

The Convention requires Parties to create the conditions to facilitate access to genetic resources for "environmentally sound uses" by other Parties (Article 15.2). What constitutes such use is left to the discretion of the Party providing the genetic resources. In order to make this determination, the provider Party will need information on the potential uses to which the genetic resources will be put.

4. IMPLEMENTATION OF ARTICLE 15 AND RELATED PROVISIONS

4.1 Examples of regional and national approaches to access frameworks

4.1.1 Legislative Frameworks

Since the entry into force of the Convention, a number of access frameworks have been developed at the regional and national levels. Information on some of these initiatives is included in Annex 1. An example of a regional legislative initiative is that adopted by the Andean Pact member countries of Bolivia, Colombia, Ecuador, Peru and Venezuela on 17 July 1996. This is described in more detail in Annex 1.

An example of national access legislation, the first of its kind, is the Philippines Executive Order No. 247 - Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes; and for other Purposes (from 1995). This is described in more detail in Annex 1.

In Fiji, draft access and benefit-sharing provisions were developed originally within the framework of the Sustainable Development Bill. Consideration is currently being given as to how these draft provisions should be enacted.

Samoa has also developed draft regulations on access to genetic resources which are expected to be appended to, and be under the authority of, the Lands and Environment Act 1989 (see Annex 1). In the meantime, interim guidelines were adopted in April 2000.

Other countries have begun to implement Article 15 of the Convention in a variety of ways (Glowka,1998), such as by:

- Introducing specific, stand-alone legislation with detailed provisions on access and benefit-sharing – either as a purely national initiative (e.g. Philippines) or as part of a common regional framework (e.g. the Andean Pact) (see Annex 1).
- Including provisions on access to genetic resources within legislation designed to implement a much broader set of objectives (relating to sustainable development, nature conservation or biodiversity (e.g. Costa Rica's 1998 Law on Biodiversity (see Annex 1)).
- Including enabling provisions within general environmental framework laws – such provisions may require designated institutions to develop specific access and benefit-sharing regulations.

- Modifying existing sectoral laws in order to incorporate access provisions – for example, adapting regulations governing national parks or forests (e.g., the forest ordinance of Sarawak State, Malaysia, was amended to control access to the genetic resources of trees).
- Taking measures intended primarily for other purposes but touching on access and benefit-sharing, e.g., the use of permits to control the export of endangered species pursuant the Convention on the International Trade in Endangered Species (CITES).

4.1.2 Contractual arrangements

The negotiation of bioprospecting contracts is likely to be central to many access frameworks, and has been undertaken even in countries where access legislation does not yet exist (see, for example, Box 1 above and Annex 2). Such contracts spell out the terms that will apply to specific samples of biological material and, when appropriately drawn up and implemented, could meet many of the requirements on access and benefit-sharing provided for in the Convention. Some of the issues and considerations which arise in relation to such agreements are outlined in section 4.7 below (Negotiating mutually agreed terms (MATs) for benefit-sharing). Some examples of existing arrangements, concluded outside of national access laws in the countries involved, are summarised in Annex 2. Where contractual access arrangements are entered into outside a national legislative framework, in order to secure appropriate benefit-sharing terms, it is still essential that the source country is fully informed beforehand as to the nature of the collection activities and intended uses of the resources. It is also important that resource holders and other stakeholders are informed and consulted before any collection activities take place.

The ability to screen samples for useful characteristics in the source country, as is done by USP in the context of the USP/Strathclyde Institute/Verata arrangement (Box 1), potentially adds further value to genetic resources and strengthens the Provider country's negotiating position.

Box 4: The Merck/INBio bioprospecting arrangement

This much publicised bioprospecting arrangement, first signed in November 1991 (prior to the adoption of the Convention on Biological Diversity) concerns an ongoing relationship between suppliers and users of genetic resources. The partnership involves Merck, a pharmaceutical company based in the US, and National Biodiversity Institute (InBio), a non-government, non-profit, scientific research institute based in Costa Rica. INBio operates under an agreement with the Ministry of Environment and Energy (MINAE), conferring it rights and obligations to use Costa Rican national parks and conservation areas. In addition to working more generally on issues relevant to the conservation and sustainable use of biodiversity, INBio enters into bioprospecting partnerships with research, academic and commercial entities, the first such partnership being with Merck.

Some of the main terms of the Merck/INBio agreement were as follows:

- the provision of approximately 2000 samples to Merck over the first two year period;
- initial payment by Merck of US$1,135,000 to be used for conservation, equipment, training and taxonomy. Of that amount, US$ 130,000 - 180,000 was invested in equipment required for collecting and processing samples;
- royalty payments to INBio upon successful commercialisation of a compound isolated from a sample. The agreed royalty rate has not be made public but 50% of any such payments received by INBio is to be transferred to MINAE for reinvestment in conservation; and
- carrying out taxonomic studies using Costa Rican para-taxologists.

Sources: S Laird, 'Contracts for Biodiversity Prospecting', in Reid et al (eds.) Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, World Resource Institute, Washington DC; W. Lesser, Sustainable Use of Genetic Resources under the Convention on Biological Diversity - exploring access and benefit-sharing issues, published by CAB International, 1998. INBio home page: http://www.inbio.ac.cr

A number of partnerships between providers and users of genetic resources also exist as a result of a United States initiative known as the International Co-operative Biodiversity Group (ICBG) programme, sponsored by the National Institutes of Health (US), the National Science Foundation (US) and the United States Agency for International Development. The stated aim of the programme is to promote biodiversity conservation and sustainable economic activity in developing countries, and to contribute to drug discovery for diseases of concern to both developing and developed countries. The programme funds bioprospecting partnerships that operate subject to contracts between developing country organisations and indigenous peoples, and US academic researchers and industry. Further information on the programme is found in Annex 2.

4.2 The process for establishing a framework to regulate access to genetic resources

Any process for establishing an access framework might involve:

- the design of legislative, administrative and/or policy measures; and
- the development of institutional capacities to implement such measures.

A country's approach to the establishment of a framework for access to genetic resources will necessarily reflect its unique legal, institutional, economic, social and cultural conditions. A wide range of considerations needs to be addressed when developing an access framework. For example, how might such a framework be established using existing and limited resources? Does regulation of access to the genetic resources of coastal and marine areas warrant alternative regulatory approaches to those governing access to terrestrial genetic resources? What mechanisms are appropriate for consulting, and for obtaining the prior informed consent of relevant stakeholders? The creation of a national access framework could therefore be a lengthy process.

Article 15 of the Convention affirms that it is a matter for national governments to determine whether, and how, to develop national legislative, administrative or policy measures to regulate access to genetic resources.

Experience in a number of countries to date indicates that there are a number of important considerations relating to the process by which an access framework is established. These include:

- developing a strategic plan to determine the overall objective of the access framework and to assist with identifying linkages with other policies and measures to implement the Convention;
- determining the amount of stakeholder participation and consultation needed to establish and implement the access framework; and
- considering the benefits of regional co-ordination and co-operation in establishing and implementing the access framework.

These considerations might involve the following preliminary practical steps:

- identifying and building consensus on national objectives and priorities;
- identifying existing legal, administrative and policy measures which might have a bearing on access and benefit-sharing (such as land tenure practices, rights of local communities, conservation and sustainable development measures, intellectual property rights regimes);
- identifying and consulting stakeholders, including government departments, agencies, representatives of local communities, non-governmental organisations and other interested parties; and
- identifying and mobilising relevant legal and technical expertise.

4.3 Issues to be addressed in access frameworks

By developing national access legislation or other measures, a country can set out minimum requirements, standards and guidelines for access to genetic resources located within its jurisdiction. Most existing and emerging regional and national access frameworks (see Annex 1) identify:

- the scope of the framework, including the resources and activities regulated (see section 4.4 below);
- the role of the national government in authorising access to genetic resources;
- the procedures that must be followed for the negotiation of mutually agreed terms (MATs) and the grant of prior informed consent (PIC) (see section 4.5 below);
- minimum terms and conditions for the grant of access, such as the information that an applicant must disclose in advance; and
- minimum standards and/or guidance to assist the negotiation of MATs on benefit-sharing, such as an indicative list of potential benefits (see section 4.7 below).

Access frameworks might also include a number of other important provisions, for example, on the participation of local communities, on monitoring and enforcement, and on penalties for non-compliance.

A number of these issues are considered briefly in the remaining part of section 4. More detailed guidance on the development of access frameworks can be found in: Glowka, A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, IUCN Environmental Law Centre, 1998.

4.4 The scope of an access framework

The scope of an access framework is determined primarily by how a government chooses to define the terms “access” and “genetic resources”.

The Convention does not define “access”. A definition of “access” in national legislation might therefore draw on:

- the geographical scope of the access framework – a country may chose to differentiate its access framework according to whether access is sought on private land, State lands (such as protected areas), customary land or marine areas, each circumstance presenting a unique array of property rights issues and stakeholder concerns;
- the genetic resources covered – this tends to vary, the remit of some legislation being particularly narrow (e.g., the Sarawak State Forest Ordinance, Malaysia only regulates the removal of tree parts for pharmaceutical research and development);
- the physical activities regulated, such as the collection and export of material; and
- the intended use of resources – the terms and conditions of access may vary according to whether the material is for academic research, conservation purposes or commercial application.

The Convention does define genetic resources, albeit broadly (see Box 3 above), and provides a starting point. Existing regional and national access frameworks have introduced measures that attempt to elaborate upon the definition used by the Convention. For example, some Parties have introduced provisions that cover:

- *derivatives*, i.e. biochemical molecules or a mixture or combination of such molecules, including raw extracts of organisms, derived from the metabolism of organisms (see Box 5);
- *synthesised products*, i.e. semi- and fully synthesised products obtained by means of artificial processes, using genes or other biochemical molecules derived from organisms as ‘templates’ (see Box 5);
- *intangible components*, i.e., knowledge, innovations and practices (individual or collective) of actual or potential value, using biological and genetic resources, and their

derivatives, whether or not such practices are subject to intellectual property rights (see Box 5); and/or

- *ex-situ genetic resources* collected before the Convention's entry into force (see Box 9).

Similarly, access frameworks might specifically exclude certain types, sources or uses of genetic resources, e.g., customary uses of genetic resources, certain uses of biological resources, and genetic resources obtained prior to the legislation's enactment (see Boxes 5 and 9).

Box 5: Derivatives of genetic resources and synthesised products

The Convention does not include 'derivatives' and 'synthesised products' within its definition of genetic resources (see Box 3). Given that such components are widely used, existing regional and national access laws have attempted to resolve the uncertainty surrounding their legal status within the context of the Convention. However, areas of ambiguity remain.

While the Andean Pact's Common System states that its objective is to regulate access to genetic resources as well as to derivatives, it falls short of specifying synthesised products within its defined scope. Other frameworks, such as Costa Rica's Biodiversity Law and the Philippines Executive Order and Implementing Regulations, encourage benefit-sharing arising from the commercial use of derivatives but leave it unclear as to whether PIC is required for access to derivatives as well as to genetic resources. This potentially creates loopholes whereby derivatives, such as raw extracts produced in the source country, could be exported without prior consent.

In practice, however, an increasing number of benefit-sharing contracts govern the extraction, isolation and screening of derivatives in source countries, as well as their subsequent export and use in product development. An example is the Memorandum of Understanding used by the United States National Cancer Institute to structure its more recent bioprospecting partnerships with source-country institutions (see Annex 4).

Source: ten Kate, K. and S. A. Laird, The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit-sharing, Earthscan, 1999, pp. 17 – 20.

4.5 Designing a prior informed consent (PIC) procedure

The Convention leaves the design of any PIC procedure to be determined at the national level. The PIC procedure could, for example, be determined by national access legislation. The PIC procedure could include:

- a designated national authority;
- the scope of application, e.g., which in-situ or ex-situ genetic resources are covered;
- the "access determination process" (the process for deciding whether access to particular resources should be granted to a particular applicant, and on what terms); and
- any procedure for participation of local and indigenous communities (see Box 6).

An "access determination process" might involve the filing of applications with the designated national authority together with payment of application fees. An applicant may be required to furnish the designated authority with requisite information, as determined by the national PIC procedure. Such information could include details of the individuals or institutions involved in the collection and use of the resources, information on the type and quantity of material to be collected, the location of the collection, the uses to which the material will be put, anticipated benefit-sharing, budgets, etc. The procedure might also provide for public notification and consultation (as required by the Philippines Implementing Regulations), the negotiation of MATs for benefit-sharing, third party access to the materials, and post-approval reporting requirements.

Provision 254 (Biodiversity Bioprospecting) of Fiji's Draft Sustainable Development Bill, for example, designated the Conservation and National Parks Authority to act as the competent national authority to review bioprospecting applications and to grant, if appropriate, a special permit. Any application for a permit would be required to contain the following information:

- a full and accurate description of the biodiversity prospecting that is to be undertaken, including the expected time and dates of such activities;
- a description of the areas where biodiversity prospecting is to be undertaken;
- the species of biological resources that is sought and a statement of the quantities of such species that shall be harvested;
- where appropriate, the nature of any intellectual property rights that may be affected concerning the traditional use of any biological resource;
- a statement concerning the methods to be used for any scientific evaluation, sampling or harvesting;
- a statement concerning the methods to be used for the storage and transportation of any biological samples;
- any agreement concluded with native land owners concerning:
  (a) access to land or resources on such land; and
  (b) rights or interests in any biological resources
- a statement concerning any impact on ecological or human health that may result from biodiversity prospecting;
- any environmental monitoring or management plans that may need to be established; and
- the nature, duration and extent of any expected commercial research and development plans.

Depending on a country's land ownership system, resources may be owned and/or managed by, for example, the national government (e.g., by national park authorities), or by communities (communal tenure) or individuals (private land). Where resources are not within the public domain, it is important that PIC is obtained from the relevant individuals or community. This requirement is reflected in a number of provisions of the Convention (Article 8(j) and Article 10(c)) (see also Box 6).

Box 6: Prior Informed Consent and Indigenous and Local Communities

The Convention acknowledges that indigenous and local communities are in many cases likely to be the ultimate providers of genetic resources and associated knowledge.

Existing regional and national access frameworks make explicit reference to indigenous and local people. Some specifically recognise the rights and decision-making capacity of indigenous and local communities with regard to their traditional practices, knowledge and innovations associated with genetic resources, classed as 'intangible components' of genetic resources by the Andean Pact's Common System on Access to Genetic Resources. The Andean Pact Common System excludes from its regulatory scope biological and genetic resources, and any associated knowledge, exchanged among indigenous and local communities in accordance with their customary practices. Such exchanges do not, therefore, require the PIC of governments.

The Philippines Executive Order No. 247 requires the prior informed consent of indigenous and local communities in all cases where biological and genetic resources are appropriated from lands owned by such communities. Moreover, such communities are to receive royalties from any commercial use to which the resource taken is put to.

Contents of box continue to next page

Box 6: Prior Informed Consent and Indigenous and Local Communities (continued from previous page)

A stated objective of the Draft Model Legislation on Community Rights and Access to Biological Resources, developed by the Scientific, Technical and Research Commission of the Organisation of African Unity (OAU), is the provision of an appropriate system of access to biological resources and community knowledge and technologies, subject to the PIC of the State and of concerned local communities.

Fiji's Draft Provisions on access to genetic resources include a requirement to have a legal agreement with the registered owners of the resource prior to giving consent to a prospective bioprospecting arrangement.

4.6 Institutions

As a preliminary matter, States will need to consider whether, and if so which, existing national institutions, including scientific and academic institutions, could play a role in controlling access to genetic resources.

In order to give effect to the prior informed consent (PIC) procedure, a designated national authority is likely to be needed to process applications and make an "access determination". Having such a focal point or competent authority would also enable potential collectors and users of genetic material to know exactly who to deal with. For example, as mentioned above, Fiji's Draft Provisions on access to genetic resources designated the Conservation and National Parks Authority as the competent national authority.

The COP has requested Parties to designate a national focal point and one or more competent national authorities to be responsible for access and benefit-sharing arrangements or to provide information on such arrangements within its jurisdiction. Names and addresses of focal points and competent authorities should be notified to the Convention Secretariat.

The national authority designated for the purposes of PIC varies between countries. A designated national authority might be:

- a government department or agency;
- a research institution;
- a private contractor; or
- a non-governmental organisation.

When designating a national authority, it might be necessary to clarify the role of all relevant stakeholders and authorities, such as protected area management authorities in regulating access. Indeed, given the cross-sectoral interests at stake, a number of countries have established, or are in the process of establishing, designated national bodies composed of representatives of government ministries and agencies, as well as other stakeholders, such as local and indigenous communities, the private sector and the research community. Such bodies are empowered to assess the merits of, and to authorise or reject, proposed access and benefit-sharing arrangements. A multi-disciplinary, technical advisory committee might also be established to provide advice to the designated national authority on, for example, the determination of what constitutes "environmentally sound use", or on terms for benefit-sharing.

In addition to processing, approving and monitoring access applications, other potential functions of a designated national authority might include:

- carrying out or co-ordinating the identification and characterisation of genetic resources to ascertain their potential use and value;
- identifying and informing potential users of national genetic resources;
- negotiating and concluding mutually agreed terms for access;

- collecting and disbursing fees, royalties, other financial returns and benefits on behalf of the State; and
- reviewing legislation regarding access and benefit-sharing with a view to making suggestions for its improvement to the relevant bodies.

A designated national authority may collect and disburse fees, royalties, other financial returns and benefits on the government's behalf. Additional institutional mechanisms for the performing these functions at the local level may be equally important wherever benefit-sharing arrangements provide for financial returns to local and indigenous communities. One common approach is to develop a local trust fund. For example, in Viti Levu, Fiji, the Verata community has established a Trust Fund to receive and manage the financial benefits of bioprospecting agreements for the purposes of local sustainable development. The Fund is managed by an independent Trust Committee. For further information on the role of local trust funds in receiving and disbursing the financial benefits of bioprospecting, see Annex 2.

4.7 Negotiating mutually agreed terms (MATs) for benefit-sharing

As noted above, any decision on how benefits arising from the use of genetic resources are to be shared must be mutually agreed. In this context, developing the capacity to identify and characterise the genetic resources within its jurisdiction might enable a provider Party to have a better understanding of their potential uses and be in a better position to negotiate possible returns. The Convention itself contains provisions requiring Parties to identify and monitor the components of biodiversity; and a capacity building initiative has been launched under the Convention.

The position of the provider Party is also likely to be enhanced through increased capacity to screen biological extracts for useful properties. The valuable compounds in an extract might then be made available to bioprospectors on terms that are more favourable to the provider Party.

Box 7: An illustrative list of benefits that may be reflected in an access and benefit sharing arrangement

1. Monetary benefits
   - "up-front" payments – fees for access (per sample) and for preparation, handling and shipping of samples.
   - fees for re-collection.
   - salaries.
   - research funding and fellowships.
   - milestone payments – made at points in the discovery and development process, as independent payments or off-set against future royalties.
   - fees from the licensing of intellectual property rights.
   - royalties – calculated on gross or net sales of end-products.

2. Non-monetary benefits
   - technology transfer – equipment, software and know-how for field collections and taxonomic work, and for extraction, fractionation and screening of samples.
   - exchange of information, results and data; notification of discoveries.
   - training, staff exchanges and education.
   - joint research and development; joint-authorship of and acknowledgement of provider in publications.
   - institutional capacity building – legal and technical personnel.
   - intellectual property rights – exclusive or joint authorship of patents; acknowledgement of provider of genetic resources in patents.
   - taxonomic inventory; deposit of voucher specimens in national collections.
   - in-kind support for conservation.
   - in-kind support for community and rural development.

The Convention does not provide explicit guidelines on how benefits should be shared. There is no definition in the Convention of "benefit" nor of what is meant by "fair and equitable". These are issues that will ultimately be decided by the parties to an access arrangement.

Existing regional and national access legislation tends to specify certain types of benefits that users must share, or that negotiators must consider sharing, when arriving at mutually agreed terms (MATs) for access and benefit-sharing arrangements (see Annex 1). Examples of benefit-sharing arrangements specified in existing regional and national measures include:

- the participation of nationals in research activities;
- the sharing of research results;
- a complete set of voucher specimens to be left in national institutions;
- support for research on the conservation and sustainable use of biological diversity;
- strengthening mechanisms for technology transfer, including biotechnology;
- strengthening the capacities of indigenous peoples and local communities with regard to the intangible components associated with genetic resources and their derivatives;
- access by nationals to all national specimens deposited in international ex-situ collections;
- the receipt by providers, without payment of a royalty, of all technologies developed from research on endemic species;
- fees, royalties and financial benefits; and
- the donation to national institutions of equipment used as part of research.

Fiji's Draft Provisions on access to genetic resources would require that, prior to a decision on the merits of an application, a legally binding agreement must be concluded with the owners of the resources, concerning, among other issues, appropriate fees for any concessions granted. The Conservation and National Parks Authority would also have to receive a legally binding agreement from the applicant specifying that the latter will:

- regularly report on the nature of any scientific research that results from the bioprospecting venture;
- provide notification of any patents or copyrights that may be sought or registered; and,
- negotiate suitable royalty agreements with the resource owner upon the registration of any patent.

Mutually agreed terms for benefit-sharing are of particular significance when dealing with institutions with ex situ collections, e.g., botanic gardens. Many ex situ collections now use Material Transfer Agreements when assigning or lending any material in their possession to third parties, e.g. to other botanic gardens or companies. It is crucial that there is consistency between the terms of such Material Transfer Agreements and the mutually agreed terms for benefit-sharing that the ex situ collection may have negotiated with the country which originally provided the material. The original access agreement may, for example, provide that the material may not be used for commercial purposes without first consulting the country of origin. The third party recipient of biological material from an *ex situ* collection needs to be bound by this obligation when it receives the material.

Mutually agreed terms for benefit-sharing can therefore be transmitted along a chain of Material Transfer Agreements, in order to protect the interests of source countries. This principle governs the Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing (see Annex 5).

In addition to benefit-sharing, MATs might address a range of issues, such as:

- definitions;

- a duty to minimise environmental impacts during collecting activities;
- ownership of collected materials;
- individual obligations that survive termination of the agreement; and
- other contractual terms such as indemnity against liability, choice of law, arbitration, etc.

While the potential benefits which may be obtained through bioprospecting arrangements are attractive, the extent to which these benefits are likely to materialise in practice to providers of genetic resources will depend upon a number of factors, including:

- ability to ensure that prior informed consent is sought and properly obtained from all relevant stakeholders before any collection takes place;
- ability to effectively negotiate appropriate benefit-sharing arrangements with prospective collectors of genetic resources;
- ability to monitor subsequent use of resources and to enforce agreed benefit-sharing arrangements.

A number of civil society groups have expressed some scepticism about the potential for bioprospecting arrangements to deliver real benefits to local communities, and about the way in which certain arrangements have been entered into and implemented (see, e.g. Proceedings of the Indigenous People's Knowledge and Intellectual Property Rights Consultation, Suva, 1995; and http://www.rafi.org). On the other hand, some industries engaged in bioprospecting have expressed the view that countries providing genetic resources, including some which have instituted access legislation have unrealistic expectations as to the levels of benefits, particularly up-front benefits, which should be provided.

5. INTERNATIONAL DEVELOPMENTS

5.1 *Ex-Situ* Genetic Resources

As noted in section 2.1, the Convention does not address the issue of access and benefit-sharing in relation to genetic resources collected prior to its entry into force and held in ex-situ collections. The majority of genetic materials (primarily plant genetic resources) are held in some 1200 collections world-wide, including in botanical gardens and gene banks such as the International Agricultural Research Centres. These were acquired prior to the Convention's entry into force and are not regulated by its provisions. This is of particular concern to developing countries where many of these resources originated.

Although technically outside the scope of the Convention, the importance of addressing the matter of ex-situ genetic resources has been acknowledged. In particular, Resolution 3 of the Nairobi Final Act - adopted at the UNEP Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity (22 May 1993) recognises:

> *4. … the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular:*
> *(a) Access to ex-situ collections not acquired in accordance with the Convention; and*
> *(b) The question of Farmers' Rights.*

At the international level, action with respect to plant genetic resources is taking place within the context of the Food and Agricultural Organization (FAO) of the United Nations. The FAO has addressed plant genetic resources since its creation in 1945.

In 1983, as a result of the increasing attention devoted to plant genetic resources, the FAO began to develop a comprehensive Global System for the Conservation and Utilisation of Plant Genetic Resources for Food and Agriculture (the Global System) aimed

at co-ordinating intergovernmental action at the global level. The objectives of the Global System are to ensure the safe conservation of plant genetic resources, and to promote their availability and sustainable utilisation for present and future generations, by providing a flexible framework for sharing benefits and burdens. The Global System covers the conservation (*ex-situ* and *in-situ*) and utilisation of plant genetic resources, including genes, genotypes and gene pools at the molecular, population, species and ecosystems levels. The System consists of two components: the Commission on Genetic Resources for Food and Agriculture (CGRFA) and the International Undertaking on Plant Genetic Resources (see section 5.2 below).

Under the International Undertaking on Plant Genetic Resources, plant genetic resources were initially treated as a "heritage of mankind", with no limitations placed on their free exchange. In 1991, however, a resolution of the FAO restricted the free exchange of plant germplasm by subordinating the heritage of mankind concept to the principle of State sovereignty over their plant genetic resources (see section 5.2 below). The free exchange of plant genetic resources is also becoming increasingly restricted because of the use of intellectual property rights in the form of patents and plant breeders' rights (see Chapter 3).

The entry into force of the Convention on Biological Diversity has raised questions of co-ordination with and priority over the FAO's activities. In particular, the need to harmonise the International Undertaking on Plant Genetic Resources with the provisions of the Convention has been acknowledged and a process is in place to do so. The fifth meeting of the Conference of the Parties urged the FAO to finalise the review of the International Undertaking. COP 5 affirmed its willingness to consider a decision that the Undertaking become a legally binding instrument with strong links to both the FAO and the CBD, and called on Parties to co-ordinate their positions in both forums (Decision V/26).

5.2 The International Undertaking on Plant Genetic Resources

In 1983, the members of the FAO Commission on Plant Genetic Resources (renamed in 1995 as the Commission on Genetic Resources for Food and Agriculture (CGRFA)) adopted the International Undertaking on Plant Genetic Resources, a non-binding agreement whose objective is to:

> *ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, evaluated and made available for plant breeding and scientific purposes (Article 1).*

The International Undertaking promotes the conservation, exchange and utilisation of plant genetic resources and is premised on the principle that plant genetic resources are a heritage of mankind and should therefore be made available without any restrictions. It requires countries that have chosen to adhere to it to make available plant genetic resource samples for scientific research, plant breeding or genetic resource conservation. The samples are to be made available free of charge, on the basis of mutual exchange or on mutually agreed terms (Article 5).

In accordance with the International Undertaking (Article 7) an International Network of *Ex-Situ* Collections has been established under the auspices of the FAO. Various countries and the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) have signed agreements placing most of their collections in the International Network. The legal status of the collections as part of the International Network are currently under discussion within the context of the revision and harmonisation of the International Undertaking.

The International Undertaking was subsequently qualified by three Annexes which sought to clarify the scope of the Undertaking. In particular, these Annexes recognised:

- that Plant Breeders Rights (see Box 8) were not necessarily inconsistent with the Undertaking and also that "free access" did not mean "free of charge" (Annex I, Resolution 4/89, 1989);
- the concept of Farmers' Rights (see Box 8) (Annex II, Resolution 5/89, 1989); and,
- that the concept of the heritage of mankind is subject to the sovereignty of States over their plant genetic resources and that Farmers' Rights should be implemented through an international fund (Annex III, Resolution 3/91, 1991).

An additional resolution, agreed by the Commission on Plant Genetic Resources in 1993, calls for the revision of the International Undertaking, starting with the integration of the three Annexes into the main text of the Undertaking.

In 1993, the FAO initiated a process to revise the International Undertaking to bring it into harmony with the Convention. This process is due to be completed in 2000. More detailed information on the revision of the International Undertaking and on ex-situ collections is provided in Annex 5.

Box 8: Plant Breeders' and Farmers' Rights

Plant Breeders' Rights are recognised internationally through the 1961 International Convention for the Protection of New Varieties of Plants (known as UPOV), as amended in 1978 and 1991. UPOV establishes a harmonised system to encourage innovation in plant breeding by requiring its Parties to grant a plant breeder an exclusive right in a plant variety the breeder has discovered and developed.

Farmers' Rights were introduced in the context of the International Undertaking on Plant Genetic Resources. They are rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. However their legal status is unclear and is currently being considered within the FAO process to revise the Undertaking.

See Chapter 3 for further information on Intellectual Property Rights.

5.3 Consideration of access to genetic resources by the Conference of the Parties to the Convention on Biological Diversity

COP 4 decided to establish an Experts' Panel to develop a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines and codes of best practices (Decision IV/8). The first meeting of the Experts' Panel took place from 4-8 October 1999. The Panel consisted of government nominees from 9 African, 10 Asian (including the Cook Islands), 7 Central and East European, 11 Latin American and Caribbean, and 11 developed countries (including Australia, the United States, Japan and some European countries). The European Community was also represented. Observers at the meeting included international organisations, non-governmental organisations and the private sector.

The findings of the Experts' Panel, as set out in its final report, UNEP/CBD/COP/5/8 (see also section 6 below), have been considered by COP 5.

COP 5 decided to reconvene the Expert Panel on Access and Benefit-Sharing, with a concrete mandate and agenda, to address outstanding issues from its first meeting, especially:

- assessment of user and provider experience in access to genetic resources and benefit-sharing, and study of complementary options;

- identification of approaches to the involvement of stakeholders in access to genetic resources and benefit-sharing processes.

The COP decided that the Experts Panel 'will include additional expertise'. The Panel will submit its report to a new Ad Hoc Open-ended Working Group on Access and Benefit-sharing, which has the mandate to develop guidelines and other approaches and to assist Parties in addressing:

- terms for PIC and MATs;
- roles, responsibilities and participation of stakeholders;
- relevant aspects relating to in-situ and ex-situ conservation and sustainable use;
- mechanisms for benefit-sharing; and
- means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities.

The objective is that these elements should serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, as well as contracts or other arrangements. COP 5 further decided that the Open-ended Working Group on Access and Benefit-Sharing will also consider issues of capacity-building, including: assessment and inventory of biological resources, as well as information management; contract negotiation skills; legal drafting skills for development of access and benefit-sharing measures; and means for the protection of traditional knowledge associated with genetic resources. The Working Group will meet before COP 6, at which its report will be considered (Decision V/26).

COP 4 also requested the financial mechanism of the Convention (the Global Environment Facility) to give priority to the funding of projects involving the development of national, sub-regional or regional access and benefit-sharing mechanisms. This request partly reflects the Nadi Statement of 3 April 1998, which called on the COP to assist Pacific island countries in developing and implementing legislative, administrative and policy measures, at both the national and regional levels, in accordance with Articles 15, 16 and 19 of the Convention. COP 5 also identified as a priority for GEF funding those projects that address access to genetic resources and benefit-sharing (Decision V/13)

COP 4 established an ad hoc, open-ended, intersessional working group to address the implementation of Article 8(j) and related provisions of the Convention on indigenous knowledge, innovations and practices. The first meeting of the ad hoc working group was held on 27-31 March 2000 in Seville, Spain. COP 5 prioritised and endorsed the working group's work plan adopted in Seville, allocating financial support to the implementation of the priority activities of its first phase, in accordance with Decision V/16.

The COP has also given some consideration to the status of ex situ collections acquired prior to the Convention's entry into force. In May 1998, COP 4 requested Parties and international organisations to provide the Secretariat with information on ex situ collections, for an intersessional meeting on the operations of the Convention in June 1999. The intersessional meeting recommended that COP 5 examine the use of voluntary measures by ex situ collections for the purposes of access and benefit-sharing. A number of Parties remain strongly opposed to the consideration of this issue by the COP, arguing that, by virtue of Article 15(3), it is explicitly outside the scope of the Convention. COP 5 decided to continue the information-gathering exercise on these *ex-situ* collections, and requested the Secretariat to gather available information through questionnaires, and report to COP 6.

6. ACTIVITIES CONCERNING ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING IN THE PACIFIC ISLANDS REGION

A number of Pacific island countries are currently considering national frameworks to regulate access to genetic resources. Furthermore, many of those developing National Biodiversity Strategies and Action Plans are incorporating this issue and agreed actions needed at a strategic level.

At the 1998 regional meeting in Nadi, Fiji, on the implementation of the CBD, participants from Pacific island countries recognised the importance to regulate access to their genetic resources. The *Nadi Statement*, adopted at that meeting, stresses the need for regional mechanisms and measures to support in-country initiatives on access to genetic resources and benefit-sharing.

A new project on access to genetic resources and benefit-sharing in the Pacific islands region has been initiated by the South Pacific Regional Environmental Programme (SPREP), the World Wide Fund for Nature South Pacific Programme (WWF-SPP) and the Foundation for International Environmental Law and Development (FIELD). The project is intended to support regional and country-level initiatives in the Pacific islands region to consider and, as appropriate, develop legal, policy and/or administrative measures to regulate access to genetic resources, and ensure appropriate benefit-sharing within the meaning of the Convention, taking into account developments at the international level. Elements of the project include:

- The development of, and initial consultation on, draft regional guidelines on access to genetic resources and benefit-sharing, between November 1999 and March 2000;
- A regional workshop on access to genetic resources and benefit-sharing, to consult on regional guidelines on access and benefit-sharing in March 2000; and
- Possible National pilot projects (2000-2001).

At the regional workshop, held in Fiji in March 2000, there was an exchange of national experiences on bioprospecting activities and recent legal developments on access to genetic resources. Legislation in this area tends to be addressed through framework environmental laws and specific regulations are not yet in place. Nonetheless, it appears that bioprospecting activities are ongoing in a number of Pacific island countries, generally under contractual arrangements.

The participants of the March 2000 workshop discussed and endorsed draft regional guidelines on access and benefit-sharing. The workshop report is included in this Information Package as Annex 7.

UNDP's Biodiversity Planning Support Programme also represents an opportunity to consider access and benefit-sharing issues within the context of National Biodiversity Strategies and Action Plans.

The Secretariat of the Pacific Community (SPC) has established a Regional Germplasm Centre within its Agriculture Programme. The aim of the Regional Germplasm Centre (RGC) is to assist Pacific island countries to conserve genetic resources, to access improved genetic resources and to maintain the biodiversity of the region. Genetic resources of the region's major crops and other important plant material will be kept at the RGC. The Secretariat of the Pacific Community has stated that germplasm distributed from the RGC will be subject to access agreements and will comply with CBD provisions on sovereign rights over genetic resources.

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UNEP/CBD/COP/2/13

UNEP/CBD/COP/3/20

UNEP/CBD/COP/3/Inf.53

UNEP/CBD/COP/4/21

UNEP/CBD/COP/4/22

UNEP/CBD/COP/4/23/Rev.1

UNEP/CBD/COP/4/Inf.7

UNEP/CBD/ISOC/3

UNEP/CBD/ISOC/Inf.5

UNEP/CBD/COP/5/8

Useful websites:

www.biodiv.org/chm/	Convention on Biological Diversity, Clearing House Mechanism
www.biodiv.org/cop5/docs.html	Documents for COP 5, 15 – 26 May 2000, Nairobi, Kenya
www.biodiv.org/Decisions/COP5/pdf/COP-5-Dec-All-e.pdf	COP 5 Decisions
www.iisd.ca/biodiv/abs/index.html	Earth Negotiations Bulletin: summary report of the October 1999 Costa Rica meeting of the Experts' Panel on access and benefit-sharing
http://www.bcnet.org	Biodiversity Conservation Network (Information on USP/SIDR/Verata arrangement)
http://www.spc.org.nc	Secretariat of the Pacific Community
http://www.rafi.org	Rural Advancement Foundation International

See also list of websites at the end of Chapter 1.

3 INTELLECTUAL PROPERTY RIGHTS AND BIOLOGICAL DIVERSITY

This chapter is intended to provide a basic introduction to those aspects of intellectual property rights of relevance to the Convention on Biological Diversity. It provides an overview of discussions to date in this field, and summarises some of the proposals that have been made relating to relevant intellectual property rights.

1. INTRODUCTION

The potential impact of intellectual property rights (IPRs) on the objectives of the Convention on Biological Diversity is a complex and controversial issue, and is the subject of ongoing discussions within the Conference of the Parties (COP) to the Convention.

IPRs may be of relevance to at least four issues addressed under the Convention:

(i) **Access to and transfer of technology, including biotechnology**: Do IPRs support or impede the transfer of technology relevant to the conservation and sustainable use of biological diversity?

(ii) **Benefit-sharing in relation to the use of genetic resources**: Do IPRs contribute to, or detract from, the fair and equitable sharing of benefits arising out of the utilisation of genetic resources?

(iii) **Protection of the traditional knowledge, innovations and practices of indigenous and local communities relating to the conservation and sustainable use of biological diversity**: Do IPRs affect the rights and interests of indigenous and local communities to control and/or benefit from applications of their knowledge over natural resources? Can indigenous and local communities use IPRs to protect their knowledge and practices?

(iv) **Incentive measures for the conservation and sustainable use of biological diversity**: Do intellectual property rights provide positive or perverse incentives for the conservation and sustainable use of biological diversity?

These issues are closely interrelated. They are discussed in more detail in section 4. First, however, section 2 provides a basic introduction to relevant terminology, and to some of the types of IPRs of relevance to the implementation of the Convention on Biological Diversity; and section 3 notes some of the international institutions active in the field of IPRs.

2. TERMINOLOGY: INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights (IPRs) protect the application of ideas and information. Essentially, an IPR entitles the holder to the exclusive right to benefit from utilising specific ideas and information. IPRs were established to encourage and reward creativity, research and innovation. As a matter of public policy, countries implementing IPR regimes have to balance the interests of the innovator (the holder of the right) against the interests of wider society in gaining access to the benefits of innovation. For this reason, IPRs are subject to limitations, such as limited terms of protection and, in certain circumstances, compulsory licensing requirements.

The IPRs of chief relevance to this Chapter are patents and plant variety rights.

2.1 Patents

Patents are granted for inventions, which are:

- **Novel**: at the date on which a patent application is officially filed for examination by a patent office, the claimed invention does not constitute part of the 'state of the art' ('prior art'), i.e., it has not already been patented or been made available to the public by means of a written or oral description, use or in any other way, before the filing date.
- **Inventive (non-obvious)**: the claimed invention involves as 'inventive step', i.e. in the light of the state of the art, the claimed invention is not obvious to 'a person skilled in the art'.
- **Capable of industrial application (useful)**.

Furthermore, a patent applicant's claims must be 'fairly based'; i.e. he must not claim more than he has invented.

A patent grants the inventor a monopoly for a limited period (e.g. a minimum of twenty years) over:

- a new product, including its manufacture, use and sale (product patent); or
- a new process to make a product (process or method patent).

During the limited period for which a patent is granted, all activities within the scope of a patent may only be undertaken by or with the consent of the patent owner. His consent may, for example, involve an exclusive license to make, use or sell the patented product, or to use a patented process, in return for a license fee and/or a royalty on sales.

Theoretically, mere discoveries are not patentable. These might include:

- a phenomenon of nature, e.g. a previously unknown gene sequence; or
- a previously unknown characteristic of a known product.

Some jurisdictions are, however, less stringent than others over the patenting of what are, allegedly, mere discoveries. This is an issue of crucial importance with regard to genetic resources and their various applications.

Binding, minimum standards for the scope and availability of patents have been set by articles 27 - 34 of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) (see section 3.2 below).

2.2 Plant Variety Rights (PVRs)

Plant Variety Rights (PVRs, also referred to as Plant Breeders' Rights) were developed within the framework of the International Convention for the Protection of New Varieties of Plants (known as UPOV) (see Boxes 1 and 2 below). Countries party to UPOV currently apply either of two versions of the UPOV Convention – the 1978 Act or the 1991 Act. The 1991 Act offers stronger PVRs. Governments had until the end 1995 to

join UPOV under its 1978 Act. All accessions to UPOV after that date are subject to its 1991 rules.

Box 1: What is a plant variety?

According to Article 1 (vi) of the International Convention for the Protection of New Varieties of Plants (UPOV) (see Box 2), a 'variety' is 'a plant grouping within a single botanical taxon of the lowest known rank,...which, irrespective of whether the conditions for the grant of a breeder's rights are fully met, can be:

- defined by [its] expression of ...characteristics resulting from a given genotype or combination of genotypes;
- distinguished from any other plant grouping by [its] expression of at least one of [these] said characteristics; and
- considered as a unit with regard to its suitability for being propagated unchanged'.

PVRs were designed to reward innovation in the development of new plant varieties at a time when patents were not widely available for living organisms. PVRs are a specialised, or sui generis, system of IPRs and are available for new plant varieties which are:

- Commercially novel – i.e. at the date of filing an application for PVRs, the claimed variety has not been sold, by or with the consent of the breeder, for the purposes of commercially exploiting the variety:
  - within the territory of the same UPOV Contracting Party earlier than 1 year before the filing date; or
  - within the territory of another UPOV Contracting Party earlier than 4 years before the filing date or, in the case of trees and vines, earlier than 6 years before the filing date.
- **Distinct** – i.e. the claimed variety is clearly distinguishable from any other variety, the existence of which is a matter of 'common knowledge' at the filing date. The filing of an application in any country, for PVRs or for the entry of a variety in an official plant varieties register, renders the variety common knowledge from the date of application, providing the application is subsequently successful.
- **Uniform** – i.e. within any one generation, individuals of the claimed variety are sufficiently uniform in their relevant characteristics, subject to variations that may be expected to arise due to propagation conditions.
- **Stable** – the relevant characteristics of the claimed variety remain unchanged after repeated propagation or at the end of each propagation cycle, i.e., they do not change between generations.

2.3 Other forms of intellectual property rights (IPRs) of potential relevance to the Convention

The other forms of IPR referred to in this Chapter are trade secrets, trade marks, geographical indications and copyright.

2.3.1 Trade secrets

These protect confidential information and allow the owner to prevent its unauthorised disclosure. Trade secret protection is available to protect information that:

- is not generally known or readily accessible to persons in the relevant field;
- has commercial value because it is secret; and
- has been subject to reasonable steps by the person lawfully in control of it to keep it secret.

Article 39 of the TRIPs Agreement sets minimum standards for the availability of trade secrets in WTO Member countries.

2.3.2 Trademarks

These apply to goods and services. The owner of a trademark has exclusive rights, enabling him to prevent third parties from using identical or similar signs for trading goods or services identical or similar to those for which the trademark has been regis-

tered, such as would confuse the public. Articles 15–21 of the TRIPs Agreement harmonise rules governing trademarks in WTO Member countries. The Agreement requires a registered trademark to confer a minimum 7-year term of protection, renewable indefinitely.

Box 2: The International Convention for the Protection of New Varieties of Plants (UPOV Convention)

The International Convention for the Protection of New Varieties of Plants was adopted in 1961 to encourage innovative plant breeding, by providing exclusive rights for plant breeders in the plant varieties they develop. It established the International Union for the Protection of New Varieties of Plants (or Union internationale pour la protection des obtentions végétales (UPOV)) - an independent, intergovernmental organisation with legal personality.

The UPOV Convention has since been revised three times, most recently by its 1991 Act. The 1991 amendments, which entered into force in April 1998, broaden the scope of protection beyond that offered by the 1978 Act, marking a shift towards more "patent-like" protection. In particular, the 1991 Act removed the automatic "farmers' privilege", which allowed farmers to use saved seed from a protected variety for replanting on the farm (but not for commercial purposes) without the PVR holder's authorisation. Parties to the 1991 Act now have a mere discretion to include the farmers' privilege in their PVR legislation, allowing farmers to use protected material within "reasonable limits" and subject to the legitimate interests of the plant breeder. The plant breeder may challenge the privilege if his legitimate interests are at stake.

The 1991 Act guarantees the plant breeder a cascade of rights. His prior authorisation must be sought for:

- acts done in relation to the propagating material of his protected variety, e.g., multiplication, offering for sale, exporting or importing;
- acts done in relation to harvested material (whole plants or parts of a plants) of his protected variety if that material has been obtained through the unauthorised use of propagating material; and
- acts in respect of products made directly from the unauthorised use of harvested material of his protected variety (UPOV Contracting Parties have the discretion to include this right in their PVR legislation):

The 1991 Act continues, however, to permit the use of protected varieties for the purposes of research (the research exemption) and for breeding new varieties (the breeders' exemption), without the prior authorisation of PVR-holders.

The 1991 differs from its predecessor, the 1978 Act, in that the PVRs it offers apply not only in relation to a protected variety but also in relation to any variety which is 'essentially derived' from a breeders' protected variety. A variety is 'essentially derived' if it:

- is predominantly derived from the initial variety;
- is clearly distinguishable from the initial variety; and
- except for differences arising from derivation, expresses the essential characteristics resulting from the initial variety's genotype.

The 1991 Act also differs from the 1978 Act in a number of other important respects:

- Coverage - Contracting Parties must bring all plant species within the scope of their PVR legislation within 10 years of acceding to the 1991 Act; the maximum under the 1978 Act was 24 species within 8 years.
- Term of protection - the 1991 Act requires a minimum of 20 years' protection, and a minimum of 25 years for trees and vines; under the 1978 Act the requirement was 15 and 18 years respectively.
- Scope of PVRs - unlike the 'cascade' of rights available under the 1991 Act, rights under the 1978 Act extended only so far as the propagating material of a plant breeder's protected variety.
- Right to double protection - the 1991 Act allows a plant variety to be protected both by a PVR and by a patent. UPOV 1978 forbade this.

As of May 2000, UPOV has 45 member states of which 14 are Parties to the 1991 Act. At the time of writing, no Pacific island country is a party to UPOV. New Zealand is Party to the 1978 Act, while Australia became a Party to the 1991 Act in January 2000.

2.3.3 Geographical indications

These identify goods as originating from particular territories regions or localities, in cases where the quality, reputation or other characteristics of goods are attributable to such geographical origins. Articles 22 - 24 of the TRIPs Agreement harmonise rules governing geographical indications in WTO Member countries. Under the Agreement, Members are required to invalidate trademarks which contain or consist of geographical indications with respect to goods not originating in the territory indicated, if such use of the indication in trademark misleads the public as to the goods' real origin.

2.3.4 Copyright

This is available for original works of authorship in whatever form or mode of expression, e.g. literary or artistic works, but not for ideas, procedures, methods of operation or mathematical concepts as such. Articles 9 - 14 of the TRIPs Agreement harmonise rules governing copyright in WTO Member countries, including a minimum 50-year term of protection. The relevant TRIPs provisions complement the Paris Act of the Berne Convention for the Protection of Literary and Artistic Works, 1971.

3. INTERNATIONAL PROPERTY RIGHTS: RELEVANT INTERNATIONAL INSTITUTIONS

3.1 International harmonisation of intellectual property rights (IPRs)

With limited exceptions, IPRs are enforceable only in the country in which they have been granted. As a result, the range of products and works to which IPRs extend have tended to vary from State to State, depending upon national IPR policy. India, for example, suspended the availability of product patents on new pharmaceuticals and agricultural chemicals but continued to permit process patents on new methods to make such products. This policy enabled these products, which were often imported and of crucial socio-economic significance, to be manufactured using different, often cheaper methods, thereby rendering them more affordable to local markets.

Furthermore, in the light of rapid advances in technology, a growing range of innovations is falling within the scope of national intellectual property laws in developed countries. Of most relevance to the Convention is the extension of IPR protection to inventions derived from or consisting of living material, such as plant varieties and biotechnological inventions, including living modified (genetically engineered) organisms. This trend is most prevalent in the USA and Europe. The patentability of biotechnological inventions under the Patents Act in New Zealand is currently the subject of consultation and reform.

Many international and regional agreements govern the availability and scope of IPRs, including the Paris Convention (patents, etc.) and the Berne Convention (copyright). These provide for cooperation and/or set minimum standards in relation to IPRs. A number are by the World Intellectual Property Organisation (WIPO) (see section 3.3 below).

Harmonisation of intellectual property laws has, in particular, been driven by the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) (see section 3.2 below). Differences between national IPR regimes led various interest groups, particularly Northern-based multinational companies seeking to protect their innovations from infringement by competitors in developing countries, to lobby for the development of international standards for intellectual property protection. The TRIPs Agreement was developed in an effort to complement and to build upon existing regional and international treaties. It sets harmonised, minimum standards for the scope and grant and of IPRs, and is binding upon all WTO Member countries.

3.2 The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)

The WTO TRIPs Agreement was finalised in 1994, at the end of the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT), and entered into force on 1 January 1995. It forms part of a bundle of rights and obligations that bind WTO Members. The Agreement sets minimum, harmonised standards for intellectual property protection within Member countries. IPRs were addressed within the Uruguay Round negotiations of the GATT/WTO for two key reasons:

- effective pressure exerted by mostly Northern industrial lobbyists, seeking greater protection against infringement of their innovations in less-regulated developing countries; and,
- the WTO's compulsory dispute-settlement system – a decisive factor for developed countries seeking to protect their comparative advantage in research and innovation.

The TRIPs Agreement's provisions on patents are illustrative of its harmonising objectives. These provisions complement and build upon existing international standards, as represented by the Stockholm Act of the Paris Convention for the Protection of Industrial Property, 1967.

Article 27(1) of the TRIPs Agreement provides that patents shall be available for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (i.e. new, non-obvious and useful). The Agreement does contain certain limited exceptions, allowing members to exclude from patent protection:

- inventions, the commercial exploitation of which it is necessary to prevent within their territory to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment (Article 27(2));
- diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27(3)(a); and
- "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". WTO members must, however, provide for the protection of plant varieties either by patents or by an effective sui generis (specialised) system (such as plant variety rights), or by any combination thereof (Article 27(3)(b)).

Practice within the GATT/WTO suggests that these exceptions are likely to be narrowly construed.

Article 27.3(b) of the TRIPs Agreement is highly controversial, given that it is perceived as endorsing the patenting of biological material. Its review (which was due to take place in 1999 within the WTO) is therefore of crucial importance.

Developing countries had until 1 January 2000 to implement their obligations under TRIPs. They also have the right to exclude product patent protection for areas of technology not previously protectable in their territories (e.g., pharmaceutical and agricultural chemical products) until 2005. The least developed countries have until 1 January 2006 to establish intellectual property regimes, with possible extensions upon request. Certain TRIPs obligations must, however, be implemented as soon as a country becomes a member of the WTO. This transition period may, however, be revisited in 2000 when the entire TRIPs Agreement is reviewed by the TRIPs Council (the main WTO body responsible for monitoring the operation of the TRIPs Agreement).

At COP 4, certain Parties and observers called for the COP to provide input to the review of TRIPs Article 27.3(b). The COP emphasised that further work was required to develop a common appreciation of the issues. At COP 5, Parties were invited to submit information about the role of IPRs in implementing access and benefit-sharing arrangements, by 31 December 2000. The COP also invited relevant international organisations to analyse IPR issues, including the provision of information on the origin of genetic resources when submitting applications for IPRs (including patents). COP 5 renewed its request for observer status on the TRIPs Council (Decision V/26).

In the Pacific islands region to date, only Fiji, Papua New Guinea and the Solomon Islands are WTO Members, and therefore bound by the terms of the TRIPs Agreement. Samoa, Vanuatu and Tonga have been admitted as observers, and the terms and conditions for their accession as full WTO Members are under negotiation.

3.3 The World Intellectual Property Organisation (WIPO)

The World Intellectual Property Organisation (WIPO) is a UN agency created in 1967 to promote international cooperation in the protection of intellectual property. WIPO administers various treaties governing legal and administrative aspects of intellectual property, e.g. the 1970 Patent Cooperation Treaty (PCT). In addition, WIPO provides assistance to developing countries for the development of intellectual property protection.

In 1998,WIPO established a programme on Global Intellectual Property Issues. Of particular relevance to the Convention are the following sub-programmes:

- **Intellectual Property Rights for New Beneficiaries**: the main objectives of this sub-programme are to identify the intellectual property needs and expectations of indigenous and local communities, and to initiate pilot projects for new approaches to the creation, protection, use and management of IPRs. A number of activities are envisaged under this sub-programme, including studies on current approaches and Roundtables on Indigenous Intellectual Property. Each Roundtable aims to facilitate an exchange of views among policymakers and indigenous peoples concerning improvements to and more effective application of the IPR system, so as to protect traditional knowledge. The first Roundtable took place on 23-24 July 1998.
- Biological Diversity and Biotechnology: the main objective of this sub-programme is to examine the links between the IPR aspects of biotechnology, and the conservation, sustainable use and benefit-sharing elements of biological resource management. The sub-programme is expected to enhance awareness on the role of intellectual property in implementing the Convention. It is also expected to promote projects for the documentation of traditional knowledge, aimed at providing a basis for benefit-sharing arising from the use of such knowledge.

The Convention on Biological Diversity's COP has requested the Convention Secretariat to liaise with WIPO. It has also invited the WIPO's development co-operation programmes to take into account capacity-building needs, in order to achieve the Convention's objectives as they relate to IPRs. At its fourth meeting, the COP requested the Secretariat to further enhance co-operation with WIPO and, in particular, to apply for observer status for the purpose of representing the Convention in meetings related to these programmes.

As of May 2000, 175 countries were Party to the Convention establishing WIPO. Of the Pacific island countries, Fiji, Samoa and Papua New Guinea are WIPO members. New Zealand and Australia are also members.

4. THE RELEVANCE OF INTELLECTUAL PROPERTY RIGHTS TO THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY

IPRs raise complex socio-economic and ethical issues, and have been the focus of much debate under the Convention on Biological Diversity. As noted in the Introduction, there are at least four key overlapping areas where IPRs may impact in a positive or negative way on implementation of the Convention.

(i) Access to and transfer of technology: do IPRs suppport or impede the transfer of technology relevant to the conservation and sustainable use of biological diversity?

(ii) Benefit-sharing: do IPRs contribute to, or detract from, the fair and equitable sharing of benefits arising out of the utilisation of genetic resources?

(iii) Traditional knowledge: do IPRs affect the rights and interests of indigenous and local communities to control and/or benefit from applications of their knowledge over natural resources?

(iv) Incentive measures: do intellectual property rights provide positive or perverse incentives for the conservation and sustainable use of biological diversity?

4.1 Access to and transfer of technology

In common with most recent multilateral environmental treaties, the Convention on Biological Diversity contains provisions on technology transfer. These types of provisions in treaties have often proved ineffective, in particular because relevant technology is often held by the private sector and subject to intellectual property protection. Unlike earlier treaties, the Convention attempts to address the relationship between technology transfer obligations and IPRs. However, it does this in a way which is ambiguous and which has yet to be clarified by the Conference of the Parties. The Convention's provisions on technology transfer, contained in Articles 16 and 19, cover:

- technology relevant to the conservation of biological diversity;
- technology relevant for its sustainable use; and
- technology which makes use of genetic resources.

Thus, the Convention covers what might be termed "classical" technology transfer - for example, the transfer of remote sensing technology which might be useful to developing countries in assessing the status of their biological diversity, as well as the transfer of the "newer" technologies, such as biotechnologies.

Developing country Parties are to have access to technology under terms that are fair and most favourable, including on concessional and preferential terms, where mutually agreed. Article 16 provides that, where relevant technology is subject to an IPR such as a patent, the transfer must be on terms, which recognise and are consistent with the adequate and effective protection of the property right. However, it also goes on to provide that Parties are to co-operate to ensure that IPRs are supportive of and do not run counter to the objectives of the Convention. This language reflects the disagreement that arose during the negotiations of the Convention as to whether or not IPRs support the objectives of the Convention, and implicitly recognises the potential for conflicts between the CBD and IPR protection. The practical effects of the apparent ambiguities in Article 16 remain unclear.

Articles 16 and 19 also cover the transfer of technologies derived from genetic resources, to the country of origin of those resources. The Convention makes it a specific requirement that all Parties create a legislative, administrative or policy framework with the aim that technology which makes use of genetic resources is transferred, on mutually agreed terms, to those providing the genetic resources, in particular, developing country Parties. This obligation extends to technology protected by patents and

other intellectual property rights. GEF funding may be available to assist with the costs of technology transfer where, for example, relevant technology is protected by an IPR.

4.2 Benefit-sharing

In their current form, IPRs, including patents and PVRs, do not require the right-holder to share any benefit derived from the exercise of the right, unless the parties involved agree to share license fees and royalties under a separate agreement.

4.2.1 Patents and benefit-sharing

In developed countries, patents are increasingly being granted for products derived from or constituting living material. Patents are, for example, regularly granted for specific applications of components of natural products. Box 3 below outlines three instances where this has happened in relation to genetic resources from the Pacific region. It should be noted that, in these cases, it is a specific application or property of the resource and not the resource itself, which is patented.

Box 3: Potential applications of genetic resources

- Kava: Various companies have patented the therapeutic uses of Kava (Piper mythesticum). A French cosmetic company has also patented the use of kava to reduce hair loss. Other uses of Kava continue to be explored by a number of companies (see Kava case study -Annex 3).

- Marine sponges: The anti-tumor properties of a marine sponge found in Fiji (cf. marsailis) have been the subject of a patent in the US.

- Mamala: This Pacific medicinal plant, found on most of the high islands stretching from New Caledonia to Tahiti, is the subject of a patent. With the assistance of Samoan healers it has been found to have an active compound, prostratin, which is of potential use in the treatment of AIDs (see Box 5 below) make links to Ch 2 with mamala example.

Note: It is not known whether these examples are subject to access or benefit-sharing arrangements.

Source: Rural Advancement Foundation International: RAFI Communique, Sept./Oct. 1997. http:www.rafi.org.

Patents confer an exclusive right. When granted for an invention based on a genetic resource, a patent does not require its holder to share any benefits with the country of origin of that resource, the communities responsible for conserving it in situ, or the communities or individuals whose knowledge may have contributed to the invention. The only exception is when a user institution and a source country organisation agree to apply for joint patent rights, in which case both parties will gain an enforceable stake in the benefits generated. For this to happen, it is usual for each party to have contributed to the development of the invention intellectually and/or financially.

In some circumstances, an exclusive patent may nevertheless facilitate benefit-sharing when made the subject of a contract. Typically, a patent generated by research and development conducted under the terms of a bioprospecting agreement (see Chapter 2) will remain the property of the user institution. That institution may, however, (as part of the mutually agreed terms in a bioprospecting agreement) undertake to pay the country or community of origin a share of royalties generated from net sales of end products, alongside other monetary and non-monetary benefits. End products are commonly marketed either by the user institution or by a licensed third party. In some cases, a source country organisation has opted for an exclusive right to market such products itself. This is contemplated in the industrial contract between the Papua New Guinea Oil Palm Research Association (PNGOPRA) and Oxford University - see Annex 2.

Alternatively, a source country institution may seek an exclusive patent right in cases where it has independently isolated and screened genetic material for use in a specified application (see the US National Cancer Institute's Memorandum of Understanding in Annex 4). In return for the right to further develop such an invention, a user institution would have to pay the source country institution a license fee and/or a royalty on net sales of final products.

Patents might also be used to facilitate benefit-sharing in other ways. It has been suggested that patent application procedures might be used to "police" access to genetic resources and compliance with access and benefit-sharing agreements. As noted in section 2 above, when submitted to national patent offices, a patent application must contain a description of the claimed invention. The description must be sufficiently clear and complete for the invention to be carried out by 'a person skilled in the art'. This enables a patent office to search relevant prior art and to examine a claimed invention for its novelty, inventiveness and industrial applicability. It has been argued that the standard of disclosure required of patent applicants should be extended to incorporate information such as:

- the country of origin of any genetic resources used in the research leading to the invention (to a certain extent, this would formalise existing practice, where patent applications often set out the origin of the resources (Sukhwani, 1998));
- proof that the prior informed consent of the provider of any genetic resources used in the invention was obtained (for example, by providing certification);
- any knowledge of indigenous and local communities which contributed to the development of the invention; and
- proof that national laws on access to genetic resources, customary laws, and benefit-sharing arrangements (such as bioprospecting agreements) have been complied with.

Given the administrative and financial burden which implementing and enforcing access and benefit-sharing measures is likely to impose on developing countries, such additional requirements for disclosure might usefully assist in implementing Article 15 of the Convention on Biological Diversity. Proof of prior informed consent may, for example, provide a strong incentive for compliance with national access measures if required as a precondition for the grant of patents in both user and provider countries. Furthermore, given that all patents (and, in certain jurisdictions, patent applications) are published in publicly accessible records and databases, proof of origin may greatly enhance the traceability of genetic resources. This might be of advantage when seeking to enforce mutually agreed terms under access and benefit-sharing agreements.

So far, no action has been taken at the international level to promote or require such disclosure. The issue has been raised periodically in the Conference of the Parties to the Convention. Some regional and national access measures do require proof of origin of genetic resources used in inventions, including consent for access, when applying for patents and/or plant variety rights, for example, the Andean Pact's Common System on Access to Genetic Resources and Costa Rica's Biological Diversity Law (see Annex 1).

4.2.2 Plant variety rights and benefit-sharing

Plant variety rights (PVRs) are an important area for consideration in relation to the fair and equitable sharing of benefits arising out of the use of genetic resources. Two key issues arise:

- availability of protection for plant varieties in the Pacific region; and
- property rights relating to plant genetic resources in ex-situ collections.

As noted in section 2, pursuant to the UPOV Convention, PVRs are available in respect of varieties that are novel, distinct, uniform and stable. These criteria appear to be geared to the activities of commercial breeders and seed companies rather than those of farm-

ers and local communities. For example, farmers have frequently bred traditional varieties for adaptability as opposed to stability or uniformity. Furthermore, a commercial breeder may make only a slight improvement to a traditional variety but nevertheless obtain UPOV-style protection for it, in accordance with the requirements of UPOV.

There is no mechanism within the UPOV system of PVRs which reflects the contributions made by countries of origin to plant breeding programmes, through their stewardship of plant genetic resources and the small-scale innovations of their farmers. The concept of Farmers' Rights has evolved at the international level as something of a counterbalance (see Box 4).

Box 4: Farmers' Rights

Plant variety rights do not recognise the contribution of farmers whose small-scale, ongoing innovation has contributed to the diversity in plant genetic resources from which new varieties can be developed. In order to redress this imbalance the concept of Farmers' Rights has been developed, within the context of the UN Food and Agriculture Organisation (Resolution 5/89 of the FAO Commission on Plant Genetic Resources).

As defined in Resolution 5/89, Farmers' Rights recognise the rights of farmers "arising from their past, present and future contribution to conserving, improving, and making available plant genetic resources, particularly those in centres of origin/diversity". Unlike traditional IPRs, Farmers' Rights do not confer private rights. As developed within the FAO, they are "vested in the international community, as trustees for present and future generations of farmers", for the purposes of ensuring that farmers receive the full benefits derived from the use of their contributions by plant breeders, and of supporting the continuation of their contributions. They do not, therefore, confer directly on farmers, or on local and indigenous communities, anything analogous to intellectual property rights.

It is envisaged that Farmers' Rights would be implemented through an International Fund for Plant Genetic Resources. As yet, however, the Fund is not in operation.

Classification of the issue of Farmers' Rights is a key element in the revision of the FAO International Undertaking on Plant Genetic Resources (see Chapter 2 on access and benefit-sharing).

Another means by which to reflect the contributions of countries and communities of origin to plant breeding programmes might be the development of non-UPOV, sui generis (specialised) systems of PVRs. Indeed, as an alternative to patent protection for plant varieties, Article 27.3(b) of the TRIPs Agreements permits the development of such sui generis systems. Current interpretations of Article 27.3(b) envisage the UPOV Convention as only one amongst a number of sui generis options. In view of this, various WTO Member countries are considering the development of sui generis systems better geared to protecting their interests in indigenous plant varieties. In the Pacific region, the most obvious and pressing example is Kava (see Kava case study in Annex 3).

Ex-situ collections and IPRs

In relation to ex-situ collections, concerns have arisen about the implications of free access and exchange policies. As noted in the Report of the First Meeting of the Working Group on IPRs, held in Suva in May 1997, a wide range of crop germplasm originating from many Pacific island countries is held in regional ex-situ collections. With the adoption of the Convention and increased awareness of biotechnology, the need to revisit distribution policies has been recognised. In general, these concerns have been addressed through the use of ex-situ germplasm acquisition agreements and material transfer agreements (MTAs). Such mechanisms are designed to ensure that material from ex-situ collections is not used as the basis for a new protected variety without some form of benefit-sharing with the country of origin of the germplasm.

As noted in Chapter 2, *ex-situ* collections of genetic resources acquired before the entry into force of the Convention on Biological Diversity are not subject to the Convention's provisions on access to genetic resources and benefit-sharing. Many ex-situ collections are, however, developing codes of practice to conform with the spirit of the Convention. The International Agricultural Research Centres (IARCs) of FAO's Consultative Group on International Agricultural Research (CGIAR) together hold the world's largest *ex-situ* collection of plant genetic resources. In 1994, each IARC signed an agreement with the FAO, designating certain germplasm in their collections as "held in trust for the benefit of the international community, in particular the developing countries" (see further Annex 5). Given revelations that certain organisations had sought IPRs on materials obtained directly from IARC collections, each of these agreements provides that the IARC concerned will seek neither legal ownership of, nor IPRs over, designated germplasm or related information. The same conditions apply to each organisation in receipt of designated germplasm from IARCs under MTAs (see further Annex 6). The designated germplasm in question includes farmers' varieties, landraces (primitive/ wild crop varieties), obsolete varieties, and modern varieties.

4.3 Protection of traditional knowledge and innovations

4.3.1 Potential uses of genetic resources and traditional knowledge

Many indigenous and local communities possess special or knowledge about biological diversity. One definition of traditional knowledge is "knowledge based on accumulated experience or continuous usage". Often, such knowledge has not been committed to writing, but passed on from generation to generation by oral teaching or demonstration. Traditional knowledge encompasses information and know-how on a wide variety of matters, including natural resources management, traditional medicines, crafts and artistic designs. Indigenous peoples generally consider traditional knowledge as incapable of being owned and therefore to be shared freely (Peteru, 1995).

Traditional knowledge and practices potentially provide crucial leads for bioprospectors in their search for "new" and useful genetic resources. In many cases, the use of traditional knowledge has been shown to significantly increase the probability of finding genetic resources of potential application in product development - one example being the case of the Mamala plant (see Box 5). Where, however, companies have gone on to develop and commercialise products based on the genetic resource concerned, as well as on any local knowledge and pre-existing uses associated with it, it has been rare for the indigenous or local community from which such knowledge was obtained to derive any benefits.

The scope of patent protection in developed countries has tended to grow with time, and it is questionable whether a number of patents granted for inventions based on genetic resources and traditional knowledge should really qualify for such protection, given that they may be neither novel nor inventive (see Boxes 5 and 6). Where such an 'invention' constitutes part of any prior traditional knowledge, strictly speaking, it should not be treated as novel. In the alternative, where an 'invention' is obvious on an assessment of traditional knowledge by a 'person skilled in the art', it should not be classed as inventive.

One reason behind the grant of such patents is that patent offices rarely take traditional knowledge into account in their assessments of prior art. Furthermore, there is no obligation for patent applicants to specify traditional knowledge upon which they have drawn, such as might assist patent office officials when examining claimed inventions for novelty and inventiveness. The development of community registers of biodiversity-related knowledge (see section 4.3.3 below) may serve to enhance recognition by both patent applicants and patent office officials.

Box 5: An example of the use of traditional knowledge: the isolation of Prostratin from the Mamala plant

The US Patents office lists a patent (No. 5,599,839) held by the three US entities relating to an antiviral composition and to methods of treating patients with viral infections. One active component of the antiviral composition is prostratin, which, the patent notes, can be purified either from a natural source or produced synthetically.

The patent states that, as part of an ongoing search for new antiviral agents, Mamala (Homolanthus acuminatus), a small endemic tree of Samoan primary forest and an important component of Samoan ethnopharmacology, was studied. Interviews with Samoan healers in Falealupo and Pesaga villages indicated that various parts of the plant are used to treat a variety of physical ailments. Bulk samples of the plant were collected and shipped back to the NCI Natural Products Repository in the USA (see Annex 4), and voucher specimens collected and deposited in herbaria of Brigham Young University and Harvard University.

The patent does not specifically record any prior informed consent for access, nor the terms of any benefit-sharing arrangements with the Samoan government, local communities or healers, for the collection and use of the resource and any associated knowledge.

Source: Rural Advancement Foundation International; US Patent 5,599,839 (U.S. Patent and Trademark Office website); and WWF: Measures to Control Access and Promote Benefit-sharing Measures: A Selection of Country Case Studies.

The Convention on Biological Diversity contains provisions which support the rights and interests of indigenous and local communities in controlling access to resources and in sharing in benefits arising out of the use of those resources (see Chapter 2 on Access and Benefit-sharing). It also provides a basis for indigenous and local communities to assert their own IPRs in relation to existing uses of biological diversity. In particular, Article 8(j) of the Convention addresses the equitable sharing of benefits arising from the utilisation of traditional knowledge, innovations and practices.

The COP has called on the Convention Secretariat to compile case studies on the relationship between IPRs and the traditional knowledge, practices and innovations of indigenous and local communities, as well as on examples of sui generis (specialised) IPR systems. At its fourth meeting, the COP also requested the Secretariat to seek ways to enhance co-operation between the Convention and WIPO on issues arising within the context of Article 8(j) and related provisions. COP 4 also established an ad hoc intersessional working group on Article 8(j) and related provisions. Included in the mandate of the working group is reference to the provision of advice as a priority in the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities (see Box 7 below).

Box 6: An example of the use of traditional knowledge: the "Ayahuasca" Patent Case

The US Patents office lists a patent (No. 5, 751) issued on 17 June 1986 which claims rights over a supposed new and distinct plant variety - dubbed "Da Vine" by the patent holder - of a plant species native to the Amazon rainforest, Banisteriopsis caapi. Shamans of many indigenous tribes in the Amazon collect and process the plant to produce a ceremonial drink - "ayahuasca" also called "yagé". The shamans use ayahuasca in religious and healing ceremonies.

In March 1999, the Coordinating Body of Indigenous Organisations of the Amazon Basin (COICA) and the Coalition for Amazonian Peoples and their Environment, represented by the Center for International Environmental Law (US), submitted a Request for Reexamination of the patent to the US Patent and Trademark Office (PTO). The Request sought the patent's cancellation on the basis that "the 'Da Vine' cultivar is neither distinct nor new". The Request's arguments focussed on the prior art. It claimed that "the medicinal and morphological characteristics on which the [patent claim] is based are well within the normal range of variation for individual plants of the species, and both the species and the characteristics described in the patent are well known,

Contents of box continue to next page

Box 6: An example of the use of traditional knowledge: the "Ayahuasca" Patent Case (continued from previous page)

not only in the scientific literature, but also in the systems of traditional knowledge of indigenous groups throughout the Amazon".

Furthermore, it was alleged that, because the variety is found in an uncultivated state, the patent contravened the US Plant Patent Act (35 United States Code, section 161). The Request also alleges that the patent is contrary to the public policy and morality clauses of the Patent Act due to B. caapi's sacred status amongst Amazonian peoples.

The application to the US PTO also called for a more general review of the treatment of traditional knowledge and biological diversity under US patent laws.

The US Patents Office has now cancelled the patent, given that publications describing Banisteriopsis caapi were 'known and available' prior to filing of the patent application. Under US patent law, no invention can be patented if described in printed publications more than one year prior to the date of the patent application.

In separate proceedings, the opponents of the patent have called for the US Patents Office to change its rules so as to require patent applicants to identify all biological resources and traditional knowledge used in claimed inventions, including the geographical origin of those resources, and to provide evidence that source countries and indigenous communities have consented to their use.

Source: David Downes, Senior Attorney, Center for International Environmental Law, Washington. http://www.ciel.org

Box 7: Future work on traditional knowledge under the Convention on Biological Diversity

The protection of indigenous knowledge, innovations and practices was discussed in a workshop on the implementation of Article 8(j), held under the auspices of the Convention in Madrid, in November 1997. The workshop was held in accordance with Decision III/14 of the Conference of the Parties. It was mandated to provide advice to the fourth meeting of the COP in May 1998 on possible future work on Article 8(j) under the Convention. The workshop recommended various options for the structure and elements of a future work programme on Article 8(j), as well as the establishment of an open-ended inter-sessional working group or a subsidiary organ to consider implementation of Article 8(j) and related provisions of the Convention.

At its fourth meeting, the COP decided to establish an ad hoc open-ended inter-sessional working group, composed of Parties and observers, in particular representatives of indigenous and local communities, to address the implementation of Article 8(j) and related provisions by:

- advising on the application and development of legal and other appropriate forms of protection for traditional knowledge, innovations and practices;
- providing the COP with advice on the implementation of Article 8(j) and related provisions, in particular on the development and implementation of a programme of work at national and international levels;
- developing a work programme based on the recommendations of the Madrid Workshop;
- identifying objectives and activities falling within the scope of the Convention and recommending priority issues; and,
- advising on mechanisms to strengthen co-operation at the international level among indigenous and local communities. (Decision IV/9)

The working group met for the first time between 27 and 31 March 2000 in Seville, Spain, and adopted a work programme, divided in two phases, that has been endorsed by COP 5. The work programme will be implemented by the Secretariat and the Ad Hoc Working Group, in collaboration with relevant organisations. The COP recognised that the maintenance of traditional knowledge depends on maintaining indigenous and local communities' cultural identities and material base, and emphasised the need for arrangements controlled and determined by them to ensure that they can make informed decisions on the release of their knowledge (Decision V/16).

4.3.2 Can intellectual property rights protect traditional knowledge and innovations?

There has been some discussion as to whether IPR regimes might be used or adapted to provide protection for applications of traditional knowledge and innovations. Traditional IPRs, such as patents, are not presently capable of, or suitable for, providing protection for traditional knowledge, innovations and practices relating to biological diversity. For example:

- To be granted a patent, an applicant needs to show novelty, inventive step and capability of industrial application. Traditional knowledge, practices and innovations have frequently been passed on from previous generations. It might therefore be difficult to fulfill the novelty requirement.
- Patents provide exclusive rights and are granted to individual natural or legal entities, rather than to communities.
- Patents protect the commercial use of inventions.
- Patent protection, and other IPRs, are of limited duration.
- To a large extent, the eligibility of an invention for patent protection, and the extent of that protection when granted, depends upon the skill with which the patent application is drafted. Significant resources may therefore be required to submit successful patent applications.

A few forms of IPRs may, however, provide some basis for the protection of the knowledge of indigenous and local communities. Trade secrets, for example, protect confidential information and enable the owner of such information to prevent unauthorised disclosure. They might therefore be used to protect knowledge regarding medicinal or other uses of particular resources held by indigenous or local communities. However, in order to qualify for trade secret protection, information must not be widely known or shared. This may be at odds with oral traditions and other practices by which useful information is held by communities. Enforcing trade secrets may also present difficulties.

Suggestions have also been made for using trademarks, geographical indications and copyright protection with regard to genetic resources and traditional knowledge.

4.3.3 Suggested sui generis systems of protecting traditional knowledge, innovations and practices

The inadequancies of existing IPR regimes, and the need to provide better protection for the traditional knowledge, innovations and practices of indigenous and local communities in the light of their increased use by corporations, have led a number of organisations and individuals to devise alternative, sui generis (specialised) IPR-type regimes. Proposed mechanisms include:

Community intellectual rights

This model has been proposed by Third World Network as an interim sui generis regime for the protection of plant varieties in accordance with the TRIPs Agreement and the Convention on Biological Diversity. The proposal would render the local community the lawful and sole custodians and stewards of all innovations (defined to include any collective and cumulative knowledge of any use, properties, values and processes of any plant varieties). Anyone seeking to use any innovation for commercial purposes would be required to make payments to the local community. The proposal would allow communities to register innovations with a Registry of Innovation to assist in protecting their interests. (http://www.twnside.org.sg).

Community registers of biodiversity-related knowledge

Community registers have been proposed by some non-governmental organisations in India to document and register the knowledge and techniques of local communities relating to biological resources (see Box 8). Information on the registers would be made available only with the knowledge and consent of the community concerned, which

could refuse or set conditions for access. Part of the rationale of the registers is that they might assist individuals and communities in demonstrating their prior knowledge and use of resources. This might assist them in obtaining a share of benefits derived from subsequent use of that knowledge. On the other hand, some fear that the registers risk placing information on knowledge of resources in the public domain. Careful design is therefore necessary. As databases they could, for example, be protected by copyright. COP 5 requested Parties to support the development of traditional knowledge registers.

Geographical indications and trademarks

Although geographical indications and trademarks are, strictly speaking, conventional IPRs, they might provide useful models for the development of sui generis systems.

Geographical indications identify goods as originating from particular territories, regions or localities to the which quality, reputation or other characteristics of such goods are attributable. As such, they could be adapted to regulate the exploitation of products based on the knowledge, innovation and practices of indigenous and local communities, so long as the characteristics of such products are uniquely attributable to those traditions. (UNEP/CBD/COP/3/22). It has, for example, been suggested that a geographical indication be obtained for quinoa (Chenopodium quinoa), a nutritious grain crop from the Andes, if it can be shown to possess distinctive characteristics resulting from its cultivation in its region of origin, according to traditional methods (Downes and Laird, 1999).

Trademarks give a producer the exclusive right to use a distinctive, recognisable and reliable mark or name to distinguish a product from those of its competitors. They might also provide a useful model for the regulation of products based on local and indigenous traditions. It has been proposed that Pacific Island Countries might develop a Pacific Kava trademark, collective mark or certification mark, identifiable with Kava products that originate from the South Pacific, as opposed to commercial Kava plantations outside the region (Peteru, 1999; Downes and Laird, 1999) (see the Kava Case Study in Annex 3).

1985 WIPO/UNESCO Model Provisions on the Protection of Expressions of Folklore

The Model Provisions specify that communities (rather than just individuals) should be recognised as innovators. They also recognise that community innovations may be ongoing or evolutionary and therefore provide for ongoing protection, compared to the limited duration of most IPRs. http://www.wipo.org

Traditional resource rights

This proposal suggests that there already exist in international agreements (such as human rights instruments) elements, which could form the basis of a sui generis regime for the protection of traditional knowledge and resources. http://users.ox.ac.uk/~wgtrr/

National and/or regional priorities and circumstances will be key to determining the need for and nature of appropriate sui generis regimes. Issues for consideration are likely to include existing arrangements for ownership and/or control of resources and knowledge, and the legal personality of indigenous and local communities.

One option is to include provisions on a sui generis system of IPRs within national laws addressing biological diversity conservation. An example of such an initiative is the Costa Rica Ley de Biodiversidad (Biological Diversity Law) adopted in April 1998. The Costa Rican Law recognises the need to protect traditional, individual or collective knowledge and innovations through appropriate legal mechanisms, and refers specifically to patents, trade secrets, plant variety rights, sui generis community intellectual rights, copyrights and farmers' rights. It requires that a participatory process be initiated to develop an appropriate sui generis system (see further Annex 1).

Box 8: Community Registers of Biodiversity-Related Knowledge: the People's Biodiversity Registers Programme in India

Peoples Biodiversity Registers, sponsored by WWF India, and co-ordinated by the Centre for Ecological Sciences of the Indian Institute of Science (IISc) and the Foundation for Revitalisation of Local Health Traditions (FRLHT), seek to:

(1) provide records of local knowledge for the use of present and future generations of village community people;

(2) promote the revitalisation of local knowledge by:

- recognising the range of such knowledge;
- rewarding outstanding knowledge, skills, techniques and conservation practices;
- validating and promoting sound local knowledge and resource management and traditions; and
- promoting inter-community transfer of knowledge for capacity enhancement.

(3) alert conservationists about the need for action concerning threatened resources and for protection of local resource rights; and

(4) protect local biological diversity from misappropriation by companies through the patenting of modified products, processes and biological resources.

Peoples Biodiversity Registers are currently under development in at least 57 villages in various Indian States. Local Communities are actively involved in the documentation of their knowledge. The project advocates a decentralised, bottom-up approach whereby communities are given incentives to participate in documentation processes. A network of databases will be created, linked to a consolidated national database that will give full credit to the origin of information, including individuals, communities or village councils. Each Peoples Biodiversity Register will be held by a local elected council (panchayat), educational institutions and a proposed district biodiversity cell serving as a computerised repository for Registers produced within the district. Registers will be periodically reviewed and updated.

Ten categories of information are held on Peoples Biodiversity Registers:

- user groups using local biological resources;
- local ecological habitats;
- local ecological history;
- extent and distribution of local collective and individual knowledge about the components of local biological diversity;
- abundance, scarcity and distribution of living organisms;
- patterns of subsistence and commercial utilisation of living resources;
- efforts to regulate the use of conservation on living resources by local communities and government agencies;
- development aspirations of local communities and how these relate to local biodiversity;
- divergences and agreements among various local groups concerning management of local resources; and
- emerging options for managing the natural resources of the study site, with particular focus on biodiversity conservation.

Regulation of access to information on Peoples Biodiversity Registers is envisaged as a means to promote benefit-sharing. In Karnataka State, draft legislation would, for example, empower panchayats to collect fees from bioprospectors, wishing to access information on Peoples Biodiversity Registers, under a system of Material Transfer Agreements and Information Transfer Agreements.

Source: Downes, D.R. and Laird, S.A., 'Community Registers of Biodiversity-Related Knowledge. The Role of Intellectual Property in Managing Access and Benefit-Sharing'. Prepared for UNCTAD Biotrade Initiative, March 1999 (Corrected Final Draft, pages 11-13).

Within the South Pacific region, Ministers attending the South Pacific Forum Trade Ministers Meeting on 1 June 1999, recommended that the Forum's member countries look to the development of rules and regulations aimed at protecting the IPRs of indigenous peoples. With respect to Kava, IPRs were also discussed at the October 1998 Second Regional Kava Symposium, held by the Kava Forum in Fiji.

4.4 Incentives for conservation and sustainable use

Article 11 of the Convention requires Parties to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of biological diversity. To be supportive of the objectives of the Convention, IPRs should therefore provide incentives for such conservation and sustainable use, while avoiding giving incentives to activities that may have adverse impacts on biological diversity. For example, some opponents of patents on plant varieties and of plant variety rights assert that the emphasis on commercial breeding leads to genetic erosion. They allege that commercial breeding promotes the use of a few elite crop varieties, while neglecting traditional varieties, to the detriment of biological diversity. It is also claimed that granting patents in respect of genetically (living) modified organisms may create risks to biological diversity since the potential impacts of such modified organisms are not yet fully known.

In this context it has been suggested that such applications for IPRs might be subject to some form of environmental impact assessment (based upon the precautionary principle), to assess their potential effects on biological diversity. It has also been suggested that patent offices should adopt a more rigorous appraisal of the usefulness of inventions. As presently established, however, national patent offices may not be equipped to carry out such tasks.

4.5 Ethical considerations

Developing IPRs or similar mechanisms for protecting the use of genetic resources and associated knowledge clearly raises a number of ethical, as well as socio-economic, considerations. These are matters for public policy, to be determined by the governments and stakeholders concerned.

Box 9: Declarations on Traditional Knowledge and Intellectual Property Rights

A number of conferences have been held addressing the concerns of indigenous and local communities to protect their resources and knowledge. Three of particular relevance for the Pacific region are:

Kari-Oca Declaration and Indigenous Peoples Earth Charter: these were adopted at the World Conference of Indigenous Peoples on Territory, Environment and Development in 1992. The Earth Charter requires, amongst other things, that indigenous peoples' intellectual and cultural property rights over genetic resources, genebanks, biotechnology and knowledge of biological diversity be guaranteed and that mechanisms for their recognition be examined and implemented.

Mataatua Declaration: the Mataatua Declaration on Cultural and Intellectual Rights of Indigenous Peoples was adopted in 1993. It declares that commercialisation of any traditional plants and medicines of indigenous peoples must be managed by the people who have inherited such knowledge; and that a moratorium should be put in place on such commercialisation until indigenous communities have developed appropriate protection mechanisms.

Suva Declaration: this was adopted at a Consultation on indigenous peoples' knowledge and intellectual property rights held in Suva in 1995. It calls for a moratorium on bioprospecting in the Pacific until appropriate protection mechanisms are in place, and urges the exclusion of lifeforms from patentability.

Most obviously, many indigenous and local communities and governments may be concerned about the "commodification" of traditional knowledge and of living organisms or material. Such concerns have, for example, been expressed in declarations such as the Mataatua Declaration and the Suva Declaration (see Box 9 below). Concern has, in particular, arisen in the context of attempts to obtain patents over human genetic resources. As noted in Chapter 2 Access and Benefit-sharing, Decision II/11 of the Conference of the Parties to the Convention on Biological Diversity reaffirmed that human genetic resources are not included within the framework of the Convention.

5. INTERNATIONAL DEVELOPMENTS

Box 10: Treaty for a Life-Forms Patents-Free Pacific and Related Protocols - 1995 Suva Consultation meeting

Participants at a regional consultation on Intellectual Property Rights and Indigenous People's Knowledge held in Suva in 1995 suggested the establishment of a Treaty for a Life-forms Patents-Free Pacific and related protocols. The document, which is not a binding legal instrument, was based on a number of underlying principles, including the principle that the conversion of life-forms, their molecules or parts, into corporate property through patent monopolies is counter-productive to the peoples of the Pacific. It argued that national laws and provisions in international agreements allowing for the patenting of life forms should be repealed (Article 3). The related protocol on bioprospecting reiterates that patenting should not be allowed of any living thing or product derived from it. This provision is stated to be without prejudice to the rights of indigenous peoples, traditional farmers and traditional fishermen to maintain exclusive control over access to, and use of knowledge, innovations, cultural traditions, and management practices concerning biological diversity and their right to just compensation for sharing any of these.

5.1 The Conference of Parties to the Convention on Biological Diversity

Intellectual property rights have been the subject of quite extensive discussions by the Conference of the Parties (COP) to the Convention on Biological Diversity. The COP has called for co-operation and consultation with WIPO. It has recognised the need for further work on the relationship between IPRs and the achievement of the Convention's objectives, and has called for case studies on the impacts of IPRs on biodiversity and on traditional knowledge, innovations and practices. The question of IPRs and sui generis regimes for the protection of traditional knowledge was a critical focus of the 1997 Madrid Workshop on Article 8(j). Its conclusions were addressed by the fourth meeting of the COP in May 1998 in discussions on access and benefit-sharing and on the implementation of Article 8(j) and its related provisions.

The COP has also asked the Convention Secretariat to liaise with the World Trade Organization Secretariat on the interrelationship between the Convention and TRIPs. At its fourth meeting, the COP emphasised that further work was required in order to develop a common appreciation of the relationship between IPRs, TRIPs and the Convention, in particular on issues relating to technology transfer, benefit-sharing and the protection of traditional knowledge, innovations and practices. An intersessional meeting of the Convention in June 1999 recommended that the COP might develop ways and options to closely follow the work done by WIPO and WTO on the relationship between IPRs, TRIPs and the Convention, and provide input into this work from the perspective of the Convention. It also recommended that the COP recognise the importance of sui generis systems to protect traditional knowledge and transmit information thereon to the WTO and WIPO.

At its fifth meeting, the COP invited WIPO to analyse issues of intellectual property rights as they relate to access to genetic resources and benefit-sharing, including the provision of information on the origin of genetic resources, if known, when submitting applications for IPRs, including patents. COP 5 further requested WIPO and UPOV to

take account of relevant provisions of the CBD, including the impact of intellectual property rights on the conservation and sustainable use of biodiversity, and in particular, the value of knowledge, innovations and practices of indigenous and local communities.

5.2 The conclusions of the October 1999 Experts' Panel on Access and Benefit-Sharing: issues relating to intellectual property rights

Pursuant to Decision IV/8 of the fourth Conference of Parties to the Convention, an Experts' Panel on access and benefit-sharing was convened in Costa Rica in October 1999 (see Chapter 2). It examined in some detail the relationship between intellectual property rights, and access and benefit sharing. The Panel was unable to reach a definitive conclusion as regards this relationship but it raised some salient issues for further consideration by COP 5 (UNEP/CBD/COP/5/8):

Prior informed consent (PIC) for access to genetic resources

Certain participants suggested that IPR applicants should submit proof of PIC for access as a precondition for the grant of IPRs in inventions involving genetic resources. Alternative suggestions were made, such as examining the efficacy of user country legislation and multilateral information systems in promoting the Convention's objectives. The Panel invited COP 5 to address this issue in depth.

Traditional knowledge related to genetic resources

The Panel called on COP 5 to consider means of achieving progress over:

- the definition of relevant terms;
- identification of the subject matter of traditional knowledge and the scope of existing rights;
- whether existing IPRs can be used to protect traditional knowledge;
- options for the development of sui generis systems;
- studying the relationship between customary laws of custodianship and use, and the transmission of traditional knowledge with formal IPR systems;
- implementing pilot projects to test means of protecting traditional knowledge based on IPR, sui generis possibilities and customary law;
- ensuring that the grant of IPRs does not preclude further customary use; and
- taking note of the work of relevant bodies at the community, national, regional and international levels, as well as that of the CBD, UNESCO, WIPO, WTO and FAO.

The role of IPRs in contractual access and benefit-sharing agreements

The Panel agreed that contractual agreements play an important role in promoting access and benefit-sharing under the CBD, and that they should be consistent with national and international law. Amongst other guiding parameters that the Panel highlighted for the conclusion of such agreements, the participants suggested that:

- provision should be made for the exploitation and use of IPRs;
- the possibility of joint IPR ownership should be accounted for; and
- the use of licenses as a means for providers to secure continued control over the use of their genetic resources should be explored.

The scope of IPR protection, prior art and monitoring

The Expert Panel was concerned that the existing scope of IPR protection might prejudice the interests of communities with regard to their knowledge, innovations and practices. They suggested that the development of traditional knowledge registers would promote the identification and accessibility of such knowledge in assessments of prior art. The Panel also touched on the need for monitoring patent applications for claimed inventions based on genetic resources and associated traditional knowledge.

As noted in chapter 2, the conclusions of the Expert Panel were considered by COP 5 in May 2000. In Decision V/26, the COP notes that the Expert Panel did not come to any conclusions on the role of IPRs in the implementation of access and benefit-sharing arrangements, and invites Parties to submit information on these issues by 31 December 2000. COP 5 requested the Secretariat to prepare a report on the basis of these submissions and to make it available for the second meeting of the Experts Panel, or the first meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

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4 GENETICALLY MODIFIED ORGANISMS AND BIOSAFETY

In January 2000, a new international agreement addressing the transboundary movement of genetically modified organisms was adopted, the Cartagena Protocol on Biosafety. A copy of the Protocol, which was adopted pursuant to Article19 (3) of the CBD, is included in Annex 6 of this package.

This Chapter is intended to provide a basic introduction to issues and regulatory challenges related to the release of genetically modified organisms (GMOs) into the environment. It provides a brief overview of the main provisions of the Protocol, and also outlines features of regulatory approaches to biosafety taken in some countries to date.

INTRODUCTION

This chapter is intended to provide a basic introduction to issues and regulatory challenges related to the release of genetically modified organisms into the environment. It provides a brief overview of the main provisions of the Cartagena Protocol on Biosafety (adopted in January 2000), and also outlines features of regulatory approaches to biosafety taken in some countries to date. A copy of the Protocol, which was adopted pursuant to Article19(3) of the CBD, is included in Annex 6 of this package.

Section 1 of this chapter introduces the issue of biosafety, providing some examples of genetically modified organisms and outlining potential benefits and risks associated with the use of modern biotechnology. In Section 2, the provisions of the CBD addressing biosafety are identified. Section 3 provides an overview of the recently adopted Cartagena Protocol on Biosafety, outlining some of its principal provisions and implications. A number of other international instruments and activities relevant to biosafety are identified in Section 4. Section 5 provides a brief outline of some national level approaches to biosafety, including regulation of the development, use, release and marketing of genetically modified organisms. Some examples of and opportunities for regional co-operation in relation to biosafety are identified in Section 6. Finally, Section 7 highlights some issues and consideration for Pacific island countries in relation to biosafety which have been identified by SPREP in a 1998 briefing paper on this issue.

A range of sources of further information and examples are identified at the end of the chapter. As far as possible, sources have been indicated which are available on the internet.

1. ISSUES

1.1 Genetically modified organisms and biosafety

The term "biosafety" as used in this chapter generally refers to the safe handling and use of genetically modified organisms (GMOs).

Genetically modified organisms are organisms produced using modern biotechnology techniques (also called "gene technology") whereby genetic material from one species is inserted into another species in order to introduce specific desired novel characteristics (traits). These characteristics may include, for example, pest-resistance, herbicide-resistance or resistance to a particular disease. The Convention on Biological Diversity does not use the term GMOs but refers instead to "Living Modified Organisms" (or "LMOs") which is the term which will be used in the remainder of this chapter.

Box 1: Examples: Bt maize; "Roundup Ready" cotton; and GM salmon

Bt maize is maize genetically modified so as to be resistant to a particular pest - a gene for a toxin derived from a naturally occurring soil bacterium is inserted into the maize, enabling it to produce the toxin, thus killing insect pests. *Bt* maize has been approved for release in a number of countries including USA and European Union countries - although some European countries have imposed bans or restrictions on its use.

"*Roundup Ready* cotton" is a cotton which has been genetically modified for tolerance to a herbicide, glyphosate, the active ingredient of *Roundup®*, a herbicide manufactured by Monsanto. *Roundup Ready* cotton is intended to assist farmers to improve weed control since crops can be treated with Roundup while the cotton is growing. - By contrast, use of *Roundup®* on unmodified cotton would also kill the cotton crop itself. The use of *Roundup Ready* cotton has been approved in the USA. An application for commercial scale release of the modified cotton is currently under consideration in Australia.

Genetically modified salmon – In New Zealand, contained research is taking place on modified Chinook salmon (*Oncorhynchus tshawytscha*). The salmon is modified, *inter alia*, with a growth-promoting gene aimed at developing salmon that can attain marketable size faster than unmodified salmon.

Sources: UK Advisory Committee on Releases to the Environment; Australia Interim Office of the Gene Technology Regulator, Summary Sheet: general (commercial) release of Roundup Ready Cotton; Environmental Risk Management Authority, New Zealand: Press Release 24 November 1999.

Regulations addressing genetically modified organisms generally exclude from their scope of application organisms which have been produced using conventional or traditional breeding methods.

In the 2000 Protocol on Biosafety, the following definitions appear[1]:

> ***Living Modified Organism*** means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology
>
> ***Living Organism*** means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses or viroids
>
> ***Modern Biotechnology*** means the application of:
>
> (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles
>
> (b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[1] Cartagena Protocol on Biosafety, Article 3, paras. (g), (h), and (i). See further section 3 below.

Other definitions of GMOs are contained in, for example, the UNEP International Technical Guidelines on Safety in Biotechnology[2], and in various examples of existing national legislation.

1.2 Why regulate Living Modified Organisms?

Biotechnology has a number of potentially useful applications. It is described in Agenda 21 as "a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA), or genetic material, in plants, animals and microbial systems, leading to useful products and technologies" (Agenda 21, Chapter 16.1).

Agenda 21 states that biotechnology "promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, 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". (Agenda 21, Chapter 16.1). Potential applications of biotechnology products exist in, inter alia, the pharmaceutical, agricultural and environmental sectors. For example, modern biotechnology techniques allow scientists to develop pest-resistant or herbicide resistant crops; plant varieties designed to produce increased yields or to yield fruit with delayed ripening characteristics; novel animal vaccines; and products for use in bio-remediation activities for environmental clean-up (Zannoni, 1997).

While modern biotechnology and applications of LMOs may offer the potential benefits described above, serious concerns have also been expressed about the potential risks to the environment, particularly biological diversity, posed by the release of LMOs into the environment. These concerns are heightened given the relatively small amount of experience with releases of LMOs to date, and the fact that any adverse effects may be manifested over the long-term.

Thus, the key aims of national biosafety regulation tend to be to protect public health and safety and to protect the environment against any possible adverse effects (below) of LMOs. As activities involving LMOs expand, and in particular as commercial scale releases increase, so the scope of national regulation tends to expand[3].

At a general level, it has been suggested that LMOs released into the environment may pose similar types of risks to those presented by alien invasive species. In relation to the deliberate release of LMOs into the environment (for example, for the field-testing or commercial growing of genetically modified crops, or the release of genetically modified fish in aquaculture or mariculture projects), concerns about biological diversity tend to relate to, for example:

- the potential dispersal of the LMO in the environment - e.g. through invasiveness or enhanced competitiveness;
- the potential transfer of the inserted genetic material (and related characteristics) to other crops or native plants - e.g. through cross-pollination;
- potential adverse effects of genetically modified crops on non-target species - for example, some studies have suggested that crops modified to be resistant to insect pests may also have adverse effects on beneficial insects and birds;
- potential impacts on soil bacteria and the nitrogen cycle;

[2] UNEP, 1995. The UNEP Guidelines refer to "organisms with novel traits", which are defined in Annex 2 to the Guidelines as "Organisms produced by genetic modification and whose resultant genetic make-up is unlikely to occur in nature. These do not include organisms obtained by conventional techniques and traditional breeding methods" "Genetic modification" is in turn defined as "Modern biotechnology used to alter genetic material of living cells or organisms in order to make them capable of producing new substances or performing new functions."

[3] See for example, consultations on the 2000 Gene Technology Bill in Australia, http://www.health.gov.au/tga/genetech.htm

- indirect effects on the environment - i.e. where changed agricultural practices associated with the management of a genetically modified (GM) crop rather than the GM crop itself has impacts on the environment.

Concerns have also been raised about the possible impacts on human health arising from the consumption of food containing or produced with LMOs. This Chapter does nor directly address food safety issues associated with foods derived from LMOs. However some national biosafety regulations do already address this issue.

In addition, in international discussions in particular, concerns have been expressed regarding the potential socio-economic impacts of the use of LMOs, for example, where the development of a particular LMO displaces a cash crop, e.g. the possibility that a GM enhanced sweetener might reduce demand for sugar.

There is no real scientific consensus to date on the extent of the risks outlined above, and opinions tend to be polarised. At the policy level therefore, there has been disagreement as to whether LMOs should be regulated on the basis of the technology used in their creation, or whether any potential risks that LMOs may present can and should be addressed under existing relevant product-safety regulations, for example on food safety, pharmaceuticals, pesticides, and herbicides etc. Thus, some countries which have adopted national biosafety frameworks have adopted technology-based legislation specifically addressing LMOs as a category. Others (e.g. USA) have chosen to rely instead on existing product-based legislation, which address risks which may be associated with particular uses of LMOs, but which could also arise with similar, but unmodified, products. Some countries which have used this latter approach have also adopted back-up or "safety net" legislation to catch those LMOs which may not be covered under existing rules[4].

Box 2: Alien/ invasive species

As noted in the 1998 SPREP paper, Biotechnology and Biosafety - The Development of a Protocol under the Framework of the Convention on Biological Diversity, from a practical perspective, alien, or invasive, species can raise similar kinds of concerns as living modified organisms (LMOs) for the conservation and sustainable use of biological diversity in fragile island ecosystems: for example, in relation to threats posed to vulnerable or endemic species. Invasive species are the subject of a special work programme of SPREP.

The Convention includes a provision on alien species in Article 8(h). This provides that the Parties shall, as far as possible and as appropriate:

Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species.

In 1993, after the adoption of the Convention, UNEP established a number of expert panels to follow-up on various issues in advance of the first meeting of the Conference of the Parties of the Convention, including one to consider the need and modalities of a protocol on biosafety. It was decided to treat living modified organisms and alien species separately under the Convention. This approach has been retained in the CBD and separate work is underway on alien species. However, as noted in the 1998 SPREP paper, although not linked at the international level, some similar mechanisms might be used at the national or regional level to address the potential risks posed by alien species and LMOs.

2. Biosafety and the Convention on Biological Diversity

The Convention on Biological Diversity specifically addresses biosafety in two Articles: Article 8 (on *In-situ conservation*) and Article 19 (on *Handling of Biotechnology and Distribution of its Benefits*).

[4] For examples of various existing and emerging national approaches, see Proceedings of International Workshop on Biosafety Regulatory Capacity-Building, Mexico City, January 1999.

Article 8(g) 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 living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.*

Article 19 of the Convention, which addresses handling of biotechnology and distribution of its benefits, provides, in paragraphs 3 and 4:

> *3. The 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 the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.*
>
> *4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.*

The inclusion of Article 19(3) in the Biodiversity Convention was contentious, as some governments saw no need for an international agreement on biosafety. In 1994, at its first meeting after the entry into force of the Convention, the governing body of the Convention, the Conference of the Parties (COP), provided for two meetings to be held to consider the need for and modalities of a Protocol. Accordingly, a meeting of experts was held (in Cairo), and an open-ended meeting (i.e. open to all Parties to the Convention, as well as observers) was held in Madrid. While there was general agreement at the Madrid meeting that certain issues, such as an advance informed agreement procedure (see below), should be included in a Protocol, other possible elements of the Protocol, such as liability and compensation and socio-economic considerations, were the subject of considerable disagreement.

At its second meeting, in 1995, the COP established an Ad Hoc Working Group on Biosafety (BSWG) to elaborate a Biosafety Protocol for consideration by the COP[5]. The COP recognised that, despite the considerable amount of knowledge on biotechnology, there were still significant gaps in our understanding of the interaction between LMOs and the environment. The BSWG was mandated to negotiate a protocol in the field of the safe transfer, handling and use of living modified organisms. The Protocol was to focus, in particular, on the transboundary movement of LMOs. In particular, the Protocol was to establish a procedure for advance informed agreement (AIA) in relation to transboundary movements of LMOs. Broadly speaking, AIA is similar to international prior informed consent regimes that are in place for the import and export of certain chemicals and hazardous wastes, i.e. the importing State is meant to receive information on the proposed transfer in advance, and is given the opportunity to accept or reject the import, based on the principles and procedures set out in the Protocol. (It is rare at present for national biosafety laws to regulate exports of LMOs so as to ensure that an exporter provides full information in advance to a country of import.)

[5] Decision II/5 of the Conference of the Parties

The BSWG held six meetings between 1996 and 1999. The final meeting of the Working Group took place in February 1999 in Cartagena, Colombia. The meeting was followed by an Extraordinary Meeting of the Conference of the Parties (ExCOP) to the Convention, which was intended to adopt the final text of the Protocol. However, States attending the meeting failed to agree on the text of the Protocol and the meeting of the COP was formally suspended.

The ExCOP resumed in January 2000 in Montreal, and the Biosafety Protocol was finally adopted on 29 January 2000.

While the Protocol was negotiated under the auspices of the Biodiversity Convention, it is a separate international legal instrument. States that are Parties to the Convention are under no obligation to become Parties to the Protocol, which is subject to its own signature, ratification and accession process. However, under the provisions of the Convention (Article 32), a State may not become a Party to a Protocol unless it is or becomes at the same time a Party to the Convention itself.

The Protocol was opened for signature at COP 5 in Nairobi in May 2000 where 68 Parties signed it, and it is currently open for signature at UN Headquarters in New York until June 4 2001. It will enter into force 90 days after the deposit of the 50th ratification.

3. 2000 CARTAGENA PROTOCOL ON BIOSAFETY

A copy of the Biosafety Protocol is included in Annex 6 to this package. The Protocol contains important new rights and obligations for countries that become Party to it relating to the transboundary movement, handling and use of LMOs. In particular, the Protocol sets out an Advance Informed Agreement (AIA) procedure, whereby an exporter wishing to export certain categories of LMOs to a country for the first time must notify the Party of import in advance and provide certain information relating to the LMO. The Party of import then has an opportunity to examine this information and may decide to accept or reject the import, or attach conditions to it, based on a risk assessment. These provisions are described in more detail below. The Protocol also contains provisions on capacity-building and financial resources.

The objective of the Protocol is, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs, taking also into account risks to human health, and specifically focusing on transboundary movement. (Article 1).

Box 3: Precautionary Principle

Principle 15, 1992 Rio Declaration on Environment and Development

In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

3.1 Scope of the Protocol and AIA procedure

The Protocol covers the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. (Article 4). However, some categories of LMOs are excluded either from all of the Protocol's pro-

visions or from its specific provisions relating to the AIA procedure. This is summarised in Box 4 and explained further below.

Box 4: Scope of the Protocol and of the AIA procedure: Articles 4–7

LMOs subject to the provisions of the Protocol

- *All* LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Art. 4)

LMOs excluded from the provisions of the Protocol

- LMOs that are pharmaceuticals for humans that are addressed by other international organisations or agreements (Art. 5)

LMOs subject to AIA provisions

- LMOs intended for intentional introduction into the environment (Art. 7(1))

LMOs excluded from the Protocol's AIA provisions

- LMOs in transit (Art. 6(1))
- LMOs destined for contained use in the Party of import (Art. 6(2))
- LMOs intended for direct use for food, feed or for processing (LMO-FFPs) (Art. 7(2))
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Art. 7(4))

3.2 Advance Informed Agreement (AIA) procedure

The AIA procedure applies to the first intentional transboundary movement into a Party of a covered LMO.

Competent authority

All Parties must designate one or more national competent authorities to be responsible for and performing the administrative functions required by the Protocol, and authorised to act on its behalf with regard to those functions. (Article 19)

Notification and information

The Party of export must notify the competent authority of the Party of import of the intended transboundary movement before it takes place, or it must require the exporter to do so. This notification must contain certain information relating to, inter alia, the exporter, the LMO, and its intended use. The required information is specified in Annex I to the Protocol.

Decision of Party of import

Within 90 days of receiving the notification, the Party of import must acknowledge receipt. Within 270 days of receiving the notification, the Party of import must communicate its import decision to the notifier and to the Biosafety Clearing House established under the Protocol (see below). In its decision, the Party of import may either:

- Approve the import of the LMO, with or without conditions;
- Prohibit the import of the LMO;
- Request additional information; or
- Inform the notifier that the import decision will be taken within a further defined period of time.

Failure by a Party of import to communicate its decisions within 270 days does not imply its consent to the import of the LMO.

Risk assessment

A Party of import must base its decision on a risk assessment carried out in a scientifically sound manner. Risk assessment requirements are addressed in Article 15 and Annex III of the Protocol. The risk assessment must be based at a minimum on information

provided in the initial notification and other available scientific evidence to identify and evaluate possible adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

While it is the obligation of the Party of import to ensure that its decision is based on a risk assessment, it may require the exporter to carry out and/or bear the costs of the risk assessment.

In reaching a decision on whether to approve the import of a particular LMO, a Party of import may also take into account the precautionary principle, and certain socio-economic considerations. The Protocol provides that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on the conservation and sustainable use of biodiversity in the Party of import, taking also into account risks to human health, shall not prevent the Party of import taking a decision in order to avoid or minimise such potential adverse effects. (Article 10(8)). The Protocol also allows the Party of import, in reaching a decision, to take into account 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 (Article 26). In considering socio-economic impacts, Parties must act consistently with their other international obligations, including, for Members of the World Trade Organization (WTO), relevant WTO rules.

As explained further in section 5 below, carrying out and/or evaluating a risk assessment on an LMO will require a significant range of technical and scientific expertise. Decision-making is likely to require a number of new, or adapted, domestic institutions in addition to the competent national authority required under the Protocol.

Confidential information

Under Article 21, the Party of import must permit the notifier to identify which information provided under the notification and information procedure is to be treated as confidential. Where requested, the notifier must give justification for this. If there is disagreement as to which information should qualify as confidential, the Party of import should consult with the notifier, prior to any disclosure. Parties must not disclose confidential information received under the Protocol, or use it for a commercial purpose, except with the written consent of the notifier. The Protocol specifies certain information which can not be considered confidential, including a general description of the LMO, a summary of the risk assessment of its effects on biodiversity and human health, and methods and plans for emergency response.

National discretion

Although the Protocol sets out a specific AIA procedure for imports of certain LMOs, it allows Parties a fair degree of flexibility in the way this is applied. However, this flexibility is subject to an overriding obligation to act in accordance with the objective of the Protocol.

- First, a Party of import may decide to apply its own domestic regulatory framework in reaching an import decision, so long as this is consistent with the Protocol (Article 9(3) and Article 14(4)). In practice, this provision seems likely to be of more relevance to the many developed countries that already have regulatory frameworks for LMOs in place.
- Second, a Party of import may decide to adopt simplified procedures for the import of certain LMOs, provided that adequate measures are applied to ensure the safe transboundary movement of LMOs in accordance with the Protocol's objective (Article 13).
- Third, Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding the intentional transboundary movement of LMOs. These must be

consistent with the objective of the Protocol and must not result in a lower level of protection than that provided in the Protocol. Parties must inform the Biosafety Clearing House of any such arrangements. The specific AIA provisions of the Protocol will not apply to intentional transboundary movements of LMOs between parties to those agreements or arrangements (Article 14).

- Fourth, Parties are allowed, in relation to AIA and the other provisions of the Protocol, to take action for the conservation and sustainable use of biodiversity that is more protective than that provided in the Protocol. However, such action must be consistent with the objective and provisions of the Protocol, and be in accordance with a Party's other obligations under international law (Article 2(4)).

3.3 LMOs not subject to AIA provisions

As indicated in Box 4, the Protocol's specific AIA procedure does not apply to the following transboundary movements of LMOs:

3.3.1 LMOs in transit

The Protocol's specific AIA procedure does not apply to LMOs in transit. This exclusion is without prejudice to any right of a Party of transit to regulate the transport of LMOs through its territory. Parties may make available to the Biosafety Clearing House its decisions regarding the transit of specific LMOs through its territory.

3.3.2 LMOs destined for contained use

Again, the Protocol's AIA procedure does not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the Party of import. Contained use is defined in Article 3(b) of the Protocol. This is without prejudice to any right of a Party to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use in its jurisdiction. i.e. Although the AIA procedure does not apply, a Party can, through its national legislation, require risk assessment and prior authorisation before the import of an LMO for contained use.

3.3.3 LMOs intended for direct use for food, feed or for processing (LMO-FFPs)

The potential application of the Protocol, and in particular the AIA procedure, to LMO-FFPs (i.e. exports of genetically modified agricultural commodities, such as GM soya or maize for food or feed use, or GM tomatoes) was among the most controversial issues in the negotiation of the Protocol.

As noted above, the specific AIA procedure set out in Articles 8, 9, 10 and 12 of the Protocol does not apply to LMO-FFPs. However, the other provisions of the Protocol do apply to LMO-FFPs and certain specific obligations regarding LMO-FFPs are set out in Articles 11 and 18(2)(a).

Article 11 establishes a multilateral information exchange procedure on LMO-FFPs through the Biosafety Clearing House. Where a Party makes a decision on domestic use of an LMO that may be exported for direct use as food or feed or for processing, it must notify the other Parties through the Biosafety Clearing House within fifteen days. Information specified in Annex II of the Protocol must be provided.

Parties to the Protocol may require prior consent for import of LMO-FFP under their relevant domestic regulatory framework. Parties with laws or regulations applicable to the import of LMO-FFPs must make these available through the Biosafety Clearing House. The Protocol also recognises that some countries may not yet have applicable laws and regulations in place. It therefore provides that developing countries (and countries with economies in transition) which do not have an applicable domestic regulatory framework in place may declare through the Biosafety Clearing House that they

will take a decision on the first import of an LMO-FFP in accordance with a risk assessment, and within a time frame of not more than 270 days. The Protocol does not specify when this 270 period begins to run, nor does it specify any direct notification procedure between the exporter and the Party of import. Failure by a Party to communicate its decision within 270 days is not to imply either consent to or refusal of the import of the LMO-FFP concerned.

As under the AIA procedure, Parties are entitled to take into account the precautionary principle in reaching decisions on imports of LMO-FFPs (Article 11(8)).

The precise implications of the provisions of Article 11 on national regulations on the import of LMO-FFPs remain somewhat unclear and may require further clarification through the meeting of the Parties.

Under Article 18, shipments of LMO-FFPs must be accompanied by documentation specifying that they "may contain" LMOs, and that they are not intended for intentional introduction into the environment. This means that if a Party to the Protocol receives a shipment from another Party of agricultural commodities which may contain LMOs, it should be alerted to this fact by the accompanying documentation, even if it has not explicitly subjected imports of LMO-FFPs to a prior consent procedure under Article 11. In the Protocol negotiations, many countries argued that shipments of LMO-FFPs should clearly be identified as LMOs. However, certain agricultural exporting countries objected to such a requirement as this would require producers to segregate GM and non-GM grains at all stages of production, whereas current practice is to commingle them. They argued that such a requirement would be too costly. The meeting of the Parties to the Protocol is to take a decision on any detailed requirements in this respect within two years of the Protocol entering into force.

3.4 Other provisions

3.4.1 Biosafety Clearing House

The Protocol establishes a Biosafety Clearing House (BCH) as part of the Clearing House Mechanism under Article 18(3) of the CBD (see Chapter 1 Overview). The function of the BCH is to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and to assist Parties to implement the Protocol. As noted above, it has specific functions regarding LMO-FFPs. Article 20(3) sets out certain categories of information that Parties are to make available to the BCH. This includes:

- Laws, regulations and guidelines for implementation of the Protocol
- Bilateral, regional and multilateral arrangements under Article 14
- Decisions on import or release of LMOs
- Summaries of risks assessments or environmental reviews of LMOs generated by regulatory processes of Parties

3.4.2 Capacity-building and financial resources

The Protocol requires Parties to cooperate in the development and strengthening of human resources and institutional capacities in biosafety in developing country Parties, particularly least developed countries and small island developing States. Despite references to co-operation in capacity-building, there are no specific commitments from developed countries with regard to capacity-building.

The financial mechanism established under the CBD (operated by the GEF) is to be the financial mechanism for the Protocol. Guidance to the financial mechanism with regard to financial resources for implementation of the Protocol, will will go through the CBD COP. In this respect, it may be that biosafety will be "competing" with other

biodiversity issues for financial support from the GEF. In this respect, it may be that biosafety will be "competing" with other biodiversity issues for financial support from the GEF. No specific guidance is given in the Protocol as to the level of financial resources that may be needed for implementation of the Protocol.

COP 5 has emphasised the importance of financial support for capacity-building for implementation of the Protocol[6]. A number of capacity-building initiatives in relation to biosafety are already either underway or in the pipeline (see section 3.7 below).

The COP also welcomed the decision of the GEF Council requesting its secretariat to develop an initial strategy for assisting countries to prepare for the entry into force of the Biosafety Protocol[7] .

3.4.3 Unintentional transboundary movement of LMOs

In addition to its extensive provisions on intentional transboundary movements of LMOs, the Protocol also addresses, in Article 17, unintentional transboundary movements. It sets out notification and consultation requirements with regard to releases of LMOs that lead or may lead to unintentional transboundary movements that are likely to have significant adverse effects. Parties must provide to the BCH details of a contact point for receiving any such notifications.

3.4.4 Illegal transboundary movements of LMOs

The Protocol requires Parties to adopt domestic measures to prevent and penalise transboundary movements of LMOs carried out in contravention of its domestic measures implementing the Protocol. Such movements are to be deemed illegal. In such cases, the affected Party may request the Party of origin to dispose of the LMOs by repatriation or destruction. Cases of illegal transboundary movement are to be notified to the BCH.

3.4.5 Liability and redress for damage caused by LMOs

The question of liability and redress for any damage caused by LMOs was another contentious issue in the negotiations. It was not possible to resolve this issue during the negotiations, and the Protocol requires the first meeting of the Parties to adopt a process with respect to the appropriate elaboration of international rules and procedures for liability and redress for damage arising out of the transboundary movements of LMOs. This process is meant to be completed within four years.

3.4.6 Institutional arrangements

The Protocol establishes institutional arrangements to carry out further work on the elaboration and review of rules for transboundary movement of LMOs. It will "share" institutions with the CBD in that the CBD COP will serve as the "meeting of the Parties" of the Protocol (Article 29). However, only countries that become Parties to the Protocol will be able to participate in decision-making by the meeting of the Parties. Non-Parties to the Protocol (including non-Parties to the Convention) will be able to participate in the meeting of the Parties only as observers,

Subsidiary bodies established under the Convention, such as the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) may also serve the protocol (Article 30). Similar rules as for the meeting of the Parties will apply with regard to participation.

The Secretariat of the Convention will also act as the Secretariat for the Protocol. Countries that become Parties to the Protocol will have to contribute to any additional costs

[6] Decision V/11 on 'Additional financial resources', paragraph 11.

[7] Decision V/13 on 'Further guidance to the financial mechanism', paragraph 1.

of Secretariat services for the Protocol, and the first meeting of the Parties will decide on budgetary arrangements in this regard.

At its first meeting, the meeting of the Parties is due to consider and approve co-operative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance (Article 30). This may result in the establishment of additional institutions.

3.4.7 Dispute settlement

The Protocol does not contain specific provisions on the settlement of disputes arising under the Protocol, but it refers back to the relevant provisions of the Convention on Biological Diversity (Article 32). Article 27 of the CBD provides for optional recourse to judicial settlement or arbitration, or a conciliation procedure that is mandatory at the request of one of the parties to a dispute.

3.5 Biosafety and the World Trade Organization[8]

Members of the World Trade Organization (WTO) have certain obligations under the WTO Agreements that, among others, limit their right to restrict imports of goods. Any country that joins the WTO automatically becomes a Party to a "package" of multilateral trade agreements, including the General Agreement on Tariffs and Trade 1994, the Agreement on Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

The General Agreement on Tariffs and Trade prohibits quantitative restrictions (including prohibitions) on imports from other WTO Members. It also prohibits discrimination between "like products" originating from Member countries. The WTO Agreements also address non-tariff (technical) barriers to trade, of potential relevance to, for example, product labelling requirements[9]. Another WTO Agreement, the Agreement on Sanitary and Phytosanitary Measures, allows WTO Members to restrict or prohibit imports of certain products on sanitary and phytosanitary grounds (for example, to prevent the introduction or spread of pests). In such cases, sanitary or phytosanitary measure must be based on a risk assessment and the measure must be necessary to protect human, animal or plant life.

Questions as to the compatibility of the application of certain national biosafety laws and WTO commitments have arisen, particularly in the context of US exports of LMOs to the European Union.

A number of countries in the Protocol negotiations were concerned that rights and obligations of States under the Protocol should not conflict with, or take precedence over, the rights and obligations of Members under the WTO Agreements. They sought to insert a "savings" clause into the Protocol stating that the provisions of the Protocol would not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement (including the WTO Agreements). This was unacceptable to many other countries which were concerned that such a provision would limit their right to rely on the Protocol in restricting or prohibiting the import of LMOs which they considered potentially damaging to the environment or to human health in their country. Their concern was exacerbated by the fact that, unlike the Protocol, the WTO has a mandatory and binding dispute settlement procedure, to which disputes between WTO members involving trade in LMOs might be submitted.

[8] It is beyond the scope of this Chapter to discuss the requirements of the WTO Agreements in detail. Further information on the WTO Agreements is available at http://www.wto.org

[9] Agreement on Technical Barriers to Trade.

In the Biosafety Protocol, the relationship of the Protocol with other international agreements is dealt with in three paragraphs of the Preamble. While one these suggests that the Protocol and WTO Agreements should be "mutually supportive", the others do not express any clear guidance as to which of the agreements would take precedence in the event of a conflict. While explicit conflicts between the provisions of the Protocol and provisions of the WTO Agreements may be rare, it cannot be excluded that disputes may arise between countries relating to the import decisions by Parties under the AIA procedure, for example where an exporter alleges that a risk assessment does not warrant an import prohibition on a particular LMO, or where a country relies upon the precautionary principle or socio-economic considerations to ban or restrict the import of an LMO. Where the country of export and the country of import are both WTO members, it remains likely that such disputes would fall to be decided under the WTO Dispute Settlement system.

It is possible that issues of trade in agricultural LMOs may be discussed further within the WTO, in the context of discussions of the WTO Agreement on Agriculture or the SPS Agreement. In the run-up to the inconclusive 1999 WTO Ministerial Meeting in Seattle, USA, some countries (Canada, Japan, and USA) proposed that biotechnology should be discussed within a special working group of the WTO.

3.6 Next steps

As noted above, 68 Parties to the CBD signed the Protocol in Nairobi at COP 5 in May 2000. The Cartagena Protocol is still open for signature or in New York at UN Headquartersfrom June 2000 until June 2001. Expectations appear to be high at present that the Protocol may well enter into force by 2002. This might mean that the first meeting of the Parties to the Protocol could be held in 2002, in conjunction with the sixth meeting of the Conference of the Parties to the CBD.

In the interim, the Extraordinary meeting of the COP in January 2000 established an Intergovernmental Committee on the Cartagena Protocol (ICCP), to undertake preparatory work for decisions to be taken at the first meeting of the Parties (Decision EM-I/3). COP 5in May 2000 will adopted important decisions regarding the work plan and budget of the Intergovernmental Committee, which is currently scheduled to hold its first meeting in Montpellier, France, ifrom 11-15 December 2000. The Chair of the ICCP will be Ambassador Philemon Yang of Cameroon. Countries have been asked by the COP to designate a national focal point for the ICCP and inform the Executive Secretary of the Convention.

The first meeting of the Parties (and hence the ICCP) has a range of important issues to consider. Among other things, it should address:

- Modalities of operation of the Biosafety Clearing House
- Compliance procedures and institutional mechanisms
- Appropriate procedures and mechanisms to facilitate decision-making by Parties of import
- A process to consider appropriate rules on liability and redress

COP 5 adopted the work plan of the ICCP in Decision V/1 which includes the issues to be considered by the ICCP. The first meeting of the ICCP in December 2000 will address the following issues:

- Identification of basic elements for appropriate procedures and mechanisms to facilitate decision-making by Parties of import
- Information-sharing issues
- Capacity building needs and establishment of a roster of experts

- Handling, transport, packaging and identification of LMOs
- Elements and options for a compliance regime

The Secretariat was requested by the COP to organise a meeting of technical experts on the Biosafety Clearing-House prior to ICCP-1. This meeting, which will bring together 30 experts[10] on information-sharing systems, database management and clearing-houses, has been provisionally scheduled to take place in Montreal (Canada) on 11-15 September 2000.

It may also initiate a process to consider specific documentation and identification requirements for LMO-FFPs.

3.7 Implications of the Protocol

The overview of the provisions of the Protocol above suggests that it is likely to have significant resource implications for countries that become Party to it. Developing and implementing appropriate national regulations to control imports of LMOs is likely to require significant human, financial and technical resources. As noted above, while the Protocol does address capacity-building and financial resources, the scope of these provisions is to yet clear, and will require further development in the form, in particular, of further guidance from the Conference of the Parties to the GEF. However, the COP has already requested the GEF to provide financial resources for capacity-building in biosafety. In addition, a number of intergovernmental institutions, including UNEP and UNCTAD are undertaking capacity-building initiatives in relation to national biosafety frameworks, and assistance may be available through such initiatives to countries wishing to begin national consultations on this issue. In the wake of the Protocol's adoption, it is likely that further such activities will be commenced. In the short-term, it will be important for countries to identify their priority capacity-building needs in biosafety.

Effective implementation of Protocol, and the benefits of protection that it offers to countries will depend on an effective national regulatory system addressing not only imports, but also the use and release of LMOs at domestic level. Developing such legislation is likely to require extensive consultation with relevant departments and agencies, the public, local industry and agriculture, and research institutions.

4. OTHER INTERNATIONAL INSTRUMENTS AND ACTIVITIES RELEVANT TO BIOSAFETY

The development of new technologies of genetic modification since the early 1970s has prompted many discussions on safety in biotechnology. Some instruments have been established which explicitly address biosafety, generally in the form of guidelines. In addition there are a number of other existing international instruments that are or may be of some relevance to the issue. It is beyond the scope of this paper to go into these in any detail. References to sources of the following instruments are given at the end of this Chapter.

UNEP Technical Guidelines for Safety in Biotechnology (UNEP Guidelines)

These were adopted by the Global Consultation of Government-designated Experts in 1995, under the auspices of UNEP. The Conference of the Parties to the CBD recognised that, pending finalisation of the Biosafety Protocol, the UNEP Guidelines could be a useful interim mechanism to facilitate the management of risks. The UNEP Guidelines provide technical guidance on evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange.

[10] Parties and Governments where invited to nominate up to five experts by 1 July 2000.

The Guidelines were developed on the basis of common elements and principles found in existing national, regional and international instruments, regulations and guidelines, and draw on experience gained through their implementation.

UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (1992)

The UNIDO Code of Conduct was developed to, among others, outline the general principles governing standards of practice for all parties involved in the introduction of organisms or their products into the environment and to encourage and assist the establishment of appropriate national regulatory frameworks, particularly where no adequate infrastructure yet existed. A survey of national biosafety frameworks suggests that a number of countries have utilised the UNIDO Code of Conduct as a basis for their national guidelines.

1951 International Plant Protection Convention (IPPC)

Broadly, the IPPC is an international treaty for co-operation in plant protection, which aims to "to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control". The IPPC allows parties to take phytosanitary measures to prevent the introduction and/or spread of pests, be based on a pest risk analysis, which covers both economic and environmental factors including possible detrimental effects on natural vegetation. LMOs that could be considered a plant pest could fall within the scope of the IPPC and be subject to its provisions.

Codex Alimentarius

This is a non-binding Code of FAO/World Health Organisation addressing food safety and related issues. The Codex Standards, guidelines and recommendations adopted to date include food safety considerations, based on current scientific knowledge including assessments of risk to human health. Broadly, if a WTO Member imposes food safety standards consistent with Codex standards, it is assumed to be in compliance with the WTO's SPS Agreement. Codex is important to the LMO issue because standards may be adopted in future on safety of foods derived from biotechnology (for example, addressing issues of potential allergenicity; possible gene transfer from LMOs; pathogenicity deriving from the organism used; nutritional considerations; risk assessment and authorisation procedures; and appropriate labelling)[11]. At its meeting in 1999, the Codex Alimentarius Commission decided to establish a task force on foods derived from biotechnology to develop such standards and guidelines. The Task Force held its first meeting in Japan from 14 to 17 March 2000, and is expected to complete its work within four years.

5. EXISTING NATIONAL APPROACHES TO BIOSAFETY

This section tries to summarise some of the key elements reflected in existing examples of national or regional biosafety regulations. However, it is not a comprehensive description of all the various approaches taken by countries that have adopted legislation to date.

In the light of the increased application of biotechnology, a number of countries, particularly developed countries, have put in place legislation and/or regulations governing the use and release of living modified organisms. Developing countries have in general, only recently begun to address this issue. A number of developing countries have initiated a national biosafety framework comprising non-binding guidelines (based on, for example, the UNIDO Guidelines mentioned in section 4 above) and the estab-

[11] In relation to the IPPC and Codex Alimentarius, see FAO and the Biosafety Protocol to the Convention on Biological Diversity, 28 July 1998, website of the FAO, http://www.fao.org

lishment of a national biosafety committee. Often these frameworks have not provided comprehensive coverage of the full range of LMOs or of all activities involving LMOs - focusing instead on activities which were actually taking place or imminent in the country concerned; such as research and development, and field testing. Several countries are in the process of adapting these frameworks into legislation, which may then extend to, for example, the import of or placing of LMOs on the market and large-scale releases into the environment.

As noted in section 1 above, two basic approaches are discernible in existing examples of biosafety rules:

- Some States have opted to regulate genetically modified products using product-based regulations – e.g. GM crops used as pesticides are regulated by pesticides agencies; and GM foods are assessed in relation to food safety rules, e.g. USA.
- Other States have implemented technology-based regulations - i.e. they have adopted regulations applicable to all LMOs.

Increasingly a mixed approach appears to be evolving as the extent and scale of GM products grows, with both general legislation on LMOs, together with certain sector or product-specific rules. Thus for example, in addition to its general (technology-based) legislation on releases of LMOs, the European Union has adopted a number of pieces of secondary legislation addressing specific GM products, such as foods, and it seems likely that more sectoral legislation of this type will be forthcoming. Australia, which has relied on a product-based approach, is currently revising and supplementing its regulatory framework for LMOs with the adoption of more general legislation on gene technology to fill gaps in the existing framework, and to address forthcoming commercial scale releases of LMOs (refer to extra notes on page 90 on this issue).

The following sections try to summarise some of the elements that might be included in a national biosafety framework:

5.1 Activities addressed

Existing examples of national biosafety frameworks[12] tend to address some or all of the following activities:

- the contained use of LMOs (e.g. research in laboratories)
- field testing of LMOs (i.e. deliberate but limited and controlled release of LMOs into the environment for the experimental purposes)
- large-scale or commercial releases into the environment (e.g. commercial crop growing)
- the import and export of LMOs
- the placing on the market of LMOs and/or products containing GMOs (e.g. as seeds; foods; animal feed etc)

Many existing regulations and guidelines do not address all of these activities. For example, some countries have to date only established guidelines for contained use of LMOs for research and development, and field testing of LMOs (not on commercial release), e.g. Philippines National Biosafety Guidelines. However, as the potential range and scale of LMO activities grows in these countries, it seems likely that the scope of the regulations will be expanded. Different procedures are frequently applied to authorisations for contained use than for other activities. These tend to focus on good laboratory practice, good management practices and ensuring that there is appropriate oversight of research activities involving LMOs.

[12] The term “framework” is used here to imply both binding and non-binding measures, including laws, decrees, regulations and guidelines.

The remainder of this section focuses principally on elements of biosafety frameworks relevant to releases of LMOs into the environment and imports of LMOs.

5.2 Elements of national biosafety frameworks

Existing examples of national biosafety frameworks make provision for a number of institutions and procedures. The list in Box 5 below is derived from a review of a number of existing national biosafety regulations and guidelines[13]. It is not necessarily exhaustive, and by no means all of the issues mentioned in the Box are addressed in all national laws.

Box 5: Possible elements of biosafety regulation

A national biosafety framework or law might:

- Define the *objective* of the regulation
- Define the *scope* of the regulation - what activities and organisms are covered
- Place *responsibility* for implementation of the regulations on a Minster or Ministers and on particular government department(or departments) or agency
- Establish or designate *advisory body(ies)* to advise on technical aspects of regulatory decisions
- Establish a *general prohibition* on activities involving LMOs unless an authorisation/licence has been obtained in accordance with regulations
- Establish a system of *permits or authorisations* for activities involving LMOs
- Allow for exemptions or "*fast-track*" or *simplified procedures* for certain LMOs with which there is extensive experience under the regulations, or which have been deemed to be "low-risk"
- Provide for *public information and consultation* on permit applications and/or on policy issues
- Set out *information required* in an application for a permit (information required may vary according to the type of LMO and/or the intended activity)
- Address the protection of commercial *confidential information*
- Establish a *risk assessment* procedure, whereby risks associated with the release or other activity are identified, in accordance with risk assessment criteria
- Allow for risk management *conditions* to be attached to permits, including any applicable labelling or marking requirements
- Set out procedures for *monitoring and review* of activities subject to permit, including compliance with conditions
- Set out *penalties and sanctions* for non-compliance
- Make provisions for *liability* for any damage arising out of activities involving LMOs
- Address *unintentional releases* and *emergency measures*
- Make certain *transitional arrangements* in respect of pre-existing activities or applications

Some of the elements in Box 5 are considered in the sections below, which address in turn:

- The objective of the biosafety framework;
- The scope of regulations;
- Relevant institutional arrangements;
- The regulatory process;
- Sanctions and penalties; and
- Miscellaneous issues.

[13] Examples of national biosafety laws and regulations can be found on the following websites: UNIDO/BINAS; UNEP International Register of Biosafety; and OECD Biotrack. In addition, Third World Network, a non-governmental organisation, has recently published a Model Biosafety Law with a brief commentary. Contact details and websites are given in the bibliography at the end of this chapter. The overview in this section has been based primarily on a review of elements contained in EU legislation, Norway's Gene Technology Act, the New Zealand Hazardous Substances and New Organisms Act and consultation documents on the Australian 2000 Draft Commonwealth Gene Technology Bill.

5.2.1 Objective

As discussed in section 1, the primary objective of a national biosafety framework will generally be to protect human health and the environment, including biological diversity. However, additional considerations may also be reflected in the objective. For example, the Australian 2000 Draft Gene Technology Bill mentions health, safety and environmental protection as the primary object of the proposed Act, but provides that it is also an object of the Act that dealings with genetically modified organisms be regulated in a way that "is consistent with Australia's national interest". This could include protection of biological diversity and maintaining diverse farming practices[14]. In other countries, it may be that protection of cultural or traditional practices or ethics could form part of the object of a national biosafety framework. For example, the Norwegian Gene Technology Act states that its purpose is "to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment".

5.2.2 Scope of regulation

As noted above, most biosafety frameworks set out both the activities to which they apply, and the organisms involved. The definition of LMO (or GMO) used generally excludes organisms obtained through conventional breeding methods. In addition to LMOs themselves, some national frameworks also cover products consisting of or containing LMOs, and even products derived from LMOs for example, food produced from LMOs (such as soya oil from GM soya).

Where a range of activities are covered, from experimental activities to field testing and large scale releases, regulations generally provide for step-by-step authorisation so that a new authorisation is required for each activity.

5.2.3 Institutional arrangements

National biosafety frameworks generally involve a range of institutions. These may include:

- A responsible government department or agency
- One or more advisory bodies
- Institutional biosafety committees
- A national biosafety committee

Responsible government department or agency

National biosafety frameworks generally designate one or more Ministry, government department or agency to be responsible for oversight of the regulation and for decision-making on authorisations. The Ministry of Environment, Ministry of Agriculture or Ministry of Science and Technology is commonly designated. As noted previously, some countries rely upon a product-based approach so the responsible Ministry or agency will vary depending upon the application of the LMO or product.

As noted in section 3 above, the Biosafety Protocol requires Parties to designate one or more competent national authorities responsible for import decisions under the Protocol.

As a starting point therefore, it will be important for a country initiating biosafety regulation to determine which Ministry(ies) or agency(ies) should be responsible for taking decisions regarding import, use and release of LMOs. This will require consideration of whether new mechanism are required, or whether, and which, existing regulatory mechanisms (e.g. quarantine; food safety bodies) might serve this purpose. For purposes of

[14] See Explanatory Guide to the Draft Commonwealth gene Technology Bill 2000, December 1999, Interim Office of the Gene Technology Regulator. http://www.health.gov.au/tga/genetech.htm

co-ordination, it will be important at the outset to identify all relevant agencies and regulators.

Advisory bodies

Many national frameworks establish an expert advisory body to provide advice on applications for authorisations and sometimes to advise generally on issues related to LMOs and biotechnology. For example, in the UK, the Advisory Committee on Releases to the Environment is charged with advising the Secretary of State on specific applications and on other issues as requested. Consideration needs to be given to the mandate and composition of any advisory body. Advisory bodies on biosafety require a range of expertise and are usually composed of members from a variety of relevant disciplines, such as:

- microbiology
- plant or animal pathology
- food safety
- genetics
- ecology
- virology
- molecular biology.
- entomology
- biochemistry
- public health
- risk assessment
- agricultural systems

It is important to address disclosure of interests by advisory body members in order to avoid conflict of interest.

Institutional biosafety committees

In relation, in particular, to the contained use of LMOs in research institutions, a number of national biosafety frameworks require institutions undertaking activities involving LMOs (e.g. universities; research institutes; companies) to establish Institutional Biosafety Committees to be responsible for ensuring that activities in the institution are carried out in a safe manner[15]. In addition, or instead, some require the designation within each relevant institution of a Biosafety Officer. In Australia, it has been proposed to certify contained use facilities and to establish an accreditation system for institutions that can demonstrate that they can maintain an Institutional Biosafety Committee in accordance with guidelines established by the regulator (Australian 2000 Draft Gene Technology Bill).

Coordination between relevant agencies and bodies

Whatever institutional approach is selected, co-ordination and consultation between relevant departments and agencies is important. Some countries have constituted National Biosafety Committees to develop biosafety policy, composed of representatives of various departments and stakeholders. As for biodiversity generally, broad representation is likely to be required, including from departments or agencies addressing environment, agriculture, quarantine, trade and industry, science and technology, and food safety, as well as from relevant sectors of society including industry, agriculture, community, environmental and consumer groups and the research community.

In relation to specific applications for import, use or release of LMOs, mechanisms are needed to ensure consultation of all relevant agencies.

[15] e.g. Australia; Malaysia; Philippines.

Public consultation frameworks

Some national frameworks also establish specific committees for public consultation on policy issues related to LMOs, and/or to consider ethical issues arising in relation to biosafety policy.

National regulations generally include provision for public consultation on specific applications for the use and release of LMOs into the environment - such as: requiring notice of the application to be given; allowing a period of time for public comment, as well as formal consultation procedures; and mechanisms for the review of regulatory decisions. Some national regulations require that a national public register of applications for the release of LMOs be kept (e.g. NZ Hazardous Substances and New Organisms Act, Article 20).

5.2.4 Regulatory process

Many national biosafety frameworks set out a general prohibition on activities involving LMOs unless a specific authorisation has been obtained in accordance with the applicable regulations.

Application for authorisation

Where explicit authorisation is required before an activity involving an LMO can be undertaken, national regulations tend to set out :

- To whom the application for authorisation should be submitted (see 3.2.2 above)
- What information should be provided in the application. This will provide the basis for the decision-making procedure (including risk assessment) and may include:
  - Identification of the LMO, parent and vector
  - Identification of possible adverse effects of the LMO on the receiving environment
  - Proposed use of the LMO
  - Any other prescribed information

In addition, biosafety regulations generally set out:

- Whether further information may be sought
- Whether information may be kept confidential, and if so what types of information and under what circumstances (e.g. commercial information)
- What types of information may not be kept confidential
- Within what time limits a decision on the application should be made
- Whether and how the public should be consulted on any application, including means for notifying the public
- The process that will be followed in determining the application

It will be noted that a number of these issues are also addressed in the Biosafety Protocol.

Risk assessment

Risk assessment is the use of scientific data to estimate the effects of exposure to potentially hazardous materials or conditions.

Decisions on whether to allow limited or large scale releases of LMOs into the environment of a country for the first time will generally be based on a risk assessment. As noted in section 3, the Biosafety Protocol requires that decisions on the first import of an LMO by a Party of import are based on a risk assessment carried out in a scientifically sound manner.

At the national level, the risk assessment may be required to be provided by the applicant as part of the application (and reviewed by the regulatory agency), or may be carried out by the regulatory agency itself based on information provided by the appli-

cant. Biosafety regulations may set out the criteria to be applied in the risk assessment. Risk assessment for LMOs is likely to involve a number of steps, including[16]:

- Consideration of the characteristics of the LMO and the proposed release, e.g.
  - Recipient or parental organisms
  - Nature of genetic modification
  - Nature of the LMO
  - Intended use or release, including scale
  - Characteristics of the potential receiving environment
  - Interaction between the above;
- Identification of characteristics which may cause adverse effects;
- Evaluation of potential consequences of each adverse effect should it occur;
- Evaluation of likelihood of the occurrence of each identified potential adverse effect;
- Estimation of risk posed by each identified characteristic of the LMO;
- Application of appropriate management strategies; and
- Determination of overall risk of the LMO.

In terms of identification of characteristics that may cause adverse effects, factors to be taken into account are likely to include:

- allergenic or toxic effects;
- effects on population dynamics of species in the receiving environment and genetic diversity of these populations;
- altered susceptibility to pathogens;
- effects on biogeochemical cycles, e.g. carbon and nitrogen recycling through changes in soil decomposition of organic material;
- potential indirect effects through spread of LMOs in the environment;
- transfer of genetic material to other organisms; and
- changes in management (e.g. pesticide or herbicide spraying in agriculture) brought about by use of the LMO.

Other issues that a country may wish to consider in the context of the regulatory process are:

- Whether "non-technical" criteria such as socio-economic, cultural, ethical and religious consideration should be taken into account. Some national frameworks refer to such considerations.
- To what extent the precautionary principle/approach should be applied where there is uncertainty as to the extent of any risks

Decision on authorisation

Having considered the application in the light of risk assessment, the regulatory authority makes a decision on the application. An application may be approved, rejected, or approved subject to certain conditions. Most biosafety regulations also allow a regulatory agency to request further information from the applicant if required.

Conditions attached to an authorisation may address a range of issues including[17]:

- Risk management measures required, including any required levels of containment
- Monitoring protocols
- Labelling requirements
- Geographic areas in which use of the LMO is authorised
- A time limit and review period for the authorisation

[16] The following list of issues is drawn from the proposed revision to the EC Directive on deliberate release of GMOs into the environment. This legislation is still under discussion in the EC. See also Annex III of the Biosafety Protocol on Risk Assessment under Article 15 of the Protocol.

[17] See, for example, Section 52, Australia 2000 Draft Commonwealth Gene Technology Bill.

Where conditions are attached the applicant should be obliged to notify the condition to other users of an LMO who may be covered by the authorisation.

National regulations also generally require an applicant to inform the regulatory agency of any new information which becomes available about the LMO which may affect the authorisation.

Inspection and enforcement

National biosafety frameworks generally include typical inspection and enforcement powers for the regulator in respect of activities involving LMOs. These might include, for example, powers of inspections, powers to require suspension of authorised activities; and powers to take emergency measures and recover costs from licensee.

5.2.5 Sanctions and penalties

Biosafety regulations generally set out the penalties and sanctions for non-compliance with the regulations or with conditions of an authorisation made thereunder.

5.2.6 Miscellaneous issues

A number of other issues are often addressed in national biosafety frameworks. For example:

Exemptions

Some national frameworks provide for exemptions from all or part of the regulation for certain types of LMOs that are deemed to be low-risk. Others establish, or allow for the establishment of, simplified or fast track authorisation for LMOs with which there is a good deal of experience and which are considered to present a low risk of harm.

Unintentional releases

Some national regulations also make provisions to deal with unintentional release of LMOs into the environment and for possible emergency measures.

Liability and compensation for damage

Some examples of national legislation explicitly address the question of liability and compensation for any damage caused by LMOs[18].

Costs of the regulatory system

The national biosafety framework may address how the regulatory system is to be financed. In Australia, it has been proposed that the regulatory system be on a full cost recovery system so that costs are met through application fees/annual fees etc.

6. REGIONAL COOPERATION ON BIOSAFETY

In a number of regions and subregions, there have been, or are emerging, attempts to co-operate on biosafety regulation. In the European Union (EU), this cooperation has taken place in the context of attempts to achieve a single European market for goods and services, and to create a "one-stop" authorisation process for the placing of GM products on the market in the European Union.

The Ministers of Agriculture of the Association of South-East Asian Nations, endorsed guidelines for harmonisation of risk assessment for releases of agricultural LMOs in October 1999. At the time of writing these guidelines were not yet publicly available, and now appear to be subject to further discussion.

[18] E.g. Chapter 4-23 Norway Gene Technology Act.

Short of harmonisation of risk assessment, or regional "one-stop" procedures, regional co-operation may be useful in terms of sharing risk assessment expertise; information sharing; clearing house functions; or research and development.

7. ISSUES FOR PACIFIC ISLAND COUNTRIES

The 1998 SPREP briefing paper set out a number of considerations and recommendations for Pacific island countries in relation to LMOs and biosafety[19]. These included:

- The need for Pacific island countries to identify the extent of current use of LMOs in their countries and potential near future uses.
- The need to assess capacity for implementation of the Biosafety Protocol, including:
  - Responsible authorities for overseeing and assessing biosafety
  - Existing relevant legislation
  - Availability of human resources for risk assessment and decision-making
  - Technical and financial assistance needed for effective implementation of the Protocol and a national biosafety framework
  - Appropriate mechanisms for information exchange
- The need to consider the long-term costs and benefits of implementing the Protocol.

Now that the Biosafety Protocol, has been adopted, early consideration of these issues has become even more important. An opportunity for initiating detailed regional consideration of these and related matters will arise in the context of a SPREP/SPC/Forum Secretariat workshop on biosafety.

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Mulongoy (ed.)Transboundary Movement of Living Modified Organisms Resulting from Modern Biotechnology: Issues and Opportunities for Policy-makers (International Academy of the Environment, 1997)

Zannoni, 'Trends in commercialisation of products of biotechnology' in Mulongoy (ed) (above, 1997)

[19] SPREP, Biotechnology and Biosafety: the Development of a Protocol under the Framework of the Convention on Biological Diversity (1998), 27-28.

Useful web-sites

www.biodiv.org	Convention on Biological Diversity (includes documentation related to the Biosafety Protocol negotiations; and links to other sites)
www.binas.unido.org	UNIDO Biosafety Information Network and Advisory Service (BINAS) (includes links to specific national regulations)
www.oecd.org/ehs/service.htm	OECD BioTrack includes copies of OECD countries' national regulations at: www.oecd.org/ehs/country.htm)
www.irptc.unep.ch.biodiv	UNEP International Register on Biosafety
www.fao.org	Food and Agriculture Organization
www.iisd.ca	Earth Negotiation Bulletin (summaries of Biosafety Protocol negotiations)
www.health.gov.au/tga/genetech	Australia: Consultations on 2000 Gene Technology Bill
www.aph.gov.au/senate/committee/submissions/ca_gene/ca_gene.htm	Australia Senate Community Affairs References Committee, Inquiry into the Gene Technology Bill 2000, List of Submissions
www.law.anu.edu.au/centres/acel/	Australian Centre for Environmental Law
www.ermanz.govt.nz	New Zealand: Hazardous Substances and New Organisms Act 1996
www.detr.gov.uk/acre/index.htm	UK: Advisory Committee on Releases to the Environment (ACRE)

National legislation

(All available on national websites listed above or via UNIDO/BINAS website listed above)

New Zealand Hazardous Substances and New Organisms Act 1996

EC Directive 90/220 on deliberate release of genetically modified organisms into the environment (Currently under revision; latest version: Common Position adopted by the Council on 9 December 1999, Official Journal of the European Communities, C 64/1, 6 March 2000)

Norwegian Gene Technology Act

Indonesia: Decree of the Minister of Agriculture No. 856/Kpts/HK.330/9/1997 on The Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products

Malaysia: National Guidelines for the Release of GMOs into the Environment

Philippines Biosafety Guidelines (1991)

Further notes to para 2, page 82: While this Chapter makes reference to the Australian Draft Gene Technology Bill, it should be noted that this Bill has been subject to extensive consultation within Australia, including critical comment. A selection of submissions on the Bill can be found on the website of the Senate Community Affairs References Committee at http://www.aph.gov.au/senate/committee/submissions/ca_gene/ca_gene.htm. For example, in response to the Draft Bill, the Australian Centre for Environmental Law has drafted a Model Act for the Comprehensive Regulation of Gene Technology which is appended to its submission to the Senate Committee.

5 COORDINATING NATIONAL IMPLEMENTATION OF THE CONVENTION ON BIOLOGICAL DIVERSITY

This chapter considers the challenges posed by co-ordinating national implementation of the Convention on Biological Diversity, including the integration of biodiversity considerations into decision-making processes. The first part of the chapter examines the need for coordination, and outlines examples of planning institutions and mechanisms for promoting such co-ordination. In the second part, a brief summary is given of some other international and regional agreements relevant to the conservation and sustainable use of biological diversity.

1. INTRODUCTION

The scope of the Convention on Biological Diversity means that its effective implementation requires the involvement of all sectors of government and of society. Article 6(b) of the Convention calls for the integration of the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes or policies. This is echoed in Article 10(a) of the Convention, which calls for consideration of the conservation and sustainable use of biological diversity to be integrated into national decision-making. Article 6(a) of the Convention requires Parties to develop 'national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes' reflecting, inter alia, measures specified by the Convention of relevance to the Contracting Parties. Such strategies, plans and programmes, e.g., national biodiversity strategies and action plans (NBSAPs), are clearly means by which to facilitate the aspirations of Articles 6(b) and 10(a). How this integration is to be achieved is, however, left for Parties to decide at the national level. The Convention does not require the establishment of particular national institutions.

While most countries have in place some form of environment agency or ministry with overall responsibility for environmental issues, many activities and concerns of relevance to the Convention generally fall within the mandates of ministries with other sectoral responsibilities. These might include, for example, forestry, agriculture, mining, fisheries, and energy, as well as other key areas such as land and coastal zone use, tourism, trade and finance. These ministries or agencies often have other responsibilities that do not coincide with the objectives of the Convention. Relevant ministries and departments may not be linked or may compete for limited resources.

The scope of the Convention also means that effective implementation will require the positive involvement and collaboration of a wide range of stakeholders, including national and local government, indigenous and local communities, non-governmental and community-based organisations, the private sector and scientific institutions. Mechanisms are needed to involve this diverse range of actors in national, provincial, and local implementation. Moreover, as seen in Chapters 1-4 the Convention introduces new issues to be considered within the context of national biodiversity planning, including access to genetic resources and benefit-sharing, and biosafety.

Section 3 of this chapter outlines examples of national planning institutions and mechanisms, which may support effective implementation of the Convention.

Section 4 highlights existing or potential areas of regional co-ordination.

The implementation of the Convention on Biological Diversity is also closely connected with that of several other international and regional agreements to which a number of Pacific island countries are Parties. At the international level, the Convention calls on the Conference of the Parties (COP), acting through the Secretariat, to contact the executive bodies of other conventions of relevance to biodiversity, with "a view to establishing appropriate forms of co-operation with them" (Article 23, paragraph 4 (h)). The benefits and importance of co-operation with other processes have been consistently emphasised and encouraged by the COP. The Convention Secretariat has therefore begun to collaborate with the secretariats of these other agreements. Such collaboration has not, however, begun to address in any detail co-ordinated implementation of these various agreements at the national level. Some of these relevant agreements are noted in Section 5.

2. THE NEED FOR COORDINATION

The UNEP/WRI/ IUCN National Biodiversity Planning Guidelines highlight a number of institutional obstacles to designing a national biodiversity plan. These include:

- difficulty in coordinating and integrating numerous stakeholders and their respective issues;
- poor coordination between government agencies and NGOs;
- lack of local perspectives in planning;
- lack of private sector involvement in planning;
- difficulty in building interagency consensus;
- lack of communication between the scientific community and policy-makers; and
- continual institutional change with economic restructuring.

(National Biodiversity Planning: Guidelines based on early experiences around the world, UNEP, World Resources Institute, IUCN, 1995)

These obstacles might equally stand in the way of effectively implementing a national biodiversity plan, once formulated.

National planning processes can offer an important opportunity to consider and to experiment with appropriate co-ordination and participation mechanisms. It is suggested that coordination is needed at many levels, including:

- the government interdepartmental level;
- between national, regional and local levels;
- between stakeholders;
- between resource owners and policy-makers;

- between different national goals and policies – i.e. integration with other national plans; and
- the policy-making and operational (implementation) level.

As indicated in section 3 below, one of the principal responses to the need for coordination has been the establishment of institutional coordinating bodies, such as biodiversity committees or sustainable development councils. While these are useful mechanisms, they alone are not likely to achieve the degree of cross-sectoral integration needed for the successful achievement of the Convention's objectives. Moreover, it has been suggested that the development and subsequent implementation of biodiversity plans and strategies might actually be hampered if too many bodies or committees are established. Indeed, "over-co-ordination" might be an obstacle in itself to effectively implementing the Convention where it over-stretches limited human and technical resources.

3. NATIONAL LEVEL COORDINATION

Sections 3.1 and 3.2 give examples of planning institutions and mechanisms, both formal and informal, and at national and local levels, used to coordinate decision-making of relevance to biological diversity. These examples are largely drawn from existing models and approaches indicated in national reports on implementation of the Convention, and in country reports to the Commission on Sustainable Development.

3.1 Planning institutions

Sustainable Development Councils

These are generally high-level mechanisms mandated to integrate policy. They are usually made up of a number of relevant government departments, local government representatives, and a range of non-governmental actors. Amongst the Pacific island countries, the Federal State of Micronesia has, by a Presidential Order, established a Sustainable Development Council, with policy and technical representation from all government sectors including the State Government.

Generally, Sustainable Development Councils are intended to provide the institutional framework for the development of integrated decision-making and priority-setting. Their typical functions include: policy formulation, analysis and evaluation; acting as focal points for co-ordination; collection and dissemination of information and data; reporting to the Commission on Sustainable Development; mobilisation of resources; and, providing a discussion and consultation forum.

If they are to work, it is important that Sustainable Development Councils are more than political institutions. They should incorporate specific links to the operational and local levels.

Convention-specific committees (Biodiversity Committees)

These have been established by a number of countries as part of their initial response to the Convention on Biological Diversity, often as a means to co-ordinate development of the relevant national biodiversity strategy and action plan. They are typically governmental, inter-departmental committees, with technical and other inputs from local government and non-governmental stakeholders. Once again, they operate at the policy level.

The development of the National Biodiversity Strategy and Action Plan in Samoa, for example, is assisted and monitored by a Steering Committee based on a Biodiversity Policy Committee, which was established in 1995 within the context of Samoa's National Environmental Management Strategy process (initiated in 1993). The Biodiversity Policy Committee is made up of representatives from: various ministries and government departments (the Ministry of Agriculture, Forests, Fisheries and Meteorology, the

Ministry of Foreign Affairs, the Department of Internal Affairs, Samoa's Visitors Bureau and the Division of Environment and Conservation at the Department of Lands, Survey and Environment - which acts as the convenor and secretary of the Committee); non-governmental organisations; and academic institutions (the University of the South Pacific and the National University of Samoa).

Various other Pacific island countries have established or are in the process of establishing biodiversity committees or other committees with responsibility for co-ordinating biodiversity-related work. A Biodiversity Implementation Committee in the Cook Islands promotes biodiversity conservation through various activities such as education and awareness-raising campaigns, planning and project design. Kiribati has established a National Biodiversity Conservation Committee. Papua New Guinea has established a Biodiversity Data Management Committee for information gathering and sharing. In Niue, work on biodiversity conservation is coordinated by the National Environment Management Strategy Committee.

Box 1: National Coordination

Example 1: Republic of the Marshall Islands

A number of different government agencies are responsible for managing the biological resources of the Republic of the Marshall Islands lie. These agencies include:

- The Ministry of Resources, Development and Works that has responsibility for resource management, development, agriculture, conservation, tourism development and public works;
- The Marshall Islands Marine Resources Authority, which has responsibility for the development and management of coastal and marine fisheries and biological resources;
- The Ministry of the Interior, which has responsibility for local government and outer island affairs; and,
- The Republic of the Marshall Islands Environmental Protection Agency (RMIEPA), which has statutory responsibility for environmental protection in the country.

The Republic of the Marshall Islands is currently in the process of formulating, through a participatory and analytical process, a National Biodiversity Strategy and Action Plan (BSAP) for the conservation and sustainable use of the country's biodiversity. All four of these agencies, which are essential to the BSAP's implementation, are included in the development of the BSAP. At present, there is no clear differentiation between conservation and development functions, with some agencies bearing responsibility for both in terms of policy development and implementation.

Source: Republic of the Marshall Islands: Convention on Biological Diversity, 1997 Preliminary National Report to the Conference of the Parties.

Example 2: Vanuatu

In 1997 Vanuatu began work on a National Biodiversity Conservation Strategy and Action Plan (NBSAP). A team based at the Environment Unit of the Ministry of Agriculture, Livestock, Forestry, Fisheries and Environment is developing and co-ordinating the NBSAP. Consultation with government and community representatives at the national and provincial level forms part of the process, including through the holding of provincial workshops. The team receives advice from an advisory committee, representatives of the key government departments, NGOs and locally based research organisations.

Source: Vanuatu National Report to the Conference of the Parties, May 1998.

Contents of box continue to next page

Box 1: National Coordination (continued from previous page)

Example 3: Fiji

The development of Fiji's Biodiversity Strategy and Action Plan was co-ordinated by the Department of the Environment of the Ministry of Local Government, Housing and Environment. However, a broad spectrum of government departments, statutory bodies, and NGOs, together with representatives from USP ,were invited to sit on the Steering Committee which had overall responsibility for preparation of the Plan. The Steering Committee met on a monthly basis. Several drafts of the BSAP were prepared and discussed.

The terms of reference for the BSAP were clear that it was to be drawn up in the context of existing strategies, policies and plans.

Wide consultation was a feature of the development of the Plan: Six Community Biodiversity Workshops were held in a variety of settings on three islands; a two day national workshop was held to consider a working draft of the BSAP; a public awareness campaign was run, using newspapers, television, radio and posters; six regional community workshops were held on three islands to consider the BSAP; and a further national workshop was held to consider the Draft BSAP.

Most of the work for the preparation of the BSAP was allocated to NGOs and/or Technical Working Groups comprising local specialists. An independent facilitator was hired to be responsible for ensuring that all government ministries and departments were aware of the BSAP and had an opportunity to comment on it.

Source: Fiji Biodiversity Strategy and Action Plan, Final Draft, October 1999

Focal points

Pacific island Parties to the Convention have responded to a request by the Conference of the Parties (COP) to the Convention to establish designated national focal points for the purposes of the Convention, as well as focal points to serve as clearing house mechanisms. While these focal points are primarily intended to provide a link between national government and the Convention Secretariat, they could play an important role in promoting national-level awareness of the Convention. Many other relevant international and regional agreements (mentioned in section 5) also encourage the designation of country focal points. Common focal points, or close liaison between focal points, could be encouraged to promote coordinated implementation of agreements with common or linked objectives.

National task forces

High-level councils, such as national sustainable development councils or biodiversity committees, might establish task forces responsible for following up policy and operational issues pertaining to implementation of specific aspects of the Convention, for example, coastal and marine or agricultural biological diversity. Representatives of all major stakeholders interested in these issues could be represented on such task forces. Both Samoa and Niue have now established National Environment Management Strategy task forces.

Technical panels

Technical panels or working groups could be established in relation to specific problem-areas to provide policy-makers (e.g., the national committees) with appropriate technical input.

Departmental focal points

Some governments have opted to designate officials in each sectoral department with special responsibility for ensuring that an environmental perspective is taken into account in all activities. However, without other policy coordination mechanisms, it may

be difficult to ensure that such officials are sufficiently influential within sectoral ministries.

Local level committees

Links between national institutions, such as those mentioned above, and local institutions need to be maintained in order to promote adequate consideration of biodiversity-related issues at all levels. Mechanisms for local level representation on such bodies are likely to be desirable.

Use of existing local institutions and authority

Existing local institutions, such as schools, churches, community-based organisations, formal and informal village institutions, and traditional authorities, are likely to play a crucial role in ensuring local level co-ordination and participation in activities relevant to the Convention, through, for example, awareness-raising programmes and consultation procedures.

Box 2: Local community cooperation

Example: Samoa

In Samoa, i*n-situ* conservation strategies have primarily been undertaken using community-based management approaches:

- Joint projects, involving village communities, Government or NGOs, and aid donors, have been developed to conserve and sustainably manage important areas for biological diversity under communal village ownership.

- Conservation Covenants have been developed for three natural areas in Samoa. These have been negotiated by conservation organisations and local Matai, and involve overseas fund-raising to provide development aid for school buildings, in exchange for an agreement to manage the natural environment of customary lands over a certain number of years (20 to 50 years depending on the area).

- A joint programme, *Traditional Fishery Reserves*, managed by AusAID and the Fisheries Division, encourages villages to establish fisheries reserves within traditional areas. The villages develop plans for managing the reserves, while technical support and guidance on establishing by-laws for the reserves are supplied by the project.

- A community-based Indigenous Forest Management programme is being implemented with funding from the German Government, to assist local communities in understanding and managing their indigenous forests.

As part of the NBSAP process, Samoa is also considering ways to increase the involvement of traditional village councils in effectively implementing relevant regulations.

Source: Government of Samoa – National Report to the Convention on Biological Diversity, December 1998.

3.2 Planning mechanisms

A variety of planning mechanisms, based on national law and policy, have the potential to promote the integration of biodiversity-related considerations into decision-making processes, including the involvement of all relevant actors. Examples are:

3.2.1 National strategies and action plans

National strategies and actions plans of relevance to the Convention's objectives include national biodiversity strategies and action plans (NBSAPs), national conservation strategies (NCSs), national environmental action plans (NEAPs), national environ-

mental management strategies (NEMS) and national sustainable development strategies (NSDSs). Some Pacific Island Countries, such as Kiribati, include their biodiversity plans and strategies in their NEMS. NBSAPs can present a key opportunity for promoting national level coordination. However, their development also requires a high level of coordination and consultation among relevant government departments and stakeholders, and a number of useful lessons have emerged form the NBSAP development process

In response to Article 6(a) of the Convention, NBSAPs are now being developed by an increasing number of Parties in order to guide implementation of the various elements of the Convention. The cross-sectoral scope of NBSAPs, including their integration with existing planning processes relating to environmental management, development, and sectors such as agriculture and fisheries, is an important consideration in light of Article 6(b) of the Convention. Formulation of NBSAPs offers an opportunity to consider whether and how existing sectoral legislation and policies on, for example, transport, mining, forestry and agriculture, take into account biological diversity considerations and to consider how inter-linkages might be enhanced. The formulation of an NBSAP is generally overseen by a national Steering Committee made up of various government departments and stakeholders (see, e.g. Box 1 above). The Marshall Islands has been formulating a NBSAP with funding from the Global Environment Facility (GEF). Other Pacific island countries receiving assistance from GEF (through UNDP) for the preparation of NBSAPs include Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Niue, Vanuatu, Papua New Guinea, Solomon Islands and Samoa. As noted in Box 1 above, the development of NBSAPs has given rise to significant degree of inter-departmental and public consultation in Pacific island countries.

WWF-South Pacific Programme and SPREP are co-ordinating work on NBSAP preparation in the region, and have held workshops for NBSAP co-ordinators. This work is being supported, inter alia, by the UNDP Biodiversity Planning Support Programme (see further section 4 and Box 4 below). At the latest workshop, held in 1999, an NBSAP checklist was developed, drawn from the direct experiences of PICs during their development of NBAP projects under GEF Enabling Activities. The checklist has identified a number of issues and problems encountered by PICs in the NBSAP process, and a number of lessons or potential solutions derived from these problems. These problems and lessons relate to a range of issues but, in relation specifically to coordination and consultation, they include[1]:

- Difficulties in identifying and engaging non-government stakeholders, due to, e.g. geographical isolation of communities and poor, limited or expensive communication and transport services
- Timeframes for NBSAP development are too short to allow a truly participatory process
- Difficulties with commitment, cooperation, and co-ordination within country agencies
- Difficulties in engaging stakeholders residing overseas
- Personnel turnover
- Other work commitments by NBSAP committee members

Among key lessons identified were:

- The importance of in-country government and NGO support for the process
- Importance of a good participatory process throughout and good identification of stakeholders
- Importance of allocation of tasks, and ensuring sufficient staff available to run NBSAP project
- Need for strategies to attract committee members and to build involvement and participation.

[1] WWF-SPP/SPREP PIC NBSAP Checklist, Annex 4 to NBSAP Coordinators Workshop Report. Also available at http:www.undp.org/bpsp.

- Need to carefully plan Steering Committee meetings and avoiding unnecessary meetings.

3.2.2 Integrated coastal zone and/or land use management

Integrated coastal area management can provide a framework for policy- and decision-making in cases where there are competing uses of land or coastal zones (e.g., where customary resource rights conflict with other economic interests), and where co-ordinating management mechanisms are deemed necessary. Work on this issue is underway under the Biodiversity Convention work programme on marine and coastal biodiversity.

3.2.3 Environmental impact assessment (EIA) and strategic impact assessment

Environmental Impact Assessment (EIA) is used to evaluate the likely impacts of proposed development projects on the environment. Strategic impact assessment is a mechanism used to evaluate the environmental effects of policies, plans or programmes. The application of project-related EIA procedures to policy-related strategic impact assessment is another potential mechanism by which to integrate concerns for biodiversity into decision-making processes.

Article 14(1) of the Convention calls on Parties to undertake EIAs of projects likely to have significant adverse effects on biological diversity. This provision was considered by the Conference of the at COP 4. The COP invited Parties, governments, national and international organisations, as well as indigenous and local communities, to submit to the Convention Secretariat information on experiences with the application of impact assessments, including strategic impact assessments, in relation to biodiversity. The COP also instructed SBSTTA to identify further actions that would promote the implementation of EIAs. Such actions might include the development of guidelines for incorporating biodiversity-related considerations into EIA procedures (Decision IV/10). COP 5 requested SBSTTA to develop guidelines for incorporating biodiversity-related issues into legislation and/or processes on strategic environmental impact assessment. The COP also encouraged the Parties to use strategic environmental assessments to assess not only the impact of individual projects, but also their cumulative and global effects; incorporating biological diversity considerations at the decision-making and/or environmental planning level (Decision V/18).

A number of Pacific island countries are in the process of developing legislation on EIA. Fiji, for example, included provisions on EIA in its Draft Sustainable Development Bill. In Samoa, draft regulations on EIA have been developed and are expected to be incorporated into the Draft Environment Bill. The Cook Islands' Rarotonga Environment Act also includes for the first time, provisions on mandatory environmental impact assessment for activities likely to significantly affect the environment.

3.2.4 Integrating information collection and management

National mechanisms for gathering and managing data relevant to biodiversity and related sectors might be rationalised or integrated.

Samoa, for example, has conducted several surveys of marine and terrestrial environments, and has established a national biodiversity database at the Division of Environment and Conservation. The database will be used to evaluate and monitor the country's biodiversity, and will provide a basis for national decision-making concerning the environment and development.

In Vanuatu, the Environment Unit has established a library and reference service. This is networked to facilitate information-sharing with other Environment Departments in the region. Papua New Guinea has also established a Biodiversity Data Management Committee to promote information gathering and sharing.

4. REGIONAL COORDINATION

Regional agencies and action plans

The capacity and expertise of regional organisations in terms of policies, operations and work programmes can be marshalled to support implementation of the Convention. Many coordination mechanisms are already in place in the Pacific islands region. Relevant organisations include SPREP, the Secretariat of the Pacific Community (SPC), the South Pacific Forum, Forum Fisheries Agency, and the University of the South Pacific. The Council of Regional Organisations in the Pacific (CROP), formerly known as the South Pacific Organisations Coordinating Committee (SPOCC), holds annual meetings with the overall aim of co-ordinating activities among these various regional organisations. In addition, the 1994 Barbados Programme of Action for Small Island Developing States remains a key organising framework for regional action on the conservation and sustainable use of biological diversity (see Box 3).

SPREP has established a number of regional projects and programmes on biodiversity. In particular, SPREP's GEF-funded South Pacific Biodiversity Conservation Programme provides assistance to Pacific Island countries in implementing the Convention on Biological Diversity through its focus on community-based conservation areas, threatened species conservation an awareness-raising initiatives. Other programmes managed and co-ordinated by SPREP include: the Regional Invasive Species Programme; the Regional Marine Mammal Conservation Programme; the Regional Marine Turtle Conservation Programme; the Regional Avifauna Conservation Programme and the Capacity Building and Environmental Management in the Pacific (CBEMP) programme. The CBEMP programme builds upon the work of the Programme of Capacity Building for Sustainable Development in the South Pacific (commonly referred to as Capacity 21) which ended in December 1997. SPREP's Biodiversity-related Conventions and Agreements Programme also provides technical, policy, training and awareness-raising initiatives to assist Pacific island countries to implement various biodiversity-related agreements, including the Convention on Biological Diversity. SPREP also co-ordinates a number of regional environmental awareness- raising projects and information programmes.

The *Action Strategy for Nature Conservation in the Pacific Islands Region 1999-2002* (1999-2002 Action Strategy) is also a key framework for regional cooperation on issues relevant to the Convention. Its mission statement is "to protect the rich natural heritage of the Pacific islands forever through the conservation and sustainable management of their natural resources and biodiversity for the benefit of the peoples of the Pacific islands and the world". The Action Strategy incorporates strategic objectives relating to biodiversity protection; policy, planning and legal frameworks,; local communities and customs; capacity-building; education, awareness and information; and financial sustainability. Among the intended outcomes of the Strategy are the use of principles of ecologically sustainable development in priority setting, budget allocation and auditing of government and regional programmes, and greater participation and representation by local people and communities in development and natural resources planning and implementation.

The *Pacific Islands Roundtable for Nature Conservation* is an extremely important regional mechanism for promoting the goals of the 1999-20002 Action Strategy. The Roundtable was launched in 1998 by SPREP, with the assistance of the Nature Conservancy. Its mandate is to increase effective conservation action in the Pacific islands by[2]:

- Fostering greater coordination and collaboration among regional and international organisations;

[2] Meeting Report, Draft 2 December 1999, Fourth Pacific Islands Roundtable for Nature Conservation, November 2-4 1999, Honolulu, Hawaii.

- Providing feedback on the effectiveness of conservation activities through monitoring and evaluation of the 1999-2002 Action Strategy;
- Identifying and addressing critical gaps in regional conservation activities; and
- Recruiting new partners for Pacific island conservation.

Box 3: The 1994 Barbados Programme of Action for the Sustainable Development of Small Island Developing States (BPA): provisions on biological diversity

The BPA provides an important framework for the national and regional coordination of implementation of the Convention on Biological Diversity. It was formulated in the light of chapter 17, section G of Agenda 21, and forms the international framework for sustainable development in small island developing states (SIDS). It was adopted at the 1994 Global Conference on the Sustainable Development of SIDS and identifies 14 agreed priority areas for action. The ninth priority area pertains to 'Biodiversity Resources' and addresses action at three levels:

National action, policies and measures

Amongst other recommendations for action, the BPA calls for: ratification and implementation of the Convention on Biological Diversity; the formulation and implementation of integrated strategies for the conservation and sustainable use of terrestrial and marine biodiversity, including protection from the introduction of alien species and the identification of sites of high biological significance; the promotion of community support for the conservation of biological diversity and the designation of protected areas; the creation and maintenance of buffer stocks or gene banks of biological resources; studies and research on biological resources, their management, and their socio-economic and cultural value; inventories of existing flora, fauna and ecosystems; protection of the technology, knowledge and practices of local and indigenous peoples, alongside the equitable sharing of benefits arising from the use of such technologies, knowledge and practices; and, support for the full involvement of NGOs, women, indigenous peoples and other stakeholders.

Regional action

Amongst other recommendations, the BPA calls for: regional studies of the socio-economic importance of biological resources, with the participation of scientific institutions, relevant international organisations and NGOs; the establishment of regional gene banks for research, alongside legal and technical procedures for the use of those biological resources; co-ordination of information exchange, training and technical assistance for the management of conservation areas and species conservation; promotion and/or strengthening of existing regional scientific institutions to operate as reference centres; strengthening of regional organisations to provide technical support for the development of biodiversity inventories, and the establishment of regional databases and gene banks; and, the development of adequate and effective legal mechanisms for the protection of intellectual property rights.

International action

Amongst other international actions, the BPA recommends: improved access to financial and technical resources for the conservation and management of biological diversity; improved access to environmentally sound biotechnology; coordination of activities amongst international organisations, UN programmmes and NGOs, in order to support regional centres and programmes for the conservation and sustainable use of biological diversity in SIDS; greater use of CITES import restrictions on endangered small island fauna and flora; support, including technical and training assistance, for the development of biodiversity inventories; and, support for action against the introduction of non-indigenous species.

In September 1999, a Special Session of the UN General Assembly on Implementation of the 1994 Barbados Plan of Action was held. In preparation for the Special Session, the Commission for Sustainable Development (CSD) reviewed and appraised the implementation of the BPA. At the Session itself, States adopted a Declaration calling on the international community to provide new and additional funds for capacity building initiatives in SIDS. States recognised that further implementation of the BPA would require further investment and external assistance, resource mobilisation, the transfer of environmentally sound technology, and capacity-building, such as education, training, awareness-raising and institutional development. As a further initiative, the Session recommended the formulation of sustainable development strategies, with clear goals and benchmarks for progress, and which reflect both individual country circumstances and wider goals.

Sources: United Nations Press Release GA/9614, ENV/DEV/524 www.un.org/ga/SIDS/ga9614.htm and the Barbados Programme of Action www.unep.ch/islands/dsidspoa.htm.

To date the Roundtable has met four times. While the Roundtable is made up of representatives of regional and international conservation organisations and donor agencies, including SPREP, USP and WWF-SPP, it has the official endorsement of all Pacific island governments, as well as representatives of local and national Pacific island groups. Meetings of the Roundtable follow-up on a wide range of specific tasks identified to advance the Action Strategy within the ongoing or planned programmes of participating agencies. Among other things, the Roundtable has developed a working inventory of activities in the region to support implementation of the Action Strategy.

The Small Island Developing States Network (SIDSnet) internet site (www.sidsnet.org) can enhance regional coordination on biodiversity conservation issues. In August 1998, the Heads of State meeting of the Pacific Forum endorsed SIDSnet as a medium to enhance regional implementation of the Barbados Programme of Action for the Sustainable Development of Small Island Developing States (BPA) (see Box 3). SIDSnet was initiated as a follow-up to the BPA in 1994. It is funded by UNDP in association with the Alliance of Small Island States (AOSIS) and aims to enhance Internet based networking for stakeholders on island sustainable development issues. The Pacific Island Internet Project, initiated by SIDSnet and the UNDP office in Fiji, is currently working to promote Internet use for development in Pacific island countries. Currently, training under this project is underway in Niue, Tokelau and Nauru.

Regional and national NGOs also play an active role in promoting regional cooperation. NGOs active on biodiversity-related issues across the Pacific islands region include the Pacific Concerns Resource Centre, WWF-South Pacific Programme, Greenpeace, The Nature Conservancy and the Foundation for the Peoples of the South Pacific. WWF-SPP, with SPREP, are involved in the UNDP Biodiversity Planning Support Programme launched in 1999 (see Box 4).

Box 4: UNDP/ UNEP Biodiversity Planning Support Programme

This programme was established by UNDP and UNEP with core financing from the GEF to strengthen national capacity to prepare and implement NBSAPs in accordance with Article 6 of the Convention. The programme will comprise:

- Gathering and dissemination of specialised information on biodiversity planning and development of information exchange mechanisms at regional level, including websites, list server and help-lines
- Development of guidelines and dissemination of 'best practice' experience of NBSAP preparation, including:
  - mainstreaming biodiversity into sectoral and economic policy development and planning;
  - developing financial strategies for NBSAP implementation; and
  - developing incentive measures.
- Regional exchange and thematic workshops in the Pacific islands region.

Executing agencies for the Programme in the Pacific islands region are SPREP and WWF-SPP (*source: http://www.undp.org/bpsp*).

Regional cooperation on biodiversity-related issues has strengthened in the Pacific islands region and can be cost-effective in assessing common problems, and in identifying priorities and appropriate solutions. The coordination of specific biodiversity-related decision-making processes might be enhanced by means of appropriate regional and subregional institutions. These might include:

Regional research and monitoring centres

The establishment of regional or subregional research centres, focusing on specific issues of priority to the South Pacific region, could facilitate co-ordinated monitoring and assessment. It could also contribute towards local capacity-building, such as the devel-

opment of centres of expertise. The South Pacific Regional Initiative on Forest Genetic Resources (SPRIG), for example, was established by three Australian institutions in collaboration with Fiji, Samoa, Vanuatu, Solomon Islands and Tonga through their forestry departments. Among other objectives, it aims to explore options for the *ex-situ* conservation of important native timber trees in Samoa and other Pacific island countries.

As noted in Chapter 2, the Secretariat of the Pacific Community has established a Regional Germplasm Centre (RGC) to assist Pacific island countries to conserve genetic resources particularly of the region's major crops.

Regional clearing houses

Regional and subregional institutions can act as clearing houses for information and technologies relevant to regional circumstances, and to co-ordinate capacity-building efforts. One example is the list-server maintained by WWF-SPP for National Biodiversity Strategy and Action Plan coordinators.

5. OTHER RELEVANT INTERNATIONAL AND REGIONAL AGREEMENTS

A large number of other international and regional agreements address issues of relevance to the Convention on Biological Diversity. A number of these are highlighted here. Many international and regional agreements pertaining to environmental protection require their Parties to undertake a range of largely similar measures, the implementation of which would support interlinkages and synergies. Such measures include, for example, requirements to:

- gather relevant information;
- provide periodic reports - steps are underway to find ways of harmonising the timing and content of national reporting requirements in relation to at least some of the biodiversity-related agreements listed below, thereby lessening the burden on Parties to provide reports containing much of the same information, at different times to different fora;
- formulate policies and to design strategies, plans and programmes - in addition to co-ordinating implementation of each agreement, Parties need to ensure that, as far as possible, the implementation of all relevant agreements is co-ordinated at the national level, so as to increase effectiveness and avoid duplication of effort; and
- raise public awareness and provide public education.

International and regional agreements whose implementation might benefit from coordination with that of the Convention on Biological Diversity fall into a number of categories.

5.1 Agreements relating to conservation and sustainable use

There are a number of international agreements addressing the conservation and sustainable use of biological diversity. Many Pacific island countries are not yet parties to these international agreements.

1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)

This agreement seeks to control the international trade in endangered species listed in its Appendices. Appendix I includes species threatened with extinction which are, or may be, affected by trade. These species are subject to particularly strict regulation, so that any trade in such species may only be authorised in very limited circumstances and upon certain conditions. Species listed in Appendix II are those which, although currently not threatened with extinction, might be so in future unless trade is subject to regulation. Appendix III includes all species identified by Parties as being subject to

egulation within their jurisdiction aimed at preventing or restricting their exploitation. Parties are required to cooperate in their international trade.

1979 Convention on Migratory Species

This Convention aims to protect migratory species and their habitats. Parties cooperate in research relating to migratory species and are to provide special protection for species listed in Appendix I of the Convention. For those species listed in Appendix II, Parties are required to endeavour to conclude "range State" agreements on their conservation and management. A number of such agreements have been concluded.

1972 Convention concerning the Protection of the World Cultural and Natural Heritage (World Heritage Convention)

This Convention promotes the protection and conservation of sites with exceptional natural and/or cultural heritage of worldwide importance (World Heritage Sites). The Convention provides criteria and conditions for the designation of World Heritage Sites, but once accepted, their international importance is recognised through listing on the World Heritage List. The Convention also establishes the World Heritage Fund. The World Heritage Convention was a subject of discussion at the Sixth South Pacific Conference on Nature Conservation and Protected Areas, held in the Federated States of Micronesia in September 1997.

1971 Convention on Wetlands of International Importance as Waterfowl Habitat (Ramsar Convention)

Parties to this Convention are required to list at least one wetland of international importance for special management and protection. The Parties to the Convention have adopted Guidelines on the sustainable use of wetlands.

1976 Convention on the Conservation of Nature in the South Pacific (Apia Convention)

The Apia Convention aims to promote nature conservation by encouraging Parties to establish and manage protected areas in the form of national parks and national reserves. The Parties are also required to protect indigenous fauna and flora through mechanisms other than the establishment of protected areas.

Becoming a Party to biodiversity-related agreements can bring both costs and benefits. Benefits might include more specific guidance on relevant aspects of the Biodiversity Convention, and access to additional (although generally very limited) sources of funding. Costs might include additional obligations such as reporting requirements. A number of these agreements are perceived as setting priorities at the international rather than national level. Many of them require similar steps, such as the establishment of protected areas, measures to regulate the taking of (specific) wild species, and the implementation of management measures for specific species or habitats.

The Sixth South Pacific Conference on Nature Conservation and Protected Areas called on international agencies and Pacific island governments to accede to and implement their obligations under those regional agreements that have a bearing on biodiversity conservation and sustainable development. It also recommended accession to the Convention on Biological Diversity and a range of other biodiversity-related conventions.

5.2 Agreements relating to the marine environment and fisheries

1982 UN Convention on the Law of the Sea (UNCLOS)

UNCLOS contains a comprehensive codification of the principles and rules relating to the seas. UNCLOS establishes rights and obligations pertaining to navigation, the conservation and use of marine resources, and the protection of the marine environment. Many aspects of the UNCLOS are of relevance to the Convention on Biological Diversity, such as obligations relating to marine living resources and requirements concern-

ing exploitation and conservation of the living resources of the Exclusive Economic Zone (EEZ).

1995 Agreement for the Implementation of the Provisions of the UN Convention on the Law of the Sea relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks (Straddling Fish Stocks Agreement)

This Agreement aims to ensure the long-term conservation and sustainable use of straddling and highly migratory fish stocks. The Agreement builds upon the conservation and management requirements of straddling and migratory stocks under UNCLOS by emphasising the precautionary approach, the protection of the marine biological diversity and the sustainable use of fisheries resources. Parties are required to adopt measures to ensure the long-term sustainability of fish stocks by, for example, adopting measures to prevent over-fishing and promoting the optimum utilisation of such stocks, and to co-operate for these purposes through regional fishery organisations.

1986 Convention for the Protection of the Natural Resources and Environment of the South Pacific Region (SPREP Convention)

This Convention aims to protect the marine and coastal environment of the "Area", comprising the 200 nautical miles zone, the Excliusive Economic Zone (EEZ), of Pacific Island Parties, those high seas areas enclosed on all sides by EEZs, and other areas of the Pacific Ocean as specified by the provisions of the Convention. Parties are required to prevent, reduce and control pollution of the Area from any source, and to ensure the sound environmental management and development of natural resources. Two Protocols have been adopted, and there is scope for the adoption of further protocols.

1989 Convention for the Prohibition of Fishing with Long Driftnets in the South Pacific

Parties to this convention undertake to prohibit nationals and vessels registered under its laws from driftnet fishing within the area covered by the convention. The convention also requires parties to prohibit the import of fish products caught using driftnets.

5.3 Other agreements arising from the UN Conference on Environment and Development

1992 United Nations Framework Convention on Climate Change

The objective of the Climate Change Convention, and the 1997 Kyoto Protocol to the Convention is to achieve the stabilisation of greenhouse gas concentrations in the atmosphere at safe levels. Parties are required to inventory their sources and sinks of greenhouse gases, and to formulate policies and measures to mitigate and/or adapt to the effect of climate change. Pursuant to the Kyoto Protocol, developed country Parties will undertake to specific quantified emissions reduction commitments.

1994 United Nations Convention to Combat Desertification in those Countries experiencing serious Drought and/or Desertification, particularly in Africa (Desertification Convention)

Parties to the Desertification Convention are required to take action to develop and integrate strategies that focus on improving the productivity of land, and the rehabilitation, conservation and sustainable management of land and water resources, leading to improved living conditions. The Desertification Convention calls for international co-operation and partnership arrangements aimed at assisting achievement of the Convention's objectives.

The Rio Agreements (including the Biodiversity Convention), address a number of common substantive and procedural issues: for example, forests are relevant to the implementation of all three agreements. Each of the Rio Conventions calls for capacity-building, scientific and technical co-operation, the development of specific national

plans and strategies, and periodic reporting. Creating synergies in implementation of the Rio agreements has been the subject of considerable international discussion.

5.4 Agreements related to trade and intellectual property rights

These constitute a substantively different set of agreements, the provisions of which may, however, impact significantly on the conservation and sustainable use of biological diversity. It is beyond the scope of this chapter to address these agreements in any detail. They are, however, listed here for reference purposes.

- World Trade Organization Agreements, including:
- the Agreement on Trade Related Intellectual Property Rights (TRIPs);
- the General Agreement on Tariffs and Trade (GATT);
- the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement); and,
- Agreement on Technical Barriers to Trade (TBT Agreement).
- the International Convention for the Protection of New Varieties of Plants (UPOV, Geneva, 1961 as amended).

The relationship of the Biodiversity Convention with the TRIPs Agreement and with UPOV is considered in Chapter 3 on Intellectual Property Rights and Biological Diversity. The relationship between biosafety and certain World Trade Organization agreements is considered briefly in Chapter 4.

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National Biodiversity Planning: A Guide based on Early Experiences around the World, UNEP, World Resources Institute, IUCN, 1995 (available on WRI website: http://www.wri.org.biodiv/nbp-home.html)

Pacific Islands Roundtable for Nature Conservation, Report of Fourth Meeting, November 2-4 1999, Honolulu, Hawaii.

SPREP, Action Plan for Managing the Environment of the South Pacific Region 1997–2000.

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Synergies in National Implementation: The Rio Agreements, UNDP, 1997

UNDP, A Guide for Countries preparing National Biodiversity Strategies and Action Plans, Biodiversity Planning Support Programme, UNDP

WWF-SPP/SPREP, Report of the NBSAP Coordinators Workshop, 1999

Papers prepared by the Convention Secretariat:

UNEP/CBD/COP/2/inf.2

UNEP/CBD/COP/3/29

UNEP/CBD/COP/3/23.

Useful Websites

Pacific Intergovernmental Organisations

http://www.sprep.org.ws	South Pacific Regional Environment Programme
http://www.forumsec.org.fj	South Pacific Forum Secretariat
http://www.spc.org.nc	Secretariat of the Pacific Community
http://www.ffa.int	Forum Fisheries Agency
http://www.usp.ac.fj	University of the South Pacific
http://www.sidsnet.org	SIDSnet

Intergovernmental Organisations

http://www.undp.org/bpsp/	UNDP Biodiversity Planning Support Programme

Non-governmental Organisations

http://www.pcrc.org.fj	Pacific Concerns Resource Centre
http://www.greenpeace.org.au	Greenpeace Australia/Pacific

Multilateral Environmental Agreements

http://www.cites.org	CITES
http://www.wcmc.org.uk/cms	Convention on Migratory Species
http://www.unesco.org/whc	World Heritage Convention
http://www.ramsar.org	Ramsar Convention on Wetlands
http://www.un.org/Depts/los	UN Convention on the Law of the Sea (and Straddling and Highly Migratory Fish Stocks Agreement)
http://www.unfccc.de	UN Framework Convention on Climate Change
http://www.unccd.de	UN Convention to Combat Desertification

NADI STATEMENT

Friday 3 April 1998

We the Participants from Pacific Island Parties to the Convention on Biological Diversity (CBD), Pacific Island States currently not party to the CBD and Non Government Organisations (NGOs),

Having met in Nadi, Fiji, from 30 March to 3 April 1998 at the first ever Pacific Islands Regional Meeting on the Implementation of the Convention on Biological Diversity,

Having considered issues of national implementation of the CBD in Pacific Island Countries (PICs) including; national coordination, biosafety, access and benefit sharing, intellectual property rights, traditional knowledge, national biodiversity strategies, national reporting, preparation for the Fourth Conference of the Parties, and regional support needed to assist these issues,

Recognising that the Declaration of Barbados and the Programme of Action for the Sustainable Development of Small Island Developing States provides a critical reference in which the actions needed to implement the Convention on Biological Diversity in the Pacific Islands Region can be integrated into measures to be taken at the national, regional and international levels to enable PICs to achieve the conservation and sustainable use of biological diversity and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources from the region,

Reaffirming that Pacific Island Countries have sovereign rights over their own natural and biological resources; that our biodiversity is among the most threatened in the world, that our ecosystems provide ecological corridors linking major areas of biodiversity around the world, that we bear responsibility for a significant portion of the world's oceans and seas and their resources, and that our efforts to conserve, protect and restore our ecosystems deserve international cooperation and partnership,

Adopt the following Recommendations for CBD Implementation in PICs, including priority areas for regional support, and for Pacific Island Party delegations to the Fourth Meeting of the Conference of the Parties (COP4) to the Convention on Biological Diversity,

Further calling on PIC Government Leaders and other relevant agencies to consider these recommendations for appropriate action.

I. National Coordination

Recognising the need to enhance and strengthen coordination amongst relevant government agencies, NGOs, local communities and indigenous people to assist national CBD implementation,

Further recognising the role of governments and the non-formal nature of many NGOs in the region, and that the CBD endorses networking as a potentially effective tool for sharing of information,

Noting the overwhelming need for capacity building for effective implementation of the CBD in PICs, including information access, and that the present GEF requirements for providing funding to NGOs involve criteria which many Pacific NGOs do not fulfil,

Recommends the following for CBD Implementation in PICs:

I.1 the South Pacific Regional Environment Programme (SPREP) and other relevant regional agencies assist, where appropriate, national governments to identify and assess mechanisms of national coordination in the region, and further appraise the effectiveness of current models of national coordination in implementing the CBD,

I.2 where necessary and in the absence of effective co-ordinating mechanisms, SPREP and other relevant regional agencies provide advice on appropriate mechanisms and model legislation for the establishment of national co-ordinating committees,

I.3 PICs, with assistance from SPREP, seek support from the CBD Secretariat and other relevant agencies to establish a Pacific Island sub-network within the Asian Regional Group made up of representatives of national co-ordinating committees within the Asian Regional Group,

I.4 PICs, SPREP and other relevant organisations seek funding to provide and/or facilitate:

- essential technical, scientific and legal assistance
- financial assistance
- appropriate training programmes in using participatory methods for community based biodiversity conservation
- the establishment of a “Protected Areas Training Centre” to train local personnel in the management of conservation areas
- the exchange and/or sharing of information and national reports from Conferences of the Parties (COPs) to the CBD and other relevant related meetings; and
- the establishment of a CBD specific database and roster of technical and legal experts from within the Pacific region and ensure that it is accessible to all within the region

I.5 SPREP advise the South Pacific Organisation Coordinating Committee (SPOCC) on regional matters relating to CBD, and further encourage SPOCC members to actively participate in discussing regional responses to the CBD.

Further recommends that PIC delegations to COP4:

I.6 request the donor community to show more flexibility in their funding and programming criteria to allow for access by NGOs,

I.7 ensure that decisions regarding programmes of work under the CBD reflect PIC priorities, including any guidance for GEF Enabling Activities for initiatives such as development of Clearing House Mechanisms (CHMs).

II. Biosafety

Recognising the usefulness of the negotiating positions outlined in the updated SPREP briefing paper "Biotechnology and Biosafety - the development of a protocol",

Further recognising that there is an urgent need to build capacity to establish and develop means to regulate, manage or control the risks involved with the use and release of living modified organisms (LMOs) resulting from biotechnology, and their potential adverse impacts on the conservation and sustainable use of biological diversity,

Noting the emerging issues of use of LMOs and biosafety in the region, potential risks of LMOs in relation to the conservation and sustainable utilisation of biological diversity, and concern about the potential consequences of refusing to import LMOs ,

Recommends the following for CBD Implementation in PICs:

II.1 PICs take appropriate measures, including the establishment of competent national authorities, to regulate and manage the introduction, release, transfer, handling and use of LMOs, and if appropriate, products containing or consisting of products derived from LMOs which may have adverse effects on the conservation and sustainable use of biological diversity,

II.2 PICs, and agencies such as SPREP and WWF, collect, disseminate and share relevant information among PICs on biosafety, and establish a regional database on LMOs,

II.3 SPREP, in partnership with relevant agencies, seek financial assistance for regional and national meetings, workshops and training on biosafety prior to and after the finalisation of the Protocol, and further recommends that every effort be made to include capacity building within the biosafety protocol for developing countries to allow them to perform risk assessment,

II.4 regional organisations, such as SPREP, Forum Secretariat (ForSec), Secretariat of the Pacific Community (SPC), University of the South Pacific (USP), and University of Papua New Guinea (UPNG), develop legal and technical expertise to assist the formulation of biosafety regulations, and to support capacity building for the enforcement of such legislation,

II.5 biosafety be included in agendas for regional meetings of Heads of Agriculture, Fisheries, Livestock and Forestry sectors and other relevant agencies.

Further recommends that PIC delegations to COP4:

II.6 strongly urge the COP4 to provide funding for full participation by developing countries in ongoing biosafety negotiations,

II.7 request SPREP to facilitate a meeting between Pacific Island country delegates and UNEP at COP 4 to discuss further the UNEP/GEF Pilot Biosafety Enabling Activity Project,

II.8 underscore that capacity-building for risk assessment and management is essential if living modified organisms (LMOs) are to be imported; that the ability to evaluate and control risks must be established before any importation is allowed; that PICs should not be burdened by the costs of such assessment and management processes; and that the financial obligation and liability for damages should be directed to the exporter,

II.9 establish an informal PIC working group on biosafety to prepare for BSWG5 and 6.

III. Access and Benefit Sharing

Recognising the need for PICs to control access to their genetic resources and to derive a fair share of the benefits from the use of these resources at an appropriate level (local, national, regional) and acknowledging the need for regional mechanisms and measures to support in-country initiatives to control access and benefit sharing,

Noting that the CBD sets out a number of key elements for access to genetic resources, which are of acute concern to PICs, including:

· obtaining the prior informed consent of the Contracting Party providing such resources

· negotiating a fair agreement on mutually agreed terms

· agreeing on the fair and equitable sharing of the benefits arising out of the use of genetic resources

· ensuring the participation of the Contracting Party providing genetic resources in scientific research utilising those resources

· seeking to ensure that the resources will be put to environmentally sound uses

Further noting the CBD's provisions on access to genetic resources do not apply to:

· *ex situ* resources collected before the Convention entered into force (Article 15(3))

· human genetic resources

· genetic resources located beyond the limits of national jurisdiction, such as in the high seas and acknowledging concerns raised by delegates to this meeting with regard to ex situ collections and high seas resources,

Recommends the following for CBD Implementation in PICs:

III.1 SPREP, ForSec, SPC and other relevant agencies work together to support PICs by:

· providing model bioprospecting agreements and guidelines

· assisting with the development and/or adaptation of national regulations for access to genetic resources, including the means to enforce and monitor such regulations

· encouraging national initiatives to collaborate with local communities to develop rules, information systems, technology and regulate access to their own resources, e.g. at the village level

· assisting with the establishment of a national registers of biodiversity

· examining options for obtaining compensation on ex situ genetic resources collected prior to the entry into force of the CBD

· exploring the possibilities of establishing a regional trust fund(s) for the distribution of benefits from regionally shared genetic resources

· further supporting technology transfer, including biotechnology, and training in sampling analysis

· investigating the development of regional approaches to regulate access to genetic resources, and that any such approaches must be fair, equitable and transparent to all parties and should reflect countries' specific interests

· enhancing public awareness programmes regarding any 'unlawful removal' of genetic resources

III.2 SPREP, ForSec, SPC, USP and other regional agencies, as appropriate, work together to assist PICs, in cooperation with their local communities, to develop appropriate policies on access to genetic resources and on the use of traditional knowledge,

III.3 SPREP, ForSec, SPC,USP work together to prepare a briefing paper on Access and Benefit Sharing, and ensure that the matter is discussed at Meetings of Economic and Finance Ministers, and at other Pacific regional meetings.

Further recommends that PIC delegations to COP4:

III.4 strongly urge the developed countries, through the Conference of the Parties, to ensure that the need for fair and equitable sharing of benefits arising out of the utilisation of genetic resources is observed at all times,

III.5 insist that any monetary and non-monetary benefits arising out of the utilization of genetic resources from PICs be equitably shared with PICs in accordance with the relevant provisions of the CBD,

III.6 urge COP4 to assist PICs to develop and implement legislative, administrative and policy measures, at both the national and regional levels, in accordance with Articles 15, 16 and 19,

III.7 urge COP4 to recognise the need for a comprehensive legal regulatory framework based on a participatory approach to be put in place for identification and development of procedures and guidelines for benefit-sharing and access to genetic resources that is appropriate to the cultural, social and economic circumstances of PICs,

III.8 underscore the need to formulate a complementary PIC multilateral agreement, internationally recognised, to regulate on a regional basis, access to genetic resources, reflecting the need for the fair and equitable sharing of benefits.

IV Intellectual Property Rights (IPRs)

Recognising that countries are at different stages in their development and understanding of IPR laws and the need for capacity building in devising IPR laws that are suitable to the Pacific Island circumstances,

Further recognising that there is a need to raise IPR issues of regional importance in the context of any COP 4 discussion on CBD input to the review of the TRIPs Agreement,

Noting that PIC Members of the World Trade Organisation (WTO) should pursue IPR concerns at the ongoing discussions in the TRIPs Council and more particularly in the review of Article 27(3) of the TRIPs Agreement in 1999,

Further noting the provisions of recommendation V.1 and V.2 regarding traditional knowledge property rights,

Recommends the following for CBD Implementation in PICs:

IV.1 that relevant institutions, such as USP, and as appropriate other agencies provide specialised training in IPR laws and the development of alternative IPR laws more suitable to Pacific Islands circumstances,

IV.2 that in light of the need to have effective protection for genetic resources and associated traditional knowledge, ForSec and other relevant regional organisations to assist PICs to consider the establishment of a regional intellectual property organisation to safeguard PIC rights in relation to genetic resources and knowledge.

Further recommends that PIC delegations to COP4:

IV.3 urge the COP4 to fully recognise and assist in strengthening customary use, application and control of genetic resources,

IV.4 explore ways to obtain financial assistance to develop further a regional programme to address IPR issues.

V. CBD Article 8(j) Traditional Knowledge

Recognising the importance of Article 8j to PICs,

Noting the recommendations made at COP 2 and COP 3 with regard to the implementation of Article 8(j) and the recommendations of the Madrid Workshop contained in UNEP/CBD/TKBD/1/CW/L.1,

Recommends the following for CBD Implementation in PICs:

V.1 PICs incorporate the provisions of Article 8 (j) in national legislation as a matter of urgency,

V.2 PICs, advised by SPREP and other relevant agencies, consider the development of a sui generis IPR system to include the following concerns:

· the recognition, protection and guidelines for the collective ownership of biological resources, folklore and knowledge related to the sustainable use of biological resources under existing customary regimes, and the continuing customary uses of biological resources

· the need to develop a mechanism to control patent applications and the confirmation of prior informed consent of local communities and indigenous peoples to the use of their knowledge and/or resources

· the relationship to implementation of Article 8 (j) and related articles of the CBD and other international instruments and initiatives including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in the area of protection and maintenance of biodiversity and traditional knowledge relating to biodiversity

V.3 SPREP, and other relevant regional agencies, to support PICs to provide assistance to customary resources owners, including awarding scholarships, to record their traditional knowledge and customs, which shall only be released with the prior informed consent of the customary owners,

V.4 SPREP and other relevant regional agencies develop a regional information base on traditional resource management for the purposes of conservation and sustainable use of biological diversity.

Further recommends that PIC delegations to COP4:

V.5 support the establishment of a work plan for the implementation of Article 8(j) and review the options and recommendations contained in document UNEP/CBD/TKBD/1/CW/L.1 and support those which are most relevant to PICs,

V.6 support the establishment of an open-ended intersessional working group that allows for the representation of indigenous peoples and local communities' views on Article 8(j) and other relevant Articles,

V.7 ensure that any COP4 decision for future work in this area include provision of funding for the participation of PICs, indigenous peoples and local communities of the Pacific Islands region.

VI. National Biodiversity Strategies and Action Programmes (NBSAPs) and National Reporting

Recognising the importance of NBSAP's as guidance for countries in identifying and implementing initiatives for the conservation and sustainable use of biodiversity, and particularly the importance of integrating the conservation and sustainable use of biodiversity into sectoral or cross-sectoral policies, plan and programmes,

Further recognising the importance of government agencies, NGOs and local communities have in the formation and implementation of NBSAPs,

Noting the importance PICs attach to the implementation of strategies and plans drawn up for sustainable development and biodiversity conservation and progress made with completing national reports to the CBD,

Noting further the capacity problems of additional workloads for implementing agencies,

Recommends the following for CBD Implementation in PICs:

VI.1 that UNDP/UNEP/World Bank GEF implementing agencies assist PICs to quickly move forward the NBSAP proposal process,

VI.2 that PICs ensure the NBSAPs integrate the conservation and sustainable use of biodiversity into sectoral or cross- sectoral policies, plans and programmes,

VI.3 that government agencies, NGOs and local communities have active participatory and consultative roles in the formulation and implementation of NBSAPs,

VI.4 UNDP, SPREP and WWF assist with dissemination of information on NBSAP processes to PICs.

Further recommends that PIC delegations to COP4:

VI.3 urge COP4 to ensure that resources be made available not only for the development but also for the implementation of NBSAPs, upon their acceptance and completion by relevant national authorities,

VI.4 bring to the attention of COP4 the need for flexibility in the design of future guidelines for national reports to be submitted to the COP, to take into account the concerns of PICs that national reports should be of greater relevance for domestic purposes.

VII. PIC Biodiversity Zone

Recognising the need to establish a PIC Biodiversity Zone stretching from the northern, western, southern and eastern extremes of PIC Exclusive Economic Zones (EEZs), while noting that there are areas of international waters encompassed within that area,

Noting that an integral part of the establishment of a PIC Biodiversity Zone would have to address requests to collect resources within this area and these should be directed to a chosen regional organisation and considered regionally via CBD Focal Points,

Recommends the following for CBD Implementation in PICs:

VII.1 that further investigation of this proposal is required in collaboration by relevant agencies including ForSec, SPREP, FFA and SPC,

VII.2 that WWF be requested to update and verify the Global 200 Ecoregion Map to all important Pacific ecosystems and include the names of all PICs.

VIII. Food and Agricultural Organization (FAO) initiative

Recognising the linkages between issues of access to genetic resources and intellectual property rights addressed under the CBD with that of initiatives of FAO,

Noting the rejection of the application for plant breeders rights over chick pea varieties from India and Iran by two companies in Australia, Pacific Island participants express serious concern with the activities of trans-national corporations involved in the development and marketing of plant genetic resources,

Recommends the following for CBD Implementation in PICs:

VIII.1 the need for strengthening of the Material Transfer Agreement between the FAO and the Consultative Group on International Agricultural Research (CGIAR) centres in light of the revision of the International Undertaking on Plant Genetic Resources, with a view to prohibiting the taking out of intellectual property rights or patents on germplasms acquired from CGIAR centres,

VIII.2 the need, through the FAO, World Health Organization (WHO), or any other appropriate international forum, to seek an advisory opinion from the International Court of Justice (ICJ) on the legality of the patenting of genetic resources of all life forms under Article 27(3) of the TRIPs, and to seek a moratorium on human cloning.

Further recommends that PIC delegations to COP4 to:

VIII.3 raise the above concerns and recommendations for action on the FAO initiative with other delegations.

CONVENTION ON BIOLOGICAL DIVERSITY

5 June 1992

Preamble

The Contracting Parties,

Conscious of the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components,

Conscious also of the importance of biological diversity for evolution and for maintaining life sustaining systems of the biosphere,

Affirming that the conservation of biological diversity is a common concern of humankind,

Reaffirming that States have sovereign rights over their own biological resources,

Reaffirming also that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

Concerned that biological diversity is being significantly reduced by certain human activities,

Aware of the general lack of information and knowledge regarding biological diversity and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,

Noting further that the fundamental requirement for the conservation of biological diversity is the *in-situ* conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

Noting further that *ex-situ* measures, preferably in the country of origin, also have an important role to play,

Recognizing the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

Recognizing also the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

Acknowledging that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

Acknowledging further that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

Noting in this regard the special conditions of the least developed countries and small island States,

Acknowledging that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

Recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

Noting that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

Desiring to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

Determined to conserve and sustainably use biological diversity for the benefit of present and future generations,

Have agreed as follows:

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, 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, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2. Use of Terms

For the purposes of this Convention:

"*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"*Biological resources*" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"*Biotechnology*" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"*Country of origin of genetic resources*" means the country which possesses those genetic resources in in-situ conditions.

"*Country providing genetic resources*" means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

"*Domesticated or cultivated species*" means species in which the evolutionary process has been influenced by humans to meet their needs.

"*Ecosystem*" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ conservation*" means the conservation of components of biological diversity outside their natural habitats.

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

"*Genetic resources*" means genetic material of actual or potential value.

"*Habitat*" means the place or type of site where an organism or population naturally occurs.

"*In-situ conditions*" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*In-situ conservation*" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*Protected area*" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"*Regional economic integration organization*" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly au-

thorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"*Sustainable use*" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"*Technology*" includes biotechnology.

Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4. Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5. Cooperation

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6. General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

Article 7. Identification and Monitoring

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I;

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies;

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components;

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;

(l) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities; and

(m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (l) above, particularly to developing countries.

Article 9. Ex-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures:

(a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;

(b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary ex-situ measures are required under subparagraph (c) above; and

(e) Cooperate in providing financial and other support for ex-situ conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of ex-situ conservation facilities in developing countries.

Article 10. Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11. Incentive Measures

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12. Research and Training

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, inter alia, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and

(c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13. Public Education and Awareness

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14. Impact Assessment and Minimizing Adverse Impacts

1. Each Contracting Party, as far as possible and as appropriate, shall:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;

(c) Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to

biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent

with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article 18. Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, *inter alia*, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The 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 the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20. Financial Resources

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of, biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi-arid zones, coastal and mountainous areas.

Article 21. Financial Mechanism

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to, the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis.

Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22. Relationship with Other International Conventions

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Article 23. Conference of the Parties

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.

2. Extraordinary meetings of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.

3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.

4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:

(a) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 26 and consider such information as well as reports submitted by any subsidiary body;

(b) Review scientific, technical and technological advice on biological diversity provided in accordance with Article 25;

(c) Consider and adopt, as required, protocols in accordance with Article 28;

(d) Consider and adopt, as required, in accordance with Articles 29 and 30, amendments to this Convention and its annexes;

(e) Consider amendments to any protocol, as well as to any annexes thereto, and, if so decided, recommend their adoption to the parties to the protocol concerned;

(f) Consider and adopt, as required, in accordance with Article 30, additional annexes to this Convention;

(g) Establish such subsidiary bodies, particularly to provide scientific and technical advice, as are deemed necessary for the implementation of this Convention;

(h) Contact, through the Secretariat, the executive bodies of conventions dealing with matters covered by this Convention with a view to establishing appropriate forms of cooperation with them; and

(i) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention in the light of experience gained in its operation.

5. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State not Party to this Convention, may be represented as observers at meetings of the Conference of the Parties. Any other body or agency, whether governmental or non-governmental, qualified in fields relating to conservation and sustainable use of biological diversity, which has informed the Secretariat of its wish to be represented as an observer at a meeting of the Conference of the Parties, may be admitted unless at least one third of the Parties present object. The admission and participation of observers shall be subject to the rules of procedure adopted by the Conference of the Parties.

Article 24. Secretariat

1. A secretariat is hereby established. Its functions shall be:

(a) To arrange for and service meetings of the Conference of the Parties provided for in Article 23;

(b) To perform the functions assigned to it by any protocol;

(c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;

(d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and

(e) To perform such other functions as may be determined by the Conference of the Parties.

2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Article 25. Subsidiary Body on Scientific, Technical and Technological Advice

1. A subsidiary body for the provision of scientific, technical and technological advice is hereby established to provide the Conference of the Parties and, as appropriate, its other subsidiary bodies with timely advice relating to the implementation of this Convention. This body shall be open to participation by all Parties and shall be multidisciplinary. It shall comprise government representatives competent in the relevant field of expertise. It shall report regularly to the Conference of the Parties on all aspects of its work.

2. Under the authority of and in accordance with guidelines laid down by the Conference of the Parties, and upon its request, this body shall:

(a) Provide scientific and technical assessments of the status of biological diversity;

(b) Prepare scientific and technical assessments of the effects of types of measures taken in accordance with the provisions of this Convention;

(c) Identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advise on the ways and means of promoting development and/or transferring such technologies;

(d) Provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity; and

(e) Respond to scientific, technical, technological and methodological questions that the Conference of the Parties and its subsidiary bodies may put to the body.

3. The functions, terms of reference, organization and operation of this body may be further elaborated by the Conference of the Parties.

Article 26. Reports

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Article 27. Settlement of Disputes

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.

2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.

3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:

(a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

(b) Submission of the dispute to the International Court of Justice.

4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.

5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Article 28. Adoption of Protocols

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.

2. Protocols shall be adopted at a meeting of the Conference of the Parties.

3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Article 29. Amendment of the Convention or Protocols

1. Amendments to this Convention may be proposed by any Contracting Party. Amendments to any protocol may be proposed by any Party to that protocol.

2. Amendments to this Convention shall be adopted at a meeting of the Conference of the Parties. Amendments to any protocol shall be adopted at a meeting of the Parties to the Protocol in question. The text of any proposed amendment to this Convention or to any protocol, except as may otherwise be provided in such protocol, shall be communicated to the Parties to the instrument in question by the secretariat at least six months before the meeting at which it is proposed for adoption. The secretariat shall also communicate proposed amendments to the signatories to this Convention for information.

3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention or to any protocol by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-third majority vote of the Parties to the instrument in question present and voting at the meeting, and shall be submitted by the Depositary to all Parties for ratification, acceptance or approval.

4. Ratification, acceptance or approval of amendments shall be notified to the Depositary in writing. Amendments adopted in accordance with paragraph 3 above shall enter into force among Parties having accepted them on the ninetieth day after the deposit of instruments of ratification, acceptance or approval by at least two thirds of the Contracting Parties to this Convention or of the Parties to the protocol concerned, except as may otherwise be provided in such protocol. Thereafter the amendments shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, acceptance or approval of the amendments.

5. For the purposes of this Article, "Parties present and voting" means Parties present and casting an affirmative or negative vote.

Article 30. Adoption and Amendment of Annexes

1. The annexes to this Convention or to any protocol shall form an integral part of the Convention or of such protocol, as the case may be, and, unless expressly provided otherwise, a reference to this Convention or its protocols constitutes at the same time a reference to any annexes thereto. Such annexes shall be restricted to procedural, scientific, technical and administrative matters.

2. Except as may be otherwise provided in any protocol with respect to its annexes, the following procedure shall apply to the proposal, adoption and entry into force of additional annexes to this Convention or of annexes to any protocol:

(a) Annexes to this Convention or to any protocol shall be proposed and adopted according to the procedure laid down in Article 29;

(b) Any Party that is unable to approve an additional annex to this Convention or an annex to any protocol to which it is Party shall so notify the Depositary, in writing, within one year from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time withdraw a previous declaration of objection and the annexes shall thereupon enter into force for that Party subject to subparagraph (c) below;

(c) On the expiry of one year from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties to this Convention or to any protocol concerned which have not submitted a notification in accordance with the provisions of subparagraph (b) above.

3. The proposal, adoption and entry into force of amendments to annexes to this Convention or to any protocol shall be subject to the same procedure as for the proposal, adoption and entry into force of annexes to the Convention or annexes to any protocol.

4. If an additional annex or an amendment to an annex is related to an amendment to this Convention or to any protocol, the additional annex or amendment shall not enter into force until such time as the amendment to the Convention or to the protocol concerned enters into force.

Article 31. Right to Vote

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 32. Relationship between this Convention and Its Protocols

1. A State or a regional economic integration organization may not become a Party to a protocol unless it is, or becomes at the same time, a Contracting Party to this Convention.

2. Decisions under any protocol shall be taken only by the Parties to the protocol concerned. Any Contracting Party that has not ratified, accepted or approved a protocol may participate as an observer in any meeting of the parties to that protocol.

Article 33. Signature

This Convention shall be open for signature at Rio de Janeiro by all States and any regional economic integration organization from 5 June 1992 until 14 June 1992, and at the United Nations Headquarters in New York from 15 June 1992 to 4 June 1993.

Article 34. Ratification, Acceptance or Approval

1. This Convention and any protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.

2. Any organization referred to in paragraph 1 above which becomes a Contracting Party to this Convention or any protocol without any of its member States being a Contracting Party shall be bound by all the obligations under the Convention or the protocol, as the case may be. In the case of such organizations, one or more of whose member States is a Contracting Party to this Convention or relevant protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Convention or protocol, as the case may be. In such cases, the organization and the member States shall not be entitled to exercise rights under the Convention or relevant protocol concurrently.

3. In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

Article 35. Accession

1. This Convention and any protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Convention or the protocol concerned is closed for signature. The instruments of accession shall be deposited with the Depositary.

2. In their instruments of accession, the organizations referred to in paragraph 1 above shall declare the extent of their competence with respect to the matters governed by the Convention or the relevant protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.

3. The provisions of Article 34, paragraph 2, shall apply to regional economic integration organizations which accede to this Convention or any protocol.

Article 36. Entry Into Force

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession.

2. Any protocol shall enter into force on the ninetieth day after the date of deposit of the number of instruments of ratification, acceptance, approval or accession, specified in that protocol, has been deposited.

3. For each Contracting Party which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the thirtieth instrument of ratification, acceptance, approval or accession, it shall enter into force on the ninetieth day after the date of deposit by such Contracting Party of its instrument of ratification, acceptance, approval or accession.

4. Any protocol, except as otherwise provided in such protocol, shall enter into force for a Contracting Party that ratifies, accepts or approves that protocol or accedes thereto after its entry into force pursuant to paragraph 2 above, on the ninetieth day after the date on which that Contracting Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Convention enters into force for that Contracting Party, whichever shall be the later.

5. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 37. Reservations

No reservations may be made to this Convention.

Article 38. Withdrawals

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, that Contracting Party may withdraw from the Convention by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Article 39. Financial Interim Arrangements

Provided that it has been fully restructured in accordance with the requirements of Article 21, the Global Environment Facility of the United Nations Development Programme, the United Nations Environment Programme and the International Bank for Reconstruction and Development shall be the institutional structure referred to in Article 21 on an interim basis, for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties or until the Conference of the Parties decides which institutional structure will be designated in accordance with Article 21.

Article 40. Secretariat Interim Arrangements

The secretariat to be provided by the Executive Director of the United Nations Environment Programme shall be the secretariat referred to in Article 24, paragraph 2, on an interim basis for the period between the entry into force of this Convention and the first meeting of the Conference of the Parties.

Article 41. Depositary

The Secretary-General of the United Nations shall assume the functions of Depositary of this Convention and any protocols.

Article 42. Authentic Texts

The original of this Convention, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Convention. Done at Rio de Janeiro on this fifth day of June, one thousand nine hundred and ninety-two.

Annex I

IDENTIFICATION AND MONITORING

1. Ecosystems and habitats: containing high diversity, large numbers of endemic or threatened species, or wilderness; required by migratory species; of social, economic, cultural or scientific importance; or, which are representative, unique or associated with key evolutionary or other biological processes;

2. Species and communities which are: threatened; wild relatives of domesticated or cultivated species; of medicinal, agricultural or other economic value; or social, scientific or cultural importance; or importance for research into the conservation and sustainable use of biological diversity, such as indicator species; and

3. Described genomes and genes of social, scientific or economic importance.

Annex II

Part 1

ARBITRATION

Article 1

The claimant party shall notify the secretariat that the parties are referring a dispute to arbitration pursuant to Article 27. The notification shall state the subject-matter of arbitration and include, in particular, the articles of the Convention or the protocol, the interpretation or application of which are at issue. If the parties do not agree on the subject matter of the dispute before the President of the tribunal is designated, the arbitral

tribunal shall determine the subject matter. The secretariat shall forward the information thus received to all Contracting Parties to this Convention or to the protocol concerned.

Article 2

1. In disputes between two parties, the arbitral tribunal shall consist of three members. Each of the parties to the dispute shall appoint an arbitrator and the two arbitrators so appointed shall designate by common agreement the third arbitrator who shall be the President of the tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.

2. In disputes between more than two parties, parties in the same interest shall appoint one arbitrator jointly by agreement.

3. Any vacancy shall be filled in the manner prescribed for the initial appointment.

Article 3

1. If the President of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Secretary-General of the United Nations shall, at the request of a party, designate the President within a further two-month period.

2. If one of the parties to the dispute does not appoint an arbitrator within two months of receipt of the request, the other party may inform the Secretary-General who shall make the designation within a further two-month period.

Article 4

The arbitral tribunal shall render its decisions in accordance with the provisions of this Convention, any protocols concerned, and international law.

Article 5

Unless the parties to the dispute otherwise agree, the arbitral tribunal shall determine its own rules of procedure.

Article 6

The arbitral tribunal may, at the request of one of the parties, recommend essential interim measures of protection.

Article 7

The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, information and facilities; and

(b) Enable it, when necessary, to call witnesses or experts and receive their evidence.

Article 8

The parties and the arbitrators are under an obligation to protect the confidentiality of any information they receive in confidence during the proceedings of the arbitral tribunal.

Article 9

Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the costs of the tribunal shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its costs, and shall furnish a final statement thereof to the parties.

Article 10

Any Contracting Party that has an interest of a legal nature in the subject-matter of the dispute which may be affected by the decision in the case, may intervene in the proceedings with the consent of the tribunal.

Article 11

The tribunal may hear and determine counterclaims arising directly out of the subject-matter of the dispute.

Article 12

Decisions both on procedure and substance of the arbitral tribunal shall be taken by a majority vote of its members.

Article 13

If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to make its award. Absence of a party or a failure of a party to defend its case shall not constitute a bar to the proceedings. Before rendering its final decision, the arbitral tribunal must satisfy itself that the claim is well founded in fact and law.

Article 14

The tribunal shall render its final decision within five months of the date on which it is fully constituted unless it finds it necessary to extend the time-limit for a period which should not exceed five more months.

Article 15

The final decision of the arbitral tribunal shall be confined to the subject-matter of the dispute and shall state the reasons on which it is based. It shall contain the names of the members who have participated and the date of the final decision. Any member of the tribunal may attach a separate or dissenting opinion to the final decision.

Article 16

The award shall be binding on the parties to the dispute. It shall be without appeal unless the parties to the dispute have agreed in advance to an appellate procedure.

Article 17

Any controversy which may arise between the parties to the dispute as regards the interpretation or manner of implementation of the final decision may be submitted by either party for decision to the arbitral tribunal which rendered it.

Part 2

CONCILIATION

Article 1

A conciliation commission shall be created upon the request of one of the parties to the dispute. The commission shall, unless the parties otherwise agree, be composed of five members, two appointed by each Party concerned and a President chosen jointly by those members.

Article 2

In disputes between more than two parties, parties in the same interest shall appoint their members of the commission jointly by agreement. Where two or more parties have separate interests or there is a disagreement as to whether they are of the same interest, they shall appoint their members separately.

Article 3

If any appointments by the parties are not made within two months of the date of the request to create a conciliation commission, the Secretary-General of the United Nations shall, if asked to do so by the party that made the request, make those appointments within a further two-month period.

Article 4

If a President of the conciliation commission has not been chosen within two months of the last of the members of the commission being appointed, the Secretary-General of the United Nations shall, if asked to do so by a party, designate a President within a further two-month period.

Article 5

The conciliation commission shall take its decisions by majority vote of its members. It shall, unless the parties to the dispute otherwise agree, determine its own procedure. It shall render a proposal for resolution of the dispute, which the parties shall consider in good faith.

Article 6

A disagreement as to whether the conciliation commission has competence shall be decided by the commission.

SIGNATORIES OF THE CONVENTION ON BIOLOGICAL DIVERSITY AT THE TIME OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT

(Rio De Janeiro, 3-14 June 1992)

Signatory	Date of signature
1. Antigua and Barbuda	5 June 1992
2. Australia	5 June 1992
3. Bangladesh	5 June 1992
4. Belgium	5 June 1992
5. Brazil	5 June 1992
6. Finland	5 June 1992
7. India	5 June 1992
8. Indonesia	5 June 1992
9. Italy	5 June 1992
10. Liechtenstein	5 June 1992
11. Republic of Moldova	5 June 1992
12. Nauru	5 June 1992
13. Netherlands	5 June 1992
14. Pakistan	5 June 1992
15. Poland	5 June 1992
16. Romania	5 June 1992
17. Bostwana	8 June 1992
18. Madagascar	8 June 1992

19. Sweden	8 June 1992
20. Tuvalu	8 June 1992
21. Yugoslavia	8 June 1992
22. Bahrain	9 June 1992
23. Ecuador	9 June 1992
24. Egypt	9 June 1992
25. Kazakhstan	9 June 1992
26. Kuwait	9 June 1992
27. Luxembourg	9 June 1992
28. Norway	9 June 1992
29. Sudan	9 June 1992
30. Uruguay	9 June 1992
31. Vanuatu	9 June 1992
32. Cote d'Ivoire	10 June 1992
33. Ethiopia	10 June 1992
34. Iceland	10 June 1992
35. Malawi	10 June 1992
36. Mauritius	10 June 1992
37. Oman	10 June 1992
38. Rwanda	10 June 1992
39. San Marino	10 June 1992
40. Seychelles	10 June 1992
41. Sri Lanka	10 June 1992
42. Belarus	11 June 1992
43. Bhutan	11 June 1992
44. Burundi	11 June 1992
45. Canada	11 June 1992
46. China	11 June 1992
47. Comoros	11 June 1992
48. Congo	11 June 1992
49. Croatia	11 June 1992
50. Democratic People's Republic of Korea	11 June 1992
51. Israel	11 June 1992
52. Jamaica	11 June 1992
53. Jordan	11 June 1992
54. Kenya	11 June 1992
55. Latvia	11 June 1992
56. Lesotho	11 June 1992
57. Lithuania	11 June 1992
58. Monaco	11 June 1992
59. Myanmar	11 June 1992
60. Niger	11 June 1992
61. Qatar	11 June 1992
62. Trinidad and Tobago	11 June 1992
63. Turkey	11 June 1992
64. Ukraine	11 June 1992
65. United Arab Emirates	11 June 1992
66. Zaire	11 June 1992
67. Zambia	11 June 1992
68. Afghanistan	12 June 1992
69. Angola	12 June 1992
70. Argentina	12 June 1992
71. Azerbaijan	12 June 1992
72. Bahamas	12 June 1992
73. Barbados	12 June 1992
74. Bulgaria	12 June 1992

75. Burkina Faso	12 June 1992
76. Cape Verde	12 June 1992
77. Chad	12 June 1992
78. Colombia	12 June 1992
79. Cook Islands	12 June 1992
80. Cuba	12 June 1992
81. Cyprus	12 June 1992
82. Denmark	12 June 1992
83. Estonia	12 June 1992
84. Gabon	12 June 1992
85. Gambia	12 June 1992
86. Germany	12 June 1992
87. Ghana	12 June 1992
88. Greece	12 June 1992
89. Guinea	12 June 1992
90. Guinea-Bissau	12 June 1992
91. Lebanon	12 June 1992
92. Liberia	12 June 1992
93. Malaysia	12 June 1992
94. Maldives	12 June 1992
95. Malta	12 June 1992
96. Marshall Islands	12 June 1992
97. Mauritania	12 June 1992
98. Micronesia	12 June 1992
99. Mongolia	12 June 1992
100. Mozambique	12 June 1992
101. Namibia	12 June 1992
102. Nepal	12 June 1992
103. New Zealand	12 June 1992
104. Paraguay	12 June 1992
105. Peru	12 June 1992
106. Philippines	12 June 1992
107. Saint Kitts and Nevis	12 June 1992
108. Samoa	12 June 1992
109. Sao Tome and Principe	12 June 1992
110. Swaziland	12 June 1992
111. Switzerland	12 June 1992
112. Thailand	12 June 1992
113. Togo	12 June 1992
114. Uganda	12 June 1992
115. United Kingdom of Great Britain and Northern Ireland	12 June 1992
116. United Republic of Tanzania	12 June 1992
117. Venezuela	12 June 1992
118. Yemen	12 June 1992
119. Zimbabwe	12 June 1992
120. Algeria	13 June 1992
121. Armenia	13 June 1992
122. Austria	13 June 1992
123. Belize	13 June 1992
124. Benin	13 June 1992
125. Bolivia	13 June 1992
126. Central African Republic	13 June 1992
127. Chile	13 June 1992
128. Costa Rica	13 June 1992
129. Djibouti	13 June 1992

130. Dominican Republic	13 June 1992
131. El Salvador	13 June 1992
132. European Economic Community	13 June 1992
133. France	13 June 1992
134. Guatemala	13 June 1992
135. Guyana	13 June 1992
136. Haiti	13 June 1992
137. Hungary	13 June 1992
138. Honduras	13 June 1992
139. Ireland	13 June 1992
140. Japan	13 June 1992
141. Mexico	13 June 1992
142. Morocco	13 June 1992
143. Nicaragua	13 June 1992
144. Nigeria	13 June 1992
145. Panama	13 June 1992
146. Papua New Guinea	13 June 1992
147. Portugal	13 June 1992
148. Republic of Korea	13 June 1992
149. Russian Federation	13 June 1992
150. Senegal	13 June 1992
151. Slovenia	13 June 1992
152. Solomon Islands	13 June 1992
153. Spain	13 June 1992
154. Suriname	13 June 1992
155. Tunisia	13 June 1992
156. Cameroon	14 June 1992
157. Iran	14 June 1992

INTRODUCTION TO THE ANNEXES

Annexes 1 – 7 provide additional technical and legal information on and illustrative examples of issues covered in the preceding Chapters, particularly Chapter 2. Examples are included of the various means by which the Convention's provisions on access to genetic resources and benefit-sharing are being implemented at the local and national levels by governments, research organisations, and other institutions in provider and user countries. These Annexes have been compiled, and in some cases reproduced or adapted, from a range of sources which are indicated at the end of each section or Annex.

In relation to Annexes 1, 2, and 4, it should be emphasised that the examples given in these Annexes are not provided as models, and their inclusion in this package does not imply any endorsement of particular approaches. They are simply provided by way of information and examples of a range of legislative and contractual initiatives on access to genetic resources and benefit sharing. Sources and references for further information, including critiques, are given in the annexes and in the overall bibliography at the end of this package.

Annex 1 Provides examples of access and benefit-sharing laws currently in force or under development in a number of countries or regions, including Samoa's Draft Access Regulations. These examples illustrate the mechanisms which some countries and regions, in light of their own circumstances, have deemed appropriate for regulating access to their genetic resources. Where possible, the examples in this Annex have been structured according to a common format so as to provide information on: the scope of the access legislation; the access determination procedure; any contractual or licensing arrangements envisaged by the legislation; terms and conditions for access to genetic resources; and provisions addressing intellectual property rights.

Annex 2 Illustrates a range of bioprospecting and collaborative research initiatives, as well as mechanisms for the management and distribution of any financial benefits at the local level.

Annex 3 Is a case study on Kava by Clark Peteru (adapted) that explores the links between access and benefit-sharing and intellectual property rights (as discussed in Chapter 3). The case study is intended to offer a South Pacific perspective on indigenous innovations and practices, and the implications of the TRIPs Agreement in terms of the ability of Pacific communities to retain their heritage.

Annex 4 Is an overview of the access and benefit-sharing policy of the United States National Cancer Institute (NCI). The NCI is a major user of biological material in drug development. This overview examines the evolution of its contractual approach to access and benefit-sharing, including its approach to value-added work in provider countries, over the past decade.

Annex 5 Provides additional information on efforts to bring *ex situ* collections of genetic resources, including those obtained prior to the Convention's entry into force, within the spirit of the Convention's provisions on access and benefit-sharing. Plant and microbial genetic resources are considered.

Annex 6 Contains the text of the 2000 Cartagena Protocol on Biosafety, which was adopted on 29 January 2000, and opened for signature in May 2000. The Protocol was negotiated further to Article 19(3) of the Convention and Decision II/5 of the Conference of the Parties. It is discussed in Chapter 4 of the Information Package.

Annex 7 Is the Report of a Regional Workshop on the *Implementation of the Convention On Bilogical Diversity in the Pacific Islands Region* which was held in Nadi, Fiji from 30 March to 3 April 1998.

ANNEX 1: ACCESS AND BENEFIT-SHARING LEGISLATION

INTRODUCTION

The number of countries world-wide currently developing national policies and laws on access and benefit-sharing is growing fast.

The aim of this Annex is to illustrate some of the initiatives that are currently underway to implement Article 15 and related provisions on indigenous and local communities, technology transfer and intellectual property rights. In the Pacific islands region, to date few countries have taken steps to regulate access to genetic resources. Fiji is seeking to do so with Draft Provisions on access to genetic resources, which were originally contained in its Sustainable Development Bill (see Chapter 2, section 4.5). Samoa is also drafting access regulations. At the Nadi Workshop on the Implementation of the Convention on Biological Diversity in the Pacific Islands Region, held in April 1998, regulating access to Pacific island biological resources was highlighted as an urgent priority (see Nadi Statement: www.sidsnet.org/pacific/sprep/biodiv/nadistatement.htm).

This Annex in section 1, outlines Samoa's Draft Access Regulations. It also reviews a sub-regional regime, involving the five Member Countries of the Andean Community. This regime is known as Decision 391: 'Common Regime on Access to Genetic Resources' and is described in Section 2 below. In 1995, the Philippines was the first country to adopt a stand-alone, national measure to regulate bioprospecting. This is known as Executive Order 247 and is reviewed in Section 3 below.

Countries are also implementing the provisions of the Convention on access to genetic resources and benefit-sharing as part of more general framework laws on biodiversity. An example of this is provided by the Costa Rican Biodiversity Law, which is analysed in Section 4.

In each case, the review:

- Outlines the scope of the provisions regulating access to genetic resources;
- Describes the 'access determination procedure' (including any requirements for consent of local communities);
- Outlines terms and conditions of access specified in the regulations; and
- Notes whether, and if so how, intellectual property rights are addressed.

1. SAMOA'S DRAFT ACCESS REGULATIONS

In 1998, the Government of Samoa, acting through its Division of Environment and Conservation, began to work with WWF–SPP to regulate bioprospecting in Samoa. Prompted by interest in Samoa's biological resources by foreign entities, the Government considered it an urgent priority to ensure that an appropriate mechanism was put in place to control access to genetic resources and ensure appropriate benefit-sharing. Samoa's Access Regu-

lations have been developed over a period of time, by means of a participatory and consultative process involving various stakeholders and experts. As of July 2000, the draft Regulations are awaiting adoption by Cabinet and may be subject to further review by certain Government departments. The Access Regulations will be brought under the Lands and Environment Act, 1989.

1.1 Scope of the draft Regulations

The overall aim of the Regulations is to ensure that all biodiversity prospecting in Samoa is carried out only with the prior approval of the Government and in accordance with the established procedure for the issuance of a bioprospecting permit.

A fast track or parallel procedure may exempt local, educational or deserving individuals from some of the procedures prescribed by the Regulations.

The Draft Regulations give the Division of Environment and Conservation responsibility for establishing and maintaining an effective system to regulate biodiversity prospecting in Samoa, in order to ensure that:

- ecological, social or economic harm is not caused by research into or exploitation of biological resources;
- the taking of biological resources does not cause an undesirable impact on Samoa's biological diversity;
- a fair return is provided for the exploitation of biological resources as well as for traditional knowledge related to these resources;
- property rights and customary rights over biological resources and traditional knowledge are safeguarded; and
- owners of biological resources, or those exercising legitimate control over those resources, are fully informed regarding the activity.

Box 1: Definitions

In the Draft Regulations:

Biodiversity prospecting means:

- the collection or exploitation of biological resources for commercial, research or sampling purposes.

Biological resources includes:

- genetic resources, organisms or parts of these, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

1.2 The access determination procedure as specified by the Draft Regulations

Any person wishing to undertake biodiversity prospecting in Samoa would have to complete the standard Application Form for a Permit for Biodiversity Prospecting and submit this to the Division of Environment and Conservation (DEC) (the designated national authority). Upon receipt of the application form the DEC is required to: (a) consult with government bodies (at least Internal Affairs and Agriculture, Forests and Fisheries) and, where appropriate, with non-government bodies; and (b) publicise the application (including all relevant information on the activities to be undertaken) on Samoan television, radio and newspapers, and allow for submissions to be made on the application.

The Minister shall take the final decision on the application, based on a report by the DEC. The Minister may:

- refuse the application;

- require that an environmental impact assessment be conducted; and/or,
- require that the applicant:
  - provides evidence of the prior informed consent of the resource owner (or person in effective control of the resources);
  - concludes an agreement with the resource owner (or person in effective control of the resources) to determine the rights of access, including any limitations on the collection of samples; the agreement must also make provisions for intellectual property rights and the payment of appropriate fees and royalties (see further section 1.4 below); and/or,
  - completes a plan which outlines the intended research programme, a suitable monitoring programme and system for recording information and resources gathered, and the process for undertaking an inventory.

The DEC must evaluate and report to the Minister on the results of any environmental impact assessment, which was considered necessary for the applicant to undertake.

Where the above-mentioned requirements are assessed by the DEC to have been fulfilled, the Minister must issue a bioprospecting permit within 30 days.

An applicant must also obtain an export permit prior to exporting out of Samoa any specimen collected pursuant to a bioprospecting permit. The export permit shall contain certain specified information and shall be approved by the DEC upon a determination that the exporter has complied with the requirements of the bioprospecting permit, and is acting consistently with local laws and international conventions.

1.3 Terms and conditions of access

Under the Draft Regulations bioprospecting permit would need to specify terms and conditions, including:

- the payment of fees or charges;
- compliance with such technology transfer arrangements, or training and employment requirements, as may be agreed to by the applicant; or
- such other conditions as specified by the Minister.

The permit must contain information on the proposed bioprospecting activities and specify the relevant terms and conditions to be undertaken, including:

- the species of biological resources that may be sought and the quantities or numbers of such species that may be collected;
- the methods that shall be used for any specific evaluation, sampling or collecting;
- the methods that shall be used for the storage or transportation of any biological samples; and
- conditions and requirements concerning any environmental monitoring or management plans that are to be established.

A permit will normally be valid for one year, unless extended for an additional year. The Minister may, under certain circumstances, vary the terms and conditions of the permit or revoke the permit altogether. An applicant may appeal a revocation within 21 days of such a revocation.

A failure to comply with a condition imposed by the permit will be an offence. The Draft Regulations stipulate powers of inspection and seizure.

1.4 Intellectual property rights

The Draft Regulations provide that, prior to the issuance of a bioprospecting permit, the Minister may require the applicant to enter into an agreement with the resource owner

(or person exercising control over the resources) to determine the rights and conditions of access. This includes the negotiation of rights in or access to intellectual property or traditional knowledge owned by or vested in any individual, group of individuals or representatives thereof, and the payment of fees, royalties or licence payments for such rights or access.

2. DECISION 391 OF THE ANDEAN COMMUNITY

On 2 July 1996, the Andean Community Member Countries of Bolivia, Columbia, Ecuador, Peru and Venezuela (hereinafter Member Countries) adopted Decision 391: 'Common System on Access to Genetic Resources' ("Decision 391"). Decision 391 is the first sub-regional access and benefit-sharing legislative measure in response to Article 15 of the Convention on Biological Diversity. It was developed over a three year period, with initial input and the participation of non-governmental organisations and governmental experts. Decision 391 became legally binding in Member Countries on 17 July 1996, upon publication in the Official Gazette of the Andean Community.

Decision 391 provides a common framework to all the Member Countries for regulating access to genetic resources. It requires collectors wishing to gain access to genetic resources within any of the Member Countries to apply for access to the Competent National Authority (designated national authority) in the country where the resources are located, and to enter into certain contractual arrangements. Member countries therefore need to take certain national action to implement the Decision.

Decision 391 promotes cooperation among the Member Countries on matters of mutual interest relating to the conservation and sustainable use of genetic resources, including the establishment of relevant scientific and technical training programmes. It establishes an Andean Committee on Genetic Resources to oversee the implementation of Decision 391 and to further its objectives, including by promoting action to manage resources common to two or more Member Countries, and to consider the establishment of an Andean Fund for the conservation of genetic resources.

Decision 391 recognises the rights and decision-making capacities of indigenous, afro-american and local communities with regard to their traditional knowledge, practices and innovations connected with genetic resources and their derivatives. It requires that, where access to genetic resources or their derivatives includes access to traditional knowledge, permission for such access is to be granted only with the prior informed consent of these communities. A process is envisaged in Decision 391 to further develop the rights of indigenous and local communities in relation to the protection of their traditional knowledge, innovations and practices. To that end, each Member Country undertook to draw up a national study.

The sovereignty of the Member Countries over their genetic resources is reaffirmed, in accordance with the Convention on Biological Diversity.

2.1 Scope of Decision 391

The aim of Decision 391 is to regulate access to genetic resources conserved in ex-situ and in-situ conditions for, among others purposes, research, bioprospecting, conservation, and industrial and commercial applications. The scope of the Decision covers genetic resources, their derivatives and intangible components (knowledge, innovations and practices) provided by the Member Countries from which they originate. It also applies to the genetic resources of migratory species, the natural ranges of which include the territories of Member Countries.

Decision 391 distinguishes between biological resources and genetic resources. While genetic resources and their derivatives are either "the property or patrimony of the Nation or State", the biological resources which contain the genetic resources might be subject to private or collective property rights, depending on national legislation. Decision 391 provides for the negotiation of different contractual arrangements, depending on whether access is to biological resources or to the genetic resources found in biological resources. So-called "accessory contracts" between the collector and those with rights in biological resources, such as private individuals or indigenous and local communities, are envisaged for these resources, whereas an "access contract" between the State and the collector is needed for genetic resources (see further section 2.3 below).

Box 2: Definitions used in Decision 391

Biological resources are defined as:

individuals, organisms or parts thereof, populations or any biotic component with actual or potential value or use contained by the genetic resource or its derivatives.

Genetic resources are defined as:

any biological material containing genetic information of actual or potential value.

A derivative is defined as:

a molecule or combination or mixture of natural molecules, including raw extracts of living or dead organisms of biological origin, derived from metabolism of living organisms.

The definition of derivatives omits synthesised products (i.e., a substance or a semi-processed extract obtained by means of an artificial process, using genetic information or other biological molecules). By explicitly including derivatives in Decision 391, the Member Countries have gone beyond the explicit terms of the Convention.

An intangible component is defined as:

any knowledge, innovation or individual or collective practice of actual or potential value associated with the genetic resource, whether or not protected by intellectual property laws.

The inclusion of the intangible components of genetic resources in Decision 391 is aimed at protecting traditional knowledge. Access to such knowledge is subject to the same procedures and requirements as are applicable for access to genetic resources themselves.

Where a transaction involves the export of biological resources, the accompanying phytosanitary certification documents must include the following statement: "not authorised for use as a genetic resource". As such, Decision 391 ensures that it is only the State that has the authority to grant access to the genetic component of biological resources.

Decision 391 includes within its scope ex-situ resources acquired prior to its entry into force, as well as prior to the entry into force of the Convention. This is apparent from the Decision's definition of "country of origin of genetic resources", i.e., "the country which possesses the genetic resources in in-situ conditions, including resources, which having originally been in such conditions, are now found in ex-situ conditions".

By including *ex-situ* resources within its scope, Decision 391 could have far-reaching implications, in particular for international ex-situ collection centres. Such centres would need to conform to the procedures and requirements of Decision 391 (two of the International Agricultural Research Centres are located within the Andean Pact region). Decision 391 requires contractual arrangements to be concluded between *ex-situ* conservation centres and the Member Countries (see section 2.3).

Decision 391 specifically excludes from its scope:

- human genetic resources; and
- the exchange of genetic resources or their intangible components by indigenous, afro-american or local communities of the Member Countries, among each other or for their own use, in accordance with their customary practices.

2.2 The access determination procedure

Decision 391 sets down the terms of the access procedure. Any person wishing to gain access to genetic resources must negotiate an "access contract" with the Competent National Authority (CNA) in the Member Country in which the resources are sought. Prior to negotiating the access contract, the prospective collector will need to present an application for access to the relevant CNA. The application will need to identify:

- the applicant;
- the supplier of genetic or biological resources and their derivatives, or of the associated intangible components;
- the national support institution or individual;
- the nature of the access activity being requested; and
- the locality or area in which the access will be made, together with the geographical coordinates.

The application must include documentation confirming that the applicant is legally entitled to enter into a contract, and a project proposal. Model documentation has been developed by the Andean Committee to guide the access application procedure.

If the applicant has satisfied the information requirements of the CNA, the application will be placed on the official record. With the exception of certain information deemed to be confidential, the application is made available for public scrutiny. The application must be evaluated within 30 working days (extendable to a maximum of 60 working days at the discretion of the CNA). Where the national legislation of the Member Country or the CNA requires it, the applicant must also comply with relevant environmental regulations and complete any necessary procedures within the time frame established before the CNA can evaluate the application.

A successful application will result in the subsequent negotiation of an "access contract". The parties to the access contract shall be the State (represented by the CNA) and the applicant. The access contract will need to take into consideration the rights and interests of the suppliers of genetic resources and their derivatives, and of biological resources and their intangible components. This is achieved, where appropriate, by concluding agreements in addition to the main access contract (see section 2.3 below).

Where the genetic resources are shared with any of the other Member Countries, their interests must be taken into account in the negotiation of the access contract. The CNA is required to notify the other Member Countries of all access applications and decisions taken thereon. The other Member Countries may present their views and any information they deem relevant. Decision 391 does not, however, expressly provide for a right to veto access. Nor does the Decision provide for a right of appeal in the event that the access application is denied. Any such right can, therefore, only be provided pursuant to national legislation enacted by the Member Countries themselves.

2.3 Types of contracts

Decision 391 envisages a range of contractual arrangements playing a role in the regulation of access to genetic resources.

The main contractual arrangement is the "access contract" between the CNA in the relevant Member Country and the applicant.

Decision 391 also envisages the negotiation of "framework access contracts", as between the CNA and universities, research centers or recognised researchers, where required for projects aimed at implementing Decision 391 or related national legislation in the Member Countries.

The Decision provides that access contracts must be concluded between a CNA and any ex-situ conservation centers located in a Member Country, and that are in possession of genetic resources originating in that Member Country. Access contracts may also be concluded between a CNA and third parties in possession of such genetic resources, such as ex-situ collections located outside the Andean region.

In addition to the main access contract, Decision 391 envisages the negotiation of supplementary contracts with the suppliers of biological resources containing the genetic resources at issue.

Firstly, where access is requested to a genetic resource or its derivatives that contain an intangible component (e.g. traditional knowledge), the applicant must agree to provide for the fair and equitable distribution of any benefits arising from that intangible component. This requirement is to be reflected in an annex to the main access contract. The annex shall be signed by the applicant and by the supplier of the intangible component. The annex shall be an integral part of the access contract such that a failure to comply with the terms of the annex terminates the main access contract.

Secondly, Decision 391 envisages so-called "accessory contracts" to the main access contract. "Accessory contracts" are signed for the purposes of developing activities pertaining to access to a genetic resource or its derivatives between the applicant and any of the following:

- the owner, holder or administrator of the property on which the biological resource containing the genetic resource is found;
- an *ex-situ* conservation centre;
- the owner, holder or administrator of the biological resource containing the genetic resource; or
- a national support institution, in connection with activities which it is to carry out and which are not included in the access contract.

The "accessory contract" cannot, of itself, authorise access to the genetic resource. Such access can only be authorised under the main access contract as between the CNA and the applicant. The "accessory contract" therefore becomes effective only upon approval of the main access contract.

2.4 Terms and conditions of access

Decision 391 sets out an indicative list of terms and conditions which will need to be reflected in the access contract and, where applicable, in any accessory contracts, including:

- participation by nationals in relevant research activities;
- strengthening mechanisms for the transfer of technology, including biotechnologies;

- opportunities to strengthen and develop national/ subregional institutional capacities;
- strengthening the capacities of indigenous and local communities with regards to the intangible components associated with genetic resources;
- the obligatory deposit of duplicates of all materials collected;
- an obligation to inform the CNA of all research results; and,
- the terms under which material obtained may be transferred to third parties.

Greater emphasis is placed on capacity-building, research and technology transfer than on economic gains such as collection fees and royalties.

Certain partial or total limitations on access are also envisaged in Decision 391. There is a total prohibition on the use of genetic resources and their derivatives for the purposes of biological warfare or other uses harmful to the environment or human health. In addition, access can be limited on account of:

- endemism, rarity or threat of extinction of species, subspecies, varieties or breeds;
- conditions of vulnerability or fragility of the ecosystem, likely to be aggravated by access activities;
- adverse effects of access activities on human health or on essential elements of inhabitants' cultural identity;
- access activities likely to have undesirable or hard to control environmental impacts on ecosystems;
- danger of genetic erosion;
- regulations governing biosafety; or
- genetic resources or geographical areas classified as strategic.

Any access arrangement that existed prior to the entry into force of Decision 391 must be renegotiated to ensure it conforms to the terms and conditions of Decision 391. A CNA may impose fines or other sanctions, including appropriate legal action to reclaim the material and obtain compensation, where the resources have been taken in breach of national regulations.

2.5 Intellectual property rights

Decision 391 provides that Member Countries will not recognise IPRs over genetic resources, derivatives, synthesised products or related intangible components that have been obtained through access activities which do not comply with the provisions of the Decision. It also provides that national intellectual property offices shall require applicants to submit both the registration number and a copy of the access contract as a prerequisite for the concession of the IPRs, when there is reasonable or concrete evidence to suggest that the products or processes for which IPRs are being sought have been obtained from genetic resources, the country of origin of which is a Member Country.

Box 3: National Experience with Decision 391 in Colombia

In February 1997, BioAndes de Colombia. S.A. - a joint venture by Andes Pharmaceuticals, Inc., a US-based biotechnology company, and ERS & Asociados, based in Bogota, Colombia - filed an application for access to Colombian biodiversity. The request was for access to State-owned property for the purposes of cancer drug discovery. No request was made for access to associated indigenous knowledge.

The BioAndes application was the first to be considered pursuant to Decision 391. The decision-making procedure took two years and included interventions from non-governmental organisations and interested persons. BioAndes submitted an initial and revised application in an attempt to meet the concerns of the Colombian Ministry of Environment. In December 1998, the Colombian Ministry of the Environment denied access to BioAndes. Some of the reasons given for rejecting the application were that:

- the taxonomic breadth of the application was too wide given that the request had sought "access to all Colombian taxonomic groups, marine and terrestrial";
- the monetary benefit-sharing scheme as outlined in the application did not meet a "minimum baseline from which to generate" the subsequent negotiation of the benefit sharing process;
- the bioassay technology (e.g., using cancer cells to test compounds for anti-cancer activity) could and would be used to screen for diseases different from cancer and that part of the scope of the research was unclear; and,
- there was a lack of clarity regarding intellectual property rights and the distribution of benefits derived therefrom.

Some have argued that this case illustrates that if regulation of access to genetic resources is too onerous, it may act as a disincentive for industry to form partnerships with the countries concerned. Andes Pharmaceuticals has consequently ceased to operate in the Andean Community countries.

Source: Columbia University School of International and Public Affairs, Environmental Policy Studies, Working Paper No. 4: "Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements", prepared for the Biodiversity Action Network.

Selected references

Rosell, M., "Access to Genetic Resources: A Critical Approach to Decision 391 'Common System on Access to Genetic Resources' of the Commission of the Cartagena Agreement", Review of European Community and International Environmental Law (RECIEL), 1997.

3. PHILIPPINES EXECUTIVE ORDER 247

The Philippines Executive Order No. 247, entitled 'Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes; and for Other Purposes' (hereinafter Executive Order 247) was the first stand-alone national instrument on access to genetic resources. It was developed in 1994 through a consultative process among various government agencies, scientific and technical experts and non-governmental organisations.

Executive Order 247 became effective on 23 May 1995, and has since been supplemented by Administrative Order 96-20, "Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources" ("Implementing Regulations") issued on 21 June 1996 by the Philippines Department of Environment and Natural Resources (DENR). The Implementing Regulations set out the procedure by which the

DENR and other concerned institutions and government bodies will administer Executive Order 247. By Administrative Order 97-27 of 31 July 1997, existing bioprospecting agreements entered into by and between government agencies and any person or institution, local or foreign, remained valid and effective up to 31 August 1997 only. After that date, all bioprospecting is required to be conducted in accordance with the terms of the Executive Order and the Implementing Regulations.

Executive Order 247 establishes the framework for regulating bioprospecting in the Philippines. It does not replace the existing permit/clearance system in the Philippines but creates a network that coordinates all the permits required under existing laws, rules and regulations. It requires anyone, whether a national or a foreign entity, wishing to collect biological or genetic resources to enter into a research agreement with the Government. Executive Order 247 distinguishes between two types of research agreements, depending on whether the bioprospecting is intended for academic purposes or commercial purposes.

Bioprospecting is permitted in protected areas with the prior informed consent of the Protected Area Management Board, in the lands of indigenous and local communities with their prior informed consent, and on private owned land with the prior informed consent of the land owner.

An Inter-Agency Committee on Biological and Genetic Resources is established to implement the Executive Order. The Inter-Agency Committee is a subsidiary body of the Department of Environment and Natural Resources (DENR). It is composed of individuals from the DENR, the Department of Science and Technology, the Department of Agriculture, the Department of Health, the Department of Foreign Affairs, as well as representatives from the Philippines' scientific community, the National Museum, non-governmental organisations and indigenous communities.

Executive Order 247 clarifies the legal status of biological and genetic resources by reference to the Philippines' Constitution, which provides that the said Constitution:

> *vests in the State the ultimate responsibility to preserve and protect the environment; and ...provides that wildlife, flora and fauna, among others, are owned by the State and the disposition, development and utilisation thereof are under its full control and supervision.*

Except for domesticated plants and animals, the State also owns wild fauna and flora found on private or communal land.

3.1 Scope of Executive Order 247

Executive Order 247 covers the prospecting of all biological and genetic resources in the public domain, by national and foreign individuals, entities or organisations, whether public or private. It governs activities involving the discovery, exploration or use of such resources for pharmaceutical development, and agricultural and commercial application. The public domain comprises those waters and lands owned by the State that have not been declared alienable and disposable. The scope of Executive Order 247 extends to wild flora and fauna found in-situ. Moreover, Executive Order 247 covers the by-products and derivatives of biological and genetic resources.

Executive Order 247 specifically excludes from its scope the traditional uses of biological resources by indigenous and local communities. Traditional uses refers to the customary utilisation of biological and genetic resources by the local community and indigenous people in accordance with written or unwritten rules, usages, customs and practices traditionally observed, accepted and recognised by them.

Box 4: Definitions in Executive Order 247

'**Bioprospecting and prospecting**' are defined as:

> the research, collection and utilisation of biological and genetic resources for purposes of applying the knowledge derived therefrom to scientifi and/or commercial purposes.

Biological resources are defined as:

> Includ[ing] genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential value for humanity such as plants, seeds, tissues and other propagation materials, animals, microorganisms, live or preserved, whether whole or in part thereof.

A **by-product** is defined as:

> Any part taken from biological and genetic resources such as hides, antlers, leathers, fur, internal organs, roots, hunks, branches, leaves, stems, flowers and the like, including compounds indirectly produced in a biochemical process or cycle.

A **derivative** is defined as:

> Something extracted from biological and genetic resources such as blood, oils, resin, genes, seeds, spores, pollen and the like, taken from or modified from a product.

3.2 The access determination procedure

Executive Order 247 distinguishes between commercial and academic uses. Commercial uses are subject to a different (more stringent) regime than are academic uses. Depending on the characterisation of the use, an applicant will be streamlined into a process for either a "Commercial Research Agreement" or an "Academic Research Agreement". The procedure for the application and processing of both types of research agreements is established in Executive Order 247 and further detailed in the Implementing Regulations.

All applications for research agreements shall be made to the Inter-Agency Committee on Biological and Genetic Resources through the Protected Area and Wildlife Bureau (acting as the Technical Secretariat). The application must include a proposal stating the purpose of the research, its source of funds and its duration, as well as a list of the biological and genetic materials sought, including the amount to be taken. The information is to be supplied in standard format, and accompanied by supporting documentation.

Where prospecting is intended in protected areas, the lands of indigenous or local communities, or privately owned land, the application will need to include a prior informed consent (PIC) certificate. An application for a Commercial Research Agreement must be accompanied by a PIC certificate. For Academic Research Agreements the appropriate PIC certificates are only required prior to the commencement of the actual bioprospecting activity. Two procedural steps are envisaged to fulfill the PIC requirement:

- public notification, which must be through various media; and
- local community and relevant sector consultations.

The burden is upon the applicant to commence the PIC procedure. A PIC certificate is, where approved, signed and issued by the relevant party (either the head of an indigenous community, head of government in a particular community, a private land owner or the Protected Area Management Board).

Where considered necessary by the Technical Secretariat, relevant documentation supporting an environmental impact assessment may be requested.

The Technical Secretariat conducts the initial review and evaluation of the application and supporting documentation, and, within 30 days of receiving of all required documentation from the collector, submits its results, including, where appropriate, a draft research agreement, to the Inter-Agency Committee for final evaluation. The application is formally approved by the relevant Government agency represented on the Inter-Agency Committee, depending on the nature and character of the prospecting activity (e.g., the DENR approves agreements relating to terrestrial wildlife; the Department of Agriculture approves agreements relating to agricultural and fishery biological resources; and so on). A research agreement is then formally signed between the applicant and the agency concerned.

A decision by the relevant Government agency to approve, disapprove or rescind an existing research agreement may be appealed to the Office of the President within 30 days. Recourse to the courts is allowed after all administrative remedies are exhausted.

3.3 Types of contracts

As noted above, all bioprospecting, except for traditional uses of biological resources by indigenous and local communities, require a research agreement to be concluded between the bioprospector and the Government. Philippines academic and research institutions, government agencies and inter-governmental institutions (such as the International Agricultural Research Centers) are eligible for an "*Academic Research Agreement*" where the genetic resources are intended for academic or scientific purposes. All other research and collection directly or indirectly intended for commercial purposes may only take place pursuant to a "*Commercial Research Agreement*".

Executive Order 247 establishes minimum terms and conditions for both types of research agreements (see section 3.4 below). Bioprospecting for commercial purposes is subject to more stringent criteria.

Box 5: Code of Conduct for Academic Collectors of Biological and Genetic Resources in the Philippines

The Philippines Government has introduced a mandatory 'Code of Conduct for Academic Collectors of Biological and Genetic Resources' as a means to complement and enforce its existing access legislation. The Code is designed to govern the activities of academic collectors operating under 'Academic Research Agreements' (ARA), and '…ensure[s] that any collection, research, use and transfer of biological and genetic resources, and related information, data and technologies shall be undertaken in full compliance with Executive Order No. 247…DAO 96-20 [the Implementing Rules and Regulations], [the] UN Convention on Biological Diversity and other existing laws, rules and regulations, and local customs and traditions'.

Responsibility for implementing the Code lies with the Inter-Agency Committee on Biological and Genetic Resources (IACBGR), the Principal (a duly recognised Philippines university or other academic institution), the Academic Collector (the person undertaking bioprospecting and who is employed by the Principal), and the government agency concerned. The Code of Conduct specifies the responsibilities of Academic Collectors before, during and after collection work. The Inter-Agency Committee periodically reviews the Code's relevance and effectiveness, while the Principal, through a monitoring team, bears the responsibility of monitoring compliance with the Code by all its academic collectors. Should the Principal fail to enforce the Code's provisions, its Academic Research Agreement (ARA) with national governmental agencies will be automatically cancelled or revoked.

With regard to *Academic Research Agreements* (ARA), the research proposal may be broader and more general in character. The ARA itself may be comprehensive in scope and cover as many areas as the applicant proposes to work in. It may stipulate that all scientists and researchers affiliated with a duly-recognised university, academic institution, governmental and non-governmental entity may benefit from the existing research agreement, rather than concluding separate agreements each time a collection is made. The institution party to the ARA is then responsible for ensuring that all researchers comply with the terms of the agreement, including ensuring, where appropriate, that any affected communities have given their prior informed consent (see box 5). The ARA will also need to include a provision requiring the Academic Collector to apply for a "*Commercial Research Agreement*" in the event that the research and collection covered by the ARA has commercial prospects. The maximum term of an ARA shall be for 5 years, renewable upon review by the Inter-Agency Committee, and a minimal fee is payable.

The maximum term for a Commercial Research Agreement (CRA) is 3 years (renewable). A fixed fee is payable, together with a "performance, compensation, ecological rehabilitation bond" deposited in favour of the Government, the amount of which is determined by the Inter-Agency Committee in accordance with the extent and scope of the project. The bond is forfeited in the event that the collector does not comply with the CRA.

In addition to the minimum terms and conditions required for all research agreement (see section 3.4 below), additional requirements in respect of a CRA are:

- if a collector is a foreign entity, the agreement must provide that Filipino scientists are to be involved in the research and collection process and, if so determined by the Inter-Agency Committee, in the technological development of any product derived from any material collected. This involvement shall be at the cost of the collector. In addition, the collector shall be encouraged to use the services of Philippine universities and research institutions and may, in some cases, be required to transfer equipment to them; and,
- where a commercial product is derived from biological or genetic resources endemic to the Philippines, the technology must be made available to a designated Philippine institution for commercial and local use without royalty payments to the collector. Other arrangements may be negotiated.

Irrespective of whether the agreement is an ARA or a CRA, where the academic or commercial collector is an agent for another entity, the agreement between the collector and that other entity must be reviewed by the Inter-Agency Committee to ensure it is consistent with Executive Order 247.

3.4 Terms and conditions of access

As noted above, Executive Order 247 lists a number of minimum terms and conditions for both types of research agreements, including:

- a limit on samples a collector may obtain/ export;
- the deposit of all specimens collected with the National Museum or designated government body;
- disclosure to the Government, and to affected indigenous and local communities, of all discoveries from the bioprospecting activities and of any commercial products derived therefrom;
- that all Filipino citizens and government bodies be allowed access to specimens deposited at internationally recognised ex-situ depositories;
- an agreement to pay royalties, and, where appropriate, other forms of compensation, to the Government, local and indigenous communities, and individual persons or designated beneficiaries, in case commercial use is derived from the biological and genetic resources taken;

- a provision allowing for the unilateral termination of the contract by the Government upon violation of any of its terms - the agreement may also be revoked on the basis of public interest and welfare; and,
- a status report on the ecological state of the area and/ or species concerned to be submitted regularly to the Inter-Agency Committee.

In addition to the minimum terms for research agreements, Executive Order 247 stipulates that any and all prospecting activities or their results must not directly or indirectly harm the biological diversity, ecological balance, or the inhabitants of the area where the collection is undertaken. It makes it the policy of the State to regulate prospecting activities to protect and conserve genetic resources, so that they are put to the sustainable use and benefit of the national interest.

All collections under a research agreement must comply with any applicable environmental laws, regulations and procedures. Any entity undertaking activities in violation of the Executive Order is subject to criminal penalties. Failure to comply with the provisions of a research agreement is a valid basis for immediate termination of the agreement and the imposition of a perpetual ban on prospecting.

Executive Order 247 requires all existing agreements to be renegotiated to conform to the principles specified in the Order, although existing research can continue pending the negotiation of a new agreement.

3.5 Intellectual property rights

Executive Order 247 does not specifically regulate intellectual property rights associated with access to genetic resources and benefit-sharing. As noted in Section 3.3 above, however, a foreign institution must agree, as a condition of access to genetic resources, to permit the use within the Philippines of any technology developed using endemic resources, without payment of royalties. This provision is considered to be controversial.

Box 6: National experience with implementing Executive Order 247

On June 29, 1998, the first Commercial Research Agreement (CRA) for drug development research was approved in accordance with Executive Order 247 and the Implementing Regulations.

The parties to the CRA are the University of the Philippines, the University of Utah (US) and the Department of Agriculture. The CRA formalises, in accordance with Executive Order 247, a pre-existing partnership between the University of the Philippines and the University of Utah (USA). The partnership was established in 1994 for research on marine organisms.

The CRA contains the minimum terms and conditions stipulated in Executive Order 247. It also provides for the following benefit-sharing arrangements:

- Short-term monetary benefits to the Government: bioprospecting fee of Philippine Pesos (Php) 10,000 per year for three years and a performance bond of Php 10,000 to be returned to the collector upon termination of the agreement provided there have been no violations of the terms and conditions of the agreement.

- Long-term monetary benefits: the collector is to pay 5% of the net revenue derived from licensing fees, milestone payments, and royalties based on the development and commercialisation of any invention using material governed by the agreement. These benefits are payable to the Department of Agriculture, the local community or private person concerned.

- Non-monetary benefits to the Government: the project collaborators are to develop an information/ education module on resource conservation and environmental protection for communities,

Contents of box continue to next page

Box 6: National experience with implementing Executive Order 247 (continued from previous page)

provide technical expertise for the development/ implementation of a monitoring scheme for marine bioprospecting, and train at least one government representative in taxonomy or natural products chemistry under short-term programmes.

- Non-monetary benefits to the Community: in the short-term, these include information campaigns on biodiversity conservation; in the long-term, they include scholarship programmes and the qualification on locals in bioprospecting, natural products chemistry or other related fields.

Source: Charles V. Barber and Antonio G.M. La Viña, "Implementing Benefit-sharing: The Philippine Experience on Executive Order 247", World Resources Institute.

Selected references

La Viña, Calida and Baylon, Foundation for the Philippine Environment (FPE) - World Resources Institute (WRI), Regulating Access to Biological and Genetic Resources in the Philippines, A Manual on the Implementation of Executive Order No. 247, 1997.

4. LEY DE BIODIVERSIDAD (BIODIVERSITY LAW) OF COSTA RICA

In April 1998, Costa Rica enacted Law No. 7788, Biodiversity Law, a comprehensive legislative measure to implement the Convention on Biological Diversity. Its overall objective is to conserve biodiversity, sustainably use its elements and fairly distribute the benefits derived therefrom. In addition to regulating access to Costa Rica's genetic resources, it contains detailed provisions on intellectual property rights, including the initiation of a process to develop a sui generis system to protect the intellectual property rights of indigenous peoples and local communities.

The Biodiversity Law establishes a National Commission for Biodiversity Management, in order to coordinate access to genetic resources, and ensure the transfer of technology and the fair distribution of benefits. The Commission is required to establish a policy on access to the genetic and biochemical elements of Costa Rica's biodiversity, in both in-situ and ex-situ conditions. The Commission must also establish legal provisions to form the basis for all future access arrangements, and for the protection of intellectual property rights (IPRs) pertaining to biological diversity. The National Commission for Biodiversity Management will determine access applications (see section 4.2 below) and will play a role in the approval of IPR awards (see section 4.4 below).

4.1 Scope of the Biodiversity Law

The Biodiversity Law regulates the use and management of the elements of biodiversity and of associated knowledge, as well as the fair distribution of any benefits and costs derived from the utilisation of such elements. It addresses the full range of issues contained in the Convention on Biological Diversity (Dutfield, 1999, pp. 89 – 92) including:

- biosafety;
- conservation and sustainable use of ecosystems and species;
- access to genetic and biochemical elements of biodiversity;
- prior informed consent;
- protection of scientific and biochemical elements of biodiversity;
- prior informed consent (PIC);

- protection of scientific and traditional knowledge associated with biodiversity using intellectual property rights and/ or sui generis systems;
- education and public awareness;
- technology transfer;
- environmental impact assessment; and
- incentive measures.

Box 7: Definitions

Access to **Genetic and biochemical elements** is defined as:

The action of obtaining samples of the elements of biodiversity existing in the wild or domesticated, in ex situ or in situ conditions, and the obtaining of associated knowledge, with the aim of research, bioprospection and economic exploitation.

A **biochemical element** is defined as:

Any material derived from plants, animals, fungi or microorganisms which contain specific characteristics, special molecules or leads to design them.

A **genetic element** is defined as:

Any plant, animal, fungi or microorganism which contains functional units of heredity.

Bioprospecting is defined as:

The systematic search, classification and investigation for commercial purposes of new sources of chemical compounds, genes, proteins, microorganisms and other products with actual or potential economic value, found in biodiversity.

The **intangible elements of biodiversity** are defined as:

...traditional, individual or collective knowledge, innovation and practice with real or potential value associated with biochemical and genetic resources whether or not protected by intellectual property systems or sui generis register systems

Knowledge is defined as

A dynamic product generated by society by different mechanisms throughout history, including that which occurs in a traditional form, as well as that generated by scientific practice.

The Biodiversity Law's scope covers the biochemical and genetic properties of both wild and domesticated elements of biodiversity. Its definition of biodiversity includes "intangible elements" (see Box 7). The Biodiversity Law reaffirms the sovereignty of the State over all elements of biodiversity and provides that the biochemical and genetic properties of wild or domesticated biodiversity elements remain in the public domain.

The Biodiversity Law specifically excludes the following from its scope of application:

- human genetic and biochemical material;
- non-commercial exchanges between indigenous peoples and local communities (commercial use exception); and
- the autonomy of universities with respect to field investigations and teaching for non-commercial purposes.

4.2 Access determination procedure

The Biodiversity Law establishes general parameters for access procedures. The Law also sets down more detailed provisions on access permits for investigations of the genetic or biochemical elements of biodiversity. The National Commission for Biodiversity Management will determine access applications through a Technical Office.

4.2.1 General provisions on the access determination procedure

The Law mandates the Technical Office of the National Commission for Biodiversity with responsibility for access procedures. Such procedures are formal and shall be recorded in an official register. Both 'ordinary' (normal) and 'summary' (special) access procedures are to be used.

'Ordinary' procedures are to be used in cases where:

- an applicant seeks access to elements of biodiversity in the public domain; or,
- where access is potentially harmful to third parties (e.g., it may concern the imposition of duties, the loss or denial of existing rights, or any other form of harm to legitimate rights); or
- where there may be a conflict of interests between the parties concerned and the Administration.

'Summary procedures' dispense with some of the more time-consuming, formal requirements of 'ordinary' procedures and are to be applied by the Technical Office in all other cases.

The Technical Office shall inform all applicants for access to elements of biodiversity that access applications must be accompanied by the PIC of the representatives of the areas where access is sought, including 'Indigenous Community Authorities' and the 'Directors of Conservation Areas'. Local communities have the right to deny access to resources and associated knowledge for cultural, spiritual, social, economic or other reasons.

The Technical Office shall create a Register for Access over Genetic and Biochemical Elements - an updated register of access granted. The Director of the Technical Office is responsible for the upkeep and authenticity of the Register's contents. The information on the Register shall be publicly accessible. Trade secrets on the Register are exempted from this requirement unless publicity is justified for reasons of biosecurity.

4.2.2 Access permits for investigations of the genetic and biochemical elements of biodiversity in Costa Rica

An access permit is required for all activities concerning investigation of genetic or biochemical elements of biodiversity undertaken in Costa Rica. Authorisations for access to material held in registered ex situ collections shall be also processed according to the provisions of the Biodiversity Law.

Applications for access permits must be filed with the Technical Office and are required to contain the following information:

- the name and complete details of the applicant;
- the identity of the scientist or professional responsible;
- exact details on the elements of biodiversity to be investigated and the locality of the proposed investigation, including the owner, administrator or holder of the real estate concerned;
- a descriptive timetable of the investigation's scope and possible environmental impact;
- the objectives and goals pursued;
- a statement that these objectives and goals were communicated under oath;
- the address for any notices to be served under this Act, with shall be in the proximity of the Technical Office; and
- the prior informed consent (PIC) granted by legitimately interested parties pursuant to the provisions of the Biodiversity Law.

An access permit is valid for three years, extendable by the Technical Standards Office. It may be granted to individuals and research institutions, and only for the genetic and

biochemical elements sought by those persons. The permit may not be assigned to other parties.

The permit neither grants nor delegates rights of actions. It refers only to intended access activities that have been established beforehand. It must clearly stipulate, amongst other information:

- the certificate origin;
- whether access includes permission or refusal to extract or export samples;
- the duplication or deposit of samples;
- the public availability and reliability of results; and
- other conditions required by the Technical Office of the National Commission for Biodiversity.

If the intended activities are non-commercial, evidence must first be provided to that effect. Different requirements will apply to such activities.

Physical or legal persons wishing to perform bioprospecting activities should register themselves on the Register for Access over Genetic and Biochemical Elements. Such registration does not imply rights to conduct bioprospecting activities.

Cooperation agreements and contracts between private persons (whether nationals or foreigners) or between private persons and registered institutions, involving access for the use of genetic or biochemical elements of Costa Rican biodiversity, require the authorisation of the Technical Office. The Technical Office shall also authorise the repeated use of genetic material or biochemical extracts for commercial uses, by granting a concession to the party interested in such use.

Furthermore, the Technical Office must also establish:

- a duty for parties in receipt of an access permit to deposit up to 10% of their investigation's budget, and up to 50 per cent of royalties, for the benefit of the protected areas, indigenous territories or private land owners that have granted access to elements of biodiversity;
- the cost of administrative fees; and
- any benefits and technology transfer which form part of prior informed consent (PIC).

4.3 Terms and conditions for access

The Biodiversity Law establishes minimum general rules for access. An access permit is required if any investigations into genetic or biochemical elements of biodiversity are to be carried out in Costa Rica.

The Law requires access applicants to obtain the prior informed consent (PIC) of the representatives of locations where access is to take place, such representatives including the regional councils for conservation areas, indigenous authorities or private land owners. The terms for such PIC must be approved by the Technical Office of the National Commission for Biodiversity Management, and must include provisions for:

- technology transfer and the equitable distribution of benefits;
- cooperative agreements and concessions; and
- the type of protection for knowledge associated with the resources in question, as demanded by the representatives of the area where access is conducted.

Other minimum requirements for access include:

- details of the manner in which access activities may contribute to the conservation of species and ecosystems; and

- the appointment of a national representative in cases where access is sought by physical or legal persons domiciled abroad.

4.4 Intellectual property rights (IPRs)

The Biodiversity Law recognises the need to protect knowledge and innovations through appropriate legal mechanisms, and refers specifically to patents, trade secrets, plant breeders' rights, sui generis community intellectual rights, copyrights and farmers' rights (see Chapter 3 for an explanation of these terms). It excludes the following from protection by IPRs:

- DNA sequences;
- plants and animals;
- non-genetically modified organisms;
- essentially biological processes for the production of plants and animals;
- natural processes or cycles per se;
- inventions essentially derived from knowledge associated with traditional biological or cultural biological practices in the public domain; and
- inventions which, through their commercial exploitation in monopoly form, can affect agriculture and livestock processes or products considered basic for nutrition and health of the country's inhabitants.

The National Biodiversity Management Commission must be consulted before any IPR award is made by the Costa Rica National Seeds Office and the Intellectual Property Registries where IPRs are sought in respect of innovations involving biodiversity elements. In such cases a certificate of origin issued by the Technical Office of the Commission and a statement of prior informed consent must be presented with the IPR application. Such consent must include that of indigenous authorities in cases where bioprospecting is to take place on their lands. Indigenous peoples and local communities are fully entitled to refuse access to their resources and knowledge for any reason.

Costa Rica already formally recognises and protects what are referred to as "sui generis community intellectual rights", to protect the intellectual property rights of indigenous and local communities. Similar to copyright, these rights have judicial recognition without the requirement of prior declaration or official registration. However, the Biodiversity Law recognises the incomplete nature of these sui generis rights, and an 18 month participatory process, involving, amongst others, indigenous groups and peasants, has been initiated to elaborate upon an appropriate sui generis system. This process will determine the nature, extent and conditions of sui generis collective intellectual rights, the form that such rights will take, who is entitled to hold such rights, and who will receive the benefits. This process will also lead to the development of a registry, comprising all intellectual rights that communities wish to register, registration being both voluntary and free. All registered rights will oblige the Technical Office of the National Commission for Biodiversity to oppose the grant of an IPR for the same element or knowledge (Dutfield 1999, pp. 91-92).

Selected references

Dutfield, G., Intellectual Property Rights, Trade and Biodiversity: the Case of Seeds and Plant Varieties, IUCN, March 1999.

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ANNEX 2: BIOPROSPECTING ARRANGEMENTS

INTRODUCTION

This Annex is intended to illustrate a range of existing examples of arrangements for bioprospecting and distribution of benefits which have been drawn up outside any framework of national legislation on access and benefit-sharing. Both commercial and academic arrangements are illustrated. The material in this Annex is intended solely to illustrate the broad range of arrangements, which have been instituted to facilitate access to genetic resources and the sharing of benefits arising out of the use of these resources. The material has been compiled and adapted for this information package from the sources indicated with kind permission. The inclusion of bioprospecting arrangements in this Annex is not intended to reflect any endorsement or recommendation of any particular type of arrangement.

Section 1: The bioprospecting arrangement between the University of the South Pacific (USP), the Strathclyde Institute for Drug Research and the Verata Community in Fiji.

Section 2: The agreement reached between the Papua New Guinea Oil Palm Research Association (PNGOPRA) and the Department of Zoology, Oxford University, governs collaborative research on an indigenous Papuan organism with the aim of developing an environmentally benign crop protection system.

Section 3: The International Cooperative Biodiversity Groups (ICBGs) Projects in Africa and Suriname each involve extensive collaboration between source- and user-country institutions. ICBG projects aim to facilitate bioprospecting by US academic and commercial institutions, while assisting source countries to realise the opportunities presented by their biological diversity, in terms of drug development, and in terms of integrated conservation and rural development. Given the comparatively large number of partners involved, each ICBG project is structured around a network of agreements. These specify the prior interest of each partner in certain aspects of the project's collaborative work programme, including work to be performed by source-country institutions, common management of intellectual property rights, the division of royalties, capacity-building and other short- and long-term benefit-sharing.

Section 4: Section 4 provides an example of a trust fund intended to return benefits to local communities. The Fund for Integrated Rural Development and Traditional Medicine, Nigeria (FIRD-TM) aims to use the financial proceeds of bioprospecting to enhance the role of indigenous medical/herbal practices in community development and the conservation of associated plant species.

1. THE UNIVERSITY OF THE SOUTH PACIFIC/STRATHCLYDE INSTITUTE FOR DRUG RESEARCH/VERATA COMMUNITY (FIJI) BIOPROSPECTING ARRANGEMENT

1.1 Introduction

On 7 May 1997, the School of Pure and Applied Science of the University of the South Pacific (USP) and the University of Strathclyde, operating through the Strathclyde Institute for Drug Research (SIDR), in Scotland, United Kingdom, entered into a bioprospecting agreement. The agreement involves the supply by USP to SIDR of extracts of Fijian plants and marine organisms for use in the discovery of drugs and agrochemicals.

In a parallel, separate agreement, USP and the tikina, or county, of Verata have agreed that USP would have access to plants and marine specimens from Verata, a traditional grouping of eight villages in eastern Viti Levu, Fiji. A draft USP/Verata agreement was prepared in early 1997. Following consultation and scrutiny by advisers to the Verata community, the agreement was eventually signed by representatives of both parties at a ceremony on 16 October 1998.

1.2 Context

The bioprospecting arrangement is part of a larger project – the Natural Products Development and Conservation in Fiji project (hereinafter NPDC) – launched in September 1995 by USP under the leadership of Dr. William Aalbersberg. The project is funded by the Biodiversity Conservation Network (BCN), an organisation based in the United States and funded by the US Agency for International Development. The NPDC aims, among other things, to: promote community-based biodiversity conservation and development; enhance USP's facilities to allow the processing of biological extracts, thereby increasing their commercial value; and stimulate development of bioprospecting policy in Fiji and throughout the Pacific islands region.

The NPDC links community participation with an international pharmaceutical bioprospecting venture. Originally, one coastal community, Verata, and one rainforest community, Namosi, were chosen as source areas. Due to funding limitations, the scope of the bioprospecting initiative was, however, limited to the Verata community only. The pharmaceutical company partner originally chosen to participate in the bioprospecting venture was Smithkline Beecham (SB). However, due to the closure of their natural products discovery division in 1996, the Strathclyde Institute for Drug Research (SIDR) has since replaced SB as the foreign partner to the arrangement.

Prior to concluding the formal bioprospecting agreements, various discussions, stakeholder meetings and workshops took place with interested parties, including the Government of Fiji (Department of the Environment), the provincial governments for native affairs with jurisdiction over Verata, members of the Verata community, and non-governmental organisations. An international group of experts led by the Rainforest Alliance, a US-based organisation, provided advice and legal assistance with the negotiation and development of the bioprospecting agreements. Since discussions on the arrangement began, the Government of Fiji has been actively involved in the development of policy and legislation to regulate access to genetic resources and benefit-sharing. The SIDR/USP/Verata bioprospecting venture has contributed to inform that process.

1.3 The SIDR/USP Agreement

The Strathclyde Institute for Drug Research (SIDR) is a research organisation within Strathclyde University, Scotland. It promotes collaborative drug research and facilitates interaction with industry. SIDR has a large library of tropical plant extracts in which it actively pursues commercial interest for therapeutic and agrochemical applications. SIDR acts as a broker by licensing extracts to pharmaceutical companies for a fee.

The SIDR/USP agreement requires USP to supply SIDR with a minimum of 500 extracts of biological material from Fijian plants. The agreement provides that SIDR will license the extracts for outside evaluation and possible commercial applications and may conduct in-house research. It is effective for three years, extendable by mutual consent of the parties. Under the terms of the agreement, USP is required to obtain the necessary permission of the Government of Fiji and to ensure the prior informed consent of the resource owners.

Benefits received by SIDR from the licensing of the extracts are to be shared with USP as follows:

- 60 per cent of funds obtained by SIDR from licensing fees. This amounts to US$ 200 per sample per year.
- Fees for re-supply of an extract. SIDR is to negotiate the price for such extracts (usually £2000-2500).
- 60 per cent of net income accruing to SIDR as a result of commercialisation by a third party. USP is to be consulted on during the negotiation of terms (including royalty rates) between SIDR and a third party.

The SIDR/USP agreement also envisages joint collaborative research and joint patents on any in-house inventions.

Other than the possibility of providing assistance in scientific work to USP there are no other financial or in-kind benefits, either to USP or to the Verata community.

SIDR acts as a broker and supplier of extracts to third party commercial licensees on the basis of license fees. SIDR uses a standard model contract for the supply of extracts to such licensees. This contract is adapted to meet the particular circumstances under which SIDR obtains its extracts. In this case, SIDR preferred to contract only with USP, leaving USP to enter into a separate agreement with Verata.

SIDR guarantees its licensees the right to commercially develop any ‘leads’ isolated from the extracts it supplies to them. Given that the SIDR/USP agreement was designed for consistency with SIDR’s standard third party licensing agreement, it made no provision for obtaining the prior informed consent (PIC) of Verata before commercialising a product. Furthermore, the SIDR/USP agreement does not address the use of intellectual property rights to protect any ethnobotanical knowledge obtained from Verata, and that might be used to assist with the identification and collection of the resources.

1.4 The USP/ Verata Agreement

Verata is a tikina, or county, comprised of eight villages and is located on the eastern coast of Viti Levu, Fiji. The system of land ownership and control in Fiji allocates most of the land (83%) and adjacent marine zones and, hence, the biological resources contained therein to indigenous Fijians. The Verata community is therefore the legal owner of the land and the resources found thereon. Operating through the Verata Tikina Council, the Verata community agreed to provide USP with access to plant and marine organisms, and to assist with the collection of samples.

The agreement seeks to fully inform, ensure the involvement in, and, where appropriate, ensure the prior informed consent of, Verata in the bioprospecting venture. To this end, Verata is to receive notification of and be invited to attend any meetings held in Fiji relevant to the negotiation of the bioprospecting agreements. Verata will also receive legal advice (costs of which are carried by the BCN grant, to the extent available), in particular on the negotiation of terms regarding the subsequent use of extracts.

In return for access to biological resources, the following benefits are to accrue to Verata:

- The entire sum of extract license fees received by USP from SIDR. This applies only during the period where USP continues to be funded by the BCN. Where no BCN funding is available Verata is to receive the extract license fee less the costs of collecting and shipping the samples (estimated at F$30 per sample). BCN funding ended in June 1999. In 1998, 250 samples were provided to SIDR. About 150 were licensed in that year with income of US$30,000 (F$62,000) received by the community.
- Training in the collection and preparations of samples, in methods of biodiversity-related and socio-economic monitoring, and in the management of small village-based enterprises. Such training shall be for "approximately" six people.
- Six-monthly community-wide workshops in resource management and community development.
- The employment "whenever possible" of Verata community members in research, collection, and technological product development.
- Financial benefits accruing from the commercialisation of a product by a third party. Verata is to share in such benefits "on an equitable basis to be negotiated by USP, Verata and the Government of Fiji". The terms of such an agreement are to be negotiated within 2 years. There is an expectation that any portion of the royalties received from SIDR will be apportioned between USP, Verata and the Fiji Government in approximately equal shares. The share of funding provided to the Fiji Government is intended for use in resource conservation and management. A portion of any funds received from the commercialisation of a product might also be made available to conservation projects run by communities in conjunction with non-governmental organisations.

Verata has established a Trust Fund to receive and manage the financial benefits of the bioprospecting arrangement. The Fund, which might also receive income from other sources, is administered by a Trust Committee. This committee is operationally independent from the Verata Tikina Council. The Fund is to be used to finance activities and initiatives to promote the sustainable development of the Verata people.

The USP/Verata agreement stipulates that Verata is to have preference for the re-supply of any species originally supplied by them, and to have unused samples returned. No species are to be endangered in any way as a result of re-collection. The agreement requires there to be monitoring of species populations. A community-based project will be undertaken if it is deemed necessary to conserve species and restore habitats.

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2. THE PAPUA NEW GUINEA OIL PALM RESEARCH ASSOCIATION BENEFIT-SHARING PARTNERSHIP WITH THE DEPARTMENT OF ZOOLOGY, OXFORD UNIVERSITY, UK

Adopted with permission from A. Wells, A Benefit-Sharing Study: Biological Crop Protection in Papua New Guinea – the Papua New Guinea Oil Palm Research Association and the Department of Zoology, Oxford University, a paper distributed at the fourth meeting of the Conference of the Parties to the Convention on Biological Diversity, May 1998.

2.1 Introduction

In August 1995 a two-year collaborative research agreement was entered into between the Papua New Guinea Oil Palm Research Association (PNGOPRA) and the Department of Zoology, Oxford University, UK. The agreement sanctioned a research project entitled "Oil Palm Insect Pests and their Natural Enemies". It was re-negotiated in 1997 to cover a period through to December 1998 and it is currently under further negotiation for a two-year extension. The project, which is based in West New Britain Province, Papua New Guinea, aims to control defoliation of oil palm by the tettigoniid insect pest Segestidae defoliaria defoliaria (a form of grasshopper), by using the native parasitic insect Stichotrema dallatorreanum (strepsiptera).

The PNGOPRA was formed in 1980 by the oil palm industry and the Government of Papua New Guinea to carry out agricultural research on behalf of the country's oil palm growers. The PNGOPRA represents private and nationally-owned plantations and milling companies, as well as individual farmers who grow oil palm on small plots. It has four main research centres, with a further two substations, located in different oil palm-growing areas of Papua New Guinea. The PNGOPRA became an incorporated association in 1998.

50 per cent of the PNGOPRA's funding consists of a levy on its corporate members. The remaining 50 per cent is reliant on project-specific foreign aid. The partnership with Oxford University was supported by funding from the European Union. The funds were donated to the PNGOPRA under an agreement with the Foreign Aid Management Division (FAMD) of Papua New Guinea's Office of National Planning and Implementation, as part of the financial support received by Papua New Guinea's oil palm industry under the Stabex (stabilisation of export earnings) mechanism of the Fourth Lomé Convention.

The Department of Zoology, Oxford University, is a focal point for research on strepsipteran parasites, a group of insects of which Stichotrema dallatorreanum is a member. The Department's research capacity, including a leading strepsiptera specialist and equipment such as electron microscopes, has been essential for taxonomic and fine-structure analyses of these tiny parasites.

Box 1: The Lomé IV Convention

The Fourth Lomé Convention is an agreement between the Member States of the European Union and 71 African, Caribbean and Pacific (ACP) States. It was signed on December 15, 1989. Over a ten-year period, it has aimed to address agriculture and food security, service provision, industrialisation, and cultural, social, regional and environmental concerns.

The Convention provides structural adjustment support, debt relief, and investment and development financing through trade preferences and the European Development Fund (EDF). Its trade and commodity provisions include mechanisms such as Stabex. Stabex is a system designed to stabilise export earnings from certain agricultural commodities. It is intended to provide ACP countries with financial support aimed at covering shortfalls in earnings due to fluctuations in prices and agricultural production. 615 million ECU was committed to Stabex in 1989, and, in 1994, 350 million ECU was disbursed. Allocations for Stabex increased 20 per cent under the Agreement Amending the Fourth Lomé Convention in November 1995.

The Fourth Lomé Convention expires in 1999. Negotiations for a new agreement began in September 1998 and are ongoing. Information on the implications of these negotiations for Pacific island countries is available from the PCRC-ECSIEP Joint Programme on the Lomé Convention on: http://www.antenna.nl/ecsiep/lome/indexlom.html.

Of the Pacific island countries, Fiji, Kiribati, Papau New Guinea, Solomon Islands, Tonga, Tuvalu, Vanuatu and Samoa are parties to the Lomé Convention.

2.2 Context

Papua New Guinea's most serious oil palm pests are leaf-eating tettigoniids (grasshoppers and bush crickets). In Oro Province, on mainland Papua New Guinea, the tettigoniid pest Segestidae novaeguineae is successfully controlled by indigenous populations of the parasite Stichotrema dallatorreanum. Between 40 per cent and 50 per cent of Oro Province's populations of Segestidae novaeguineae are reported to be infected with the parasite. Stichotrema dallatorreanum does not, however, occur in West New Britain Province. This province is located on New Britain island, in the Bismarck archipelago, and supports 70 per cent of Papua New Guinea's oil palm. There, severe defoliation is caused by the tettigoniid pest Segestidae defoliaria defoliaria and, for the past fifteen to twenty years, estates and small holders have used Monocrotophus, a highly toxic, trunk-injected, organophosphate insecticide, as a means of control.

If properly used, Monocrotophus is confined to injected trees and so has a negligible effect on non-target species. However, its toxicity is a user hazard. It is hard to apply consistently in the rainy season, difficult to monitor on small-holdings in remote areas and is frequently applied too late to prevent yield loss. Monocrotophus treatment is also expensive. Oil palm estate companies are therefore required by PNGOPRA to pay a levy to fund the use of Monocrotophus on small holders' plots, in addition to meeting the costs of their own treatment programmes.

Given the disadvantages of Monocrotophus, the PNGOPRA has recognised that the most effective, long-term strategy will be a low-impact, cost-effective and environmentally acceptable integrated pest management system. The collaborative research project between the PNGOPRA and Oxford University is intended to support this aim by investigating the introduction of the parasite Stichotrema dallatorreanum from its wild population base on mainland Papua New Guinea into West New Britain Province so as to control defoliation by Segestidae defoliaria defoliaria. The ability of this parasite to control its natural tettigoniid host, Segestidae novaeguineae, in Oro Province is an indicator of its potential success.

All stages of the project are undertaken in close collaboration. PNGOPRA and Oxford University do, however, bear greater responsibility for different aspects of the project. Oxford leads work on:

- Determining the histology of the parasite Stichotrema dallatorreanum, such as its means of reproduction and its feeding behaviour.
- Investigating the host-parasitic relationship of Stichotrema dallatorreanum in its natural host, Segestidae novaeguineae. This includes comparative analyses of the morphology, gut contents, body composition and reproduction of infected and uninfected Segestidae novaeguineae. Analyses of the longevity and fecundity of Stichotrema dallatorreanum once inside a host are also undertaken.

Scientists at PNGOPRA are primarily responsible for:

- Collecting specimens of Segestidae novaeguineae infected with the parasite Stichotrema dallatorreanum from field conditions in Oro Province, and then exporting them for analysis at Oxford.
- Investigating the infection of the target species, Segestidae defoliaria defoliaria, by Stichotrema dallatorreanum under captive conditions. Specimens of successfully infected Segestidae defoliaria defoliaria are also sent to Oxford for analysis.
- Releasing infected Segestidae defoliaria defoliaria into selected sites in West New Britain Province, followed by monitoring of the effects on wild populations of Segestidae defoliaria defoliaria.

The success of this project would assist PNGOPRA in improving the management practices of major oil palm estates and small holders alike. The project also provides the Department of Zoology at Oxford with access to Stichotrema dallatorreanum. As an unusual form of biodiversity, it presents novel research opportunities.

Before collecting and exporting specimens, the PNGOPRA was required under law to obtain the consent of Papua New Guinea's Department of Environment and Conservation. This Department regulates all access to the country's biodiversity for research purposes. The PNGOPRA also informed small holders of the project's intentions.

Some of the small-holder members of PNGOPRA cultivate oil palm on land subject to customary land rights. Where the elements of biodiversity sought are subject to customary land and resource rights (97% of Papua New Guinea's land and resources are held as such), there are constitutional guarantees that the relevant rights holders are duly recognised. The Land Groups Incorporation Act, 1974, is one such basis for the equitable sharing of benefits from sustainable development activities and biodiversity prospecting.

2.3 Benefits

The PNGOPRA is a benefit-sharing framework in its own right, established to service the needs of private and State-owned estates as well as indigenous small holders. The advantages of sustainable pest control, should the project prove successful, will therefore be shared amongst all stakeholders in the PNGOPRA.

Under the 1995 agreement, Oxford University is obliged to provide the PNGOPRA with progress reports on its analysis of the parasite Stichotrema dallatorreanum every six months and must submit results to the PNGOPRA for approval 60 days in advance of their publication.

Oxford University has the right to claim any inventions that it might develop during the course of the project as its intellectual property. However, subject to the further negotiation of terms and the University's receipt of a share of royalties, the PNGOPRA is guaranteed the exclusive right to use and market such inventions.

Given its primary purpose as a teaching and research institution, the University has also ensured under its 1995 agreement with the PNGOPRA that its employees, students, agents and appointees have the right to discuss the project, and to publish results as part of the project's work.

With regard to technology transfer, the 1995 agreement provides that equipment bought on project funds for the purposes of Oxford's work on the project will either be donated to Oxford University or transferred back to the PNGOPRA upon completion of work. The decision to transfer all such equipment back to the PNGOPRA has now been taken.

Collaborative research efforts between the partner institutions, including joint authorship of papers and visits by Oxford collaborators to the field, have significantly contributed to research on strepsipteran parasites, and have resulted in the transfer of expertise and experience to the PNGOPRA's researchers. In addition, the PNGOPRA's field assistants and technicians have received training for the purposes of the project, including training in the use of light and malaise traps.

The PNGOPRA has also been able to develop a database of local insects in the course of its collecting activities that can help to support conservation activities.

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3. THE INTERNATIONAL CO-OPERATIVE BIODIVERSITY GROUPS (ICBG) PROJECTS IN AFRICA AND SURINAME

Note: The summary which follows has been drawn from case studies submitted to the Convention Secretariat. Full references are provided at the end of this section.

3.1 Introduction and Overview of the ICBG Programme

In 1992, three agencies of the United States Government–the National Institutes of Health, the National Science Foundation and the US Agency for International Development–launched the International Cooperative Biodiversity Groups (ICBG) initiative as an integrated conservation and development programme.

The stated aims of the programme are to stimulate bioprospecting, to provide models for the sustainable use of biodiversity, and to assess the feasibility of bioprospecting as a means to:

- improve human health through discovery of natural products with medicinal properties;
- conserve biodiversity through valuation of natural resources, training and infrastructure building to aid in management; and
- promote sustainable economic activity of communities, primarily in less developed countries.

The ICBG programme currently funds five groups working in eight countries in Latin America and Africa. The programme is managed by the Fogarty International Centre of the National Institute of Health (US). Each ICBG programme is directed by a principal investigator based at a US university, and involves a consortium of collaborating partners, including academic research institutions in developing countries, local and international non-governmental organisations working in the host countries, and, in most cases, a pharmaceutical company.

The following table (also referred to as Box 2) summarises the five ICBG consortia, and the research activities and collaborating institutions involved.

Group Leader	Programme Site (Country)	Programme Mission (Summary)	Principal Collaborating Institutions (N.B. the list of collaborating institutions is not exhaustive)
Dr David Kingston of Virginia Polytechnic Institute and State University	**Suriname**	Study of rain forest plants	* The Forest People of Suriname, Conservation International – Surname. * The National Herbarium of Suriname. * The Missouri Botanic Garden. * Bedrijf Geneesmiddelen Voorziening Suriname. * Bristol-Myers Squibb Pharmaceuticals Research Institute.
Dr Jerrold Mainwald of Cornell University	Guanacaste Conservation Area, **Costa Rica**	Study of insects and related organisms from dry tropical forests	* INBio, of Costa Rica. * Universidad de Costa Rica. * Bristol-Myers Squibb Pharmaceuticals Research Institute
Dr Barbara Timmermann of Arizona University	Latin America (**Argentina, Chile, Mexico**)	Study of arid land plants	* Instituto de Recursos Biologicos de Argentina. * Universidad Nacional de la Patagonia. * Pontificia Universidad Catolica de Chile. * Universidad Nacional Autonoma de Mexico. * Purdue University. * G.W.L. Hansen's Disease Center. * The Medical and Agricultural Divisions of Wyeth-Ayerst/American Cyanamid Co.
Dr Walter Lewis of Washington University	Andean tropical Rain Forest (**Peru**)	Study of plants that have been used medicinally for generations in Andean tropical rainforest of Peru.	* Several organisations of Aguaruna people under the leadership of the Confederation de Nacionalidades Amazonas del Peru. * The Universidad Sans Marcos. * The Universidad Peruana Cayetano-Heredia. * Monsanto-Searle Co.
Dr Brian G. Schuster of Walter Reed Army Institute of Research	Africa (**Cameroon & Nigeria**)	Study cures for parasitic diseases from rain forest plants of Africa.	* The Smithsonian Institution of America. * Bioresources Development and Conservation Programme. * The University of Dschang. * The International Centre for Ethnomedicine and Drug Development (Nigeria).

The programme supports cooperative agreements between the US Government and the principal investigator of each ICBG consortium ("the group leader"–see Box 2 in previous page). This allows the US Government to continue to be involved in the projects through scientific advisory committees that comprise representatives from the National Institutes of Health, the National Science Foundation and the US Agency for International Development (the three US funding Agencies). In addition to the main cooperative agreement between the US Government and the principal investigator, each ICBG consortium has concluded one or more associated contracts between its collaborating partners. These associated contracts are diverse in nature, but primarily take the form of research and benefit-sharing agreements.

3.2 Benefit Sharing Characteristics of the ICBG Projects

The three US funding Agencies are not parties to the various research and benefit-sharing arrangements reached between the collaborating partners of each ICBG consortium, and cannot, therefore, stipulate the specific contractual terms of these arrangements. However, each applicant for an ICBG award was required to make a formal, written agreement governing the treatment of intellectual property rights and benefit-sharing. Furthermore, the funded consortia were asked to develop workable agreements to fit the nature of the organisations, countries, communities, and resources involved within the general framework of the ICBG programme's principles.

The benefits which can accrue to source countries under the ICBG agreements are both monetary, consisting of royalties and advance monetary payments ("up-front" payments), and non-monetary, such as equipment, training/capacity building and infrastructure. Each of the ICBG bioprospecting arrangements introduces a variety of source country capacity-building projects including training and equipment to enhance parataxonomy, geographic information systems and other database technologies, natural products and bio-chemistry research, and sample preparation and storage. Infrastructure development efforts to date have included provisions of vehicles, renovation and improvement of laboratories, community health clinics and herbaria. Other benefits include the human and institutional relationships that have developed in the course of the projects and which are likely to outlive the duration of the project. For example, the African ICBG is helping to strengthen an African non-governmental alliance, the Bioresources Development and Conservation Programme (see further below), involving university biomedical and biodiversity researchers, government officials, traditional healers, community leaders and herbal medicine producers.

Most of the ICBG projects use trust fund mechanisms to channel and distribute benefits to the local communities and other interested parties in the source country (see further sections 3.4.3 and 5 below).

3.3 The International Cooperative Biodiversity Groups (ICBG) – Africa Project

3.3.1 Overview

The African ICBG project is the largest of the ICBG projects, involving collaboration between: the Walter Reed Army Institute of Research (US); the Smithsonian Tropical Research Institute (US); the University of Dschang (Cameroon); the International Centre for Ethnomedicine and Drug Development (Nigeria); the Bioresources Development and Conservation Programme; and various other institutions in Africa and the United States.

The Bioresources Development and Conservation Programme (BCDP) is an international umbrella organisation established in 1991 at the inaugural meeting of the Steering Committee at the University of Nigeria. BDCP was formally launched at the Rio Earth Summit meeting in 1992 as an African forum on biodiversity conservation. It is

based in the US with autonomous branches in both Nigeria and Cameroon (as well as Guinea – which is not, however, involved in the ICBG project). The BDCP is the primary administrator, monitor and arbiter of the various interests involved in the African ICBG project.

The main focus of the African ICBG project is the establishment of an integrated programme for discovery of biologically active plants for drug development and biodiversity conservation. The project area is within the rainforest belt of West and Central Africa (Nigeria and Cameroon), which contains the second largest expanse of moist tropical forest in the world. Plants growing in this region have been sources of several medicinal agents.

The main objectives of the African ICBG are:

- to provide an inventory of plants in the study areas and collect samples to be screened for possible biological activity. These will be used to expand the AfriMed database of African medicinal plants. The aim is to carry out testing up until the pre-clinical stage;
- to establish permanent biodiversity plots for monitoring and documenting changes in the plant diversity and ecology of the area;
- to conduct an economic value assessment of the biological resources in the area; and
- to assist in capacity building of local institutions, through training of African scientists in areas of ethnobiology, inventory, phytochemical analysis and research management.

3.3.2 Benefit-sharing

The African ICBG benefit-sharing arrangement is based on deriving maximum benefits from the process of drug discovery, rather than relying on the promise of future royalties that may not materialise. Essentially, the benefits in the African ICBG can be loosely categorised as: "long term" benefits, i.e., those that might result from product commercialisation, and "process" benefits, i.e., those resulting from the research and development phase of the project.

Long-term benefits

The long-term benefits are outlined in the Co-operative Research and Development Agreement (CRADA) which details the benefit-sharing arrangement. The CRADA deals with the following matters: the scope of the research and its administration; issues relating to intellectual property rights and traditional knowledge, including licensing, royalties, and trade secrets; and, sourcing issues. (Box 3 below summarises the distribution of royalties among the collaborating members as specified in the CRADA).

Box 3: Royalties under the ICBG – Africa project

20 per cent of all royalties and other considerations generated from licenses of IPR shall be distributed equitably among those parties contributing intellectually to the creation of the IPR, taking into account their relative contribution and ensuring that inventors in each case receive not less than 15 per cent.

50 per cent of all royalty income and other considerations shall be donated to BDCP to be used solely for programmes and projects designed to promote sustainable economic development relating to biodiversity conservation in Nigeria and Cameroon. In order to distribute these benefits, an independent Trust Fund has been established (see section 4 below).

30 per cent of all royalty income and other considerations shall be donated to a Tropical Disease Drug Development Program based at the Walter Reed Army Institute.

Under the CRADA, the Walter Reed Army Institute of Research is responsible for administering the intellectual property rights generated by the project. Walter Reed was apparently selected because it is the only non-commercial member of the African ICBG project with both the financial and administrative capacity to negotiate the best licensing agreements with potential licensees. If promising compounds are isolated during the ICBG project that demonstrate potential as drugs, applications for patents on these compounds will be filed in the name of all the individual investigators who participated in making the inventions in question, including any contributing African scientists and traditional healers. The CRADA also provides that the US, Nigerian and Cameroon Governments each retain a non-exclusive license to all the intellectual property rights developed under the Agreement.

"Process" benefits

The following institutions have participated in the process of research and development under the ICBG – Africa project:

(i) Academic institutions

International Centre of Ethnomedicine and Drug Development (Inter CEDD), Nigeria

InterCEDD is involved in the project on a number of levels, including in vitro anti-microbial and anti-viral studies, and the extraction of plants collected in Nigeria. InterCEDD is benefiting from:

- Technology transfer, e.g., the supply of bioassays for microbiological screening.
- Infrastructure and equipment, e.g., extraction equipment, basic running supplies and access to a four-wheel drive vehicles through BDCP-Nigeria.
- Expertise and know-how building and training, e.g.: support for two post-doctoral students to receive training in anti-viral drug development and the use of transferred technology in the US for one year; and, training researchers in biodiversity monitoring, forest inventory, the commercialisation of biological resources (including biodiversity prospecting and intellectual property rights) and economic value assessments for forest products.

University of Ibadan (Nigeria)

The University's Malaria Research Centre is responsible for testing the extracts given to it by InterCEDD for malaria leads. It benefits from:

- Technology transfer, e.g., the transfer from Walter Reed of molecular biology technology.
- Infrastructure and equipment, e.g., computers and basic supplies.
- Expertise and know-how building and training – similar to that received by InterCEDD.

University of Dschang (Cameroon)

The University of Dschang is conducting yield studies for Ancistrocladus korupensis, as well as phytochemical studies. (Note: Ancistrocladus korupensis is a forest vine that was first collected in Korup National Park, Cameroon, in 1987 by staff of the Missouri Botanical Gardens, under contract from the US National Cancer Institute. The plant was found to exhibit certain anti-HIV/AIDS properties. Increased interest in the plant subsequently catalysed discussion in Cameroon and the development of a national policy and legislative measures to control access to Cameroon's resources and ensure appropriate benefit-sharing). Examples of benefits accruable to the University are:

- Technology transfer, e.g., bioassay technology for microbiological screening.
- Infrastructure and equipment, e.g., extraction equipment, basic running supplies, materials to conduct bioassay and funding for two full-time staff members to conduct research.

- Expertise and know-how building and training, e.g., in addition to training affiliated post-doctorals in the US, staff at the University receive training in bioassay techniques.

(ii) Local non-governmental organisations

The NGO most involved in the African ICBG project is the Bioresources Development and Conservation Programme (BDCP), which acts as the main administrator of the ICBG project. It benefits from:

- Infrastructure and equipment transfer, e.g., vehicles and computers and other equipment for the project.

(iii) Traditional healers' associations

BDCP is collaborating with the main herbalists association in Nigeria, known as the Nigerian Union of Medical Herbal Practitioners ("the Union"). Examples of process benefits to the Union are as follows:

- ICBG/BDCP staff have assisted the Union with attaching botanical labels to plants (for educational purposes) in their medicinal plant garden.
- ICBG/BDCP staff have facilitated the Union's receipt of $2,500 from the Rain Forest Alliance (a US-based, non-governmental organisation), to meet its basic running costs. The Union chose to put these funds towards the purchase of a car for use in performing "house calls" in remote areas. Other funds made available through the ICBG programme have been put towards the costs of building a herbal medicine hospital.
- ICBG staff have assisted the Union in hosting a workshop on traditional medicine and national development.
- The ICBG project has also provided immediate financial reciprocity in the form of advance payments and access fees that the Union has used to expand its herbal garden and pharmacy.
- Individual members of the Union are compensated in two ways: direct cash payments for plant materials and services surrounding their collection; and, as contributors to the drug development process, inclusion in both patents and resultant royalty payments for "inventors".

BDCP has also facilitated the establishment of the Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM) – see section 4 below.

(iv) Local communities

The African ICBG project works with the local authorities (for example, chiefs, traditional healers, village councils, development associations, etc) of those communities in which ownership and authority are clearly defined. The working arrangements that have been put in place are the result of several months of discussions with influential members of these communities, and of negotiations with appropriate government agencies.

Plant material is collected directly from local communities who receive the following in return:

- Small cash payments made to individual collectors/informants.
- Assistance with development projects, e.g., health care, roads, schools etc.
- Consultation with local healers by the medical members of the ICBG team and assistance in treating life-threatening illnesses.

Within each community, collaborating herbalists are given some form of immediate compensation in recognition of time spent for interview and to pay for actual plant material collected. This payment is considered as separate from the access fees paid to the Union or village council.

In one community, the ICBG/BDCP staff have facilitated the establishment of a Community Development Fund, with initial funds in the form of an "access fee" in exchange for the inventory of local ethnobiological knowledge. Local community members have been paid for both information supplied and assistance in the field as guides, plant collectors, and porters.

(v) Governments

At the governmental level, ICBG/BDCP funds have provided support to the Enugu State Forestry Department for the rehabilitation of the Enugu Regional Herbarium, Nigeria.

In Cameroon, BDCP has provided assistance to the Ministry of Environment and Forests for a lawyer to review the terms of a proposed agreement between the US National Cancer Institute and the Cameroonian Government regarding past collections made in Cameroon, particularly with regards to the potential anti-HIV vine Ancistrocladus korupensis.

3.4 The International Co-operative Biodiversity Group – Suriname Project

3.4.1 Overview

The Suriname ICBG project is led by Dr David Kingston of the Virginia Polytechnic Institute and State University (US). The other participants are Conservation International (an international, non-governmental, conservation organisation); Bedrijf Geneesmiddelen Voorziening Suriname (BGVS), a pharmaceutical company owned by the Surinamese Government; the Missouri Botanic Gardens (US); and Bristol-Myers Squibb Pharmaceutical Research Institute, an American pharmaceutical company. The local tribal communities most involved in the project are the Saramaka Maroons.

The overall aim of the Suriname ICBG project is to promote drug discovery while conserving biodiversity and ethnobotanical knowledge. The specific goals of the project are:

- to record and secure the value of tribal knowledge;
- to develop the identification and the documentation of Suriname biodiversity and the capacity in doing so;
- to increase local capacity for pharmaceutical research and production;
- to develop commercial drugs from plant extracts; and
- to compensate tribal communities through a trust fund endowed with immediate payments as well as a portion of future royalties (see section 5 below).

The main responsibilities of the parties in the project are laid out in the International Co-operative Biodiversity Grant Research Agreement. It specifies each participant's rights to licence fees and royalties generated by any drug products that result from the project. A separate cooperative agreement has been concluded between Conservation International (CI) and the Saramaka community to conduct ethnobotanical research and to collect samples in collaboration with the Saramaka people.

Box 4: ICBG Suriname – collaborating partners and their role

Virginia Polytechnic Institute and State University: as the principal investigator, is responsible for overall co-ordination of the project; also isolates compounds from extracts and performs screens for anti-cancer activity.

Conservation International (Suriname): responsible for ethnobotanical collections, documentation of traditional knowledge, and conservation initiatives.

The Missouri Botanic Gardens: responsible for the random collection of specimens for both floristic inventory and drug discovery, using botanical collection methods, and provides training in botanical collection for herbarium staff and university students.

Berdrif Geneesmiddelen Voorziening Suriname: a pharmaceutical company owned by the Surinamese government; performs extraction work and carries out in-country screening of isolated compounds.

Bristol-Myers Squibb Pharmaceutical Research Institute: an American pharmaceutical company responsible for the majority of screening and drug discovery.

3.4.2 Benefit-sharing

Long-term benefits

Arrangements for long-term benefit-sharing under the Suriname ICBG project are reflected in:

- the Research Agreement which sets out the terms of ownership, licensing, and royalty fee structure for any potential drug development;
- a "Statement of Understanding" between the local communities, CI-Suriname and Bedrijf Geneesmiddelen Voorziening Suriname (BGVS), which further defines the parties' intentions regarding the distribution of royalties among Surinamese institutions; and
- the Forest Peoples' Fund (see section 3.4.3 below).

The Research Agreement provides that, where a product is the result of collaborative work with the Saramaka people, any patent must be filed for joint ownership. The Agreement also outlines relevant considerations and the method used for calculating the distribution of royalties among the relevant parties.

The "Statement of Understanding" between the Chief of the Saramaka people, CI-Suriname and BGVS details the division of future royalties allocated to the various Surinamese institutions involved in the project (see box 5 below).

Box 5: Distribution of royalties amongst Suriname's institutions

Derived From Ethnobotanical Collection		Derived From Random Collection	
Institution	Royalty %	Institution	Royalty %
Forest People's Fund	50	Forest People's Fund	30
BGVS (pharmaceutical co.)	10	BGVS (pharmaceutical co.)	10
STINASU (NGO)	5	STINASU (NGO)	10
National Herbarium	5	National Herbarium	10
Forest Service	10	Forest Service	10
CI-Surname	5	CI-Surname	10
Future Institutions	10	Future Institutions	20

While the Research Agreement and the "Statement of Understanding" both govern the distribution of future royalties, the Forest People's Trust Fund was established in 1994 to provide more immediate compensation to local communities for their ethnobotanical contributions to the ICBG project, as well as to provide a means to distribute any longer-term benefits that might arise through royalty payments (see further section 3.4.3 below).

Short-term benefits

In addition to long-term benefits, the more immediate or short-term benefits for the various participants in the project have included the following:

(i) Local communities

Individuals in communities that have been involved in the ICBG project in Suriname have benefited from: employment, e.g., as field collectors and support staff for the collection team; the transfer of equipment; and, training in "random" botanical collection techniques. In 1997, a management course for community-based NGOs was held in three villages.

The communities in general have benefited from the Forest People's Fund (FPF) (see section 3.4.3). The Fund compensates these communities for their ethnobotanical contributions to the project, creates conservation incentives, finances sustainable manage-

ment projects, provides research and training exchanges, and supports healthcare and other socially and environmentally sound projects. The following are examples of community-based projects that have benefited from the ICBG research project:

Afinga

Money and material supplies are often allocated to communities through their leaders or through village development foundations such as Afinga[1]. So far, the FPF has funded five major projects including three managed by Afinga. Afinga's projects include, amongst others, a sewing project and an agricultural project.

The Shaman Apprentice Programme

In an effort to preserve the knowledge of traditional healers, the programme encourages young community members to work with shamans and learn their ethnobotanical knowledge.

(ii) The National Herbarium

The project is contributing to the development of Suriname's national botanical inventory and to improvements to the structure of the National Herbarium. Improvements to the Herbarium include air conditioner replacement, roof repair, and the provision of additional offices, storage space and basic supplies, including new computers, books, journal subscriptions and herbarium supplies. Several species collected under the project were previously under-represented in the National Herbarium. Two employees of the Herbarium have each received seven weeks of training at the Missouri Botanical Garden.

(iii) The Government

The Surinamese Government has participated in a number of workshops sponsored by Conservation International (CI). CI-Suriname is also assisting the Malaria Task force of the Ministry of Health, including by means of a $2,500 donation. Furthermore, CI is developing a Geographic Information Systems (GIS) component for the project, based in Paramaribo. The Government has requested use of the GIS to plan their sustainable development strategy.

3.4.3 The Forest People's Fund (FPF)

The Forest People's Fund (FPF) was established in 1994 as a long-standing, financial institution, so as to deliver to Surinamese tribal communities immediate benefits from the access granted to their forest resources. It was established with an up-front payment from Bristol-Myers Squibb and funds small scale, sustainable economic development and health projects. These projects are designed and proposed by the communities themselves. In addition, the Fund intends to provide an established structure with which to channel potential future royalties derived from the commercialisation of end-products.

Objectives

The objectives of the FPF are as follows:

- to compensate the local communities for their ethnobotanical contributions to the ICBG project;
- to create conservation incentives;
- to finance sustainable management projects;
- to provide research and training exchanges; and
- to support other socially and environmentally sound projects

Administration and Governance

The FPF is administered by the Forest People's Foundation, headquartered in Paramaribo, Suriname. The Fund's governing body is the Board of Directors, comprised of five

[1] Afinga is a grassroots organisation, established in 1994. This group has a membership of about 35, the majority of whom are women. The organisation was formed to develop and manage sustainable development projects, and receives money from the Forest People's Fund.

members, including two representatives of indigenous/ tribal communities, two representatives from CI and one nominated by Bedrijf Geneesmiddelen Voorsiening Suriname (BGVS). The Board reviews project proposals submitted by the local communities for financing.

Funding

The FPF was established with a $ 50,000 contribution from Bristol-Myers Squibb, followed by another $10,000 donation in 1996.

Distribution of Benefits

The Board's decision to fund a proposed project depends on whether that project advances the purpose of the Fund. That purpose is to "stimulate people of the interior and related living persons who contribute to and participate in the preservation and long-term protection of biodiversity and to provide them with social, educational, and economic assistance".

The FPF channels money and supplies through local community leaders, or through village foundations, such as Afinga (see above).

Sources

Maurice M. Iwu and Sarah A. Laird, The International Co-operative Biodiversity Group Drug Development and Biodiversity Conservation in Africa: Case Study of a Benefit-sharing Plan. http://www.biodiv.org/chm/techno/gen-res.html/cases#cases.

M. Guérin-NcManus, L. Famolare, I. Bowles, S. Malone, R. Mittermeier and A. Rosenfeld, Bioprospecting in Practice; A Case Study of the Suriname ICBG Project and Benefit-Sharing under the Convention on Biological Diversity. http://www.biodiv.org/chm/techno/gen-res.html/cases#cases.

References

www.nih.gov/fic/opportunities/icbg.html Information on ICBG projects

www.rafi.org Rural Advancement Foundation International

4. THE FUND FOR INTEGRATED RURAL DEVELOPMENT AND TRADITIONAL MEDICINE (FIRD-TM) - NIGERIA

Adapted from: Nnadozie, K., (1999), Profile - Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM), BDCP-Nigeria.

4.1 Overview

The Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM or the Fund) was established in Nigeria by Bioresources Development and Conservation Programme (BDCP). The Board of Management of the Trust Fund was inaugurated on September 30 1997. The Fund was established as a private, non-governmental and non-profit body, with the overall objective of facilitating and ensuring the equitable distribution of benefits derived from bioprospecting, and promoting the conservation of biological resources (see Box 6 below).

The Fund is an independent body with constituents from several sectors, including senior government officials, leaders of traditional healers associations, representatives of village councils and technical experts from scientific organisations. It has been de-

signed to provide short- and medium-term benefits in the form of immediate cash payments to individuals or groups, and sponsorship for community development projects.

Box 6: Objectives of FIRD-TM

Provision of Benefits

To serve as the channel through which benefits and economic rewards are distributed to the areas from which source plants for drug or other product development are found, in order to compensate individuals, rural communities and local institutions in accordance with stipulated modalities.

Biodiversity Conservation

To apply revenues available to the Fund to such projects or ventures that will promote the conservation of biological diversity and drug development, as well as the economic well being of target rural communities.

Improvement of Standard of Living

To improve the standard of living of families in target areas through community development initiatives, information, education and communication, and to mobilise volunteer efforts amongst local people in order to improve themselves and the environment, and ensure the sustainable utilisation of biological resources.

Alleviation of Poverty

To garner and channel support and assistance to rural families, particularly women and children, and engage in other activities that will help in poverty alleviation.

Promotion of Local Collaboration

To collaborate and consult, based on the circumstances of each case, with town associations, village heads and professional guilds of healers, in order to determine the nature of compensation to apply or the projects to embark upon in their localities.

Securing Collaborative agreements

To compensate, as appropriate, the scientists and other individuals who contributed to the identification and processing of medicinal or source plants.

Obtaining Contributions

To obtain contributions, in funds and in kind, for the development and support of projects to be undertaken by the Fund.

Other Activities

To engage in all other activities as may be necessary to further attain the objectives for which the Fund is established and, to this end, to combine activities or co-operate with other institutions and agencies whose objectives are consistent with the purposes of the Fund.

4.2 Governance and administration

The three principal organs of the FIRD-TM are:

The Board of Trustees

The property of the Fund legally resides in the Board of Trustees, which has the powers to dissolve or wind up the affairs of the Fund. It plays no part in the day-to-day running of the Fund.

The Advisory Body

The Advisory Body consists of experts in fields of relevance to the Fund's objectives, as well eminent persons who can identify with and contribute towards achieving those objectives.

The Board of Management

The Board of Management manages all the affairs of the Fund and acts on behalf of the Fund in all matters within its scope. Its decides on issues of policy, and reviews and approves work plans. It does not, however, directly participate on the implementation of the projects it approves. There are 10 members of the Board, consisting of:

- 1 traditional ruler – a retired state chief-pharmacist;
- 4 traditional medical practitioners – executives in the National Association of Traditional Medicinal Practitioners from various parts of Nigeria;
- 1 representative of the Department of Planning, Research and Statistics of the Federal Ministry of Health;
- the Co-ordinating Director for Science of the National Agency for Science and Engineering Infrastructure in the Federal Ministry of Science and Technology;
- 2 pharmaceutical scientists who have worked closely with traditional medical practitioners (one being the Executive Secretary of the West African Pharmaceutical Federation); and
- one ecologist.

Secretariat

An administrative secretary administers the secretariat of the Fund and its everyday business, maintains records of the Fund's activities and oversees all other staff employed by the Fund.

4.3 Funding

The FIRD-TM has so far been funded by the following:

- Bioresources Development and Conservation Programme and its collaborators, especially through the ICBG programme (see Section 3 of this Annex). All pre-incorporation and inauguration expenses were borne by BDCP.
- At the inauguration of the Board, an initial donation of $40,000 was received from the Healing Forest Conservancy, a US-based NGO.
- Substantial donations were received from Orange Drugs Limited and the Indigenous Pharmaceutical Manufacturers Association of Nigeria.

Further funding is sought from international donor agencies and there have also been pledges of further support and assistance from various sources, both in the public and private sectors.

To ensure sustainability, a proportion of the funds available to the Fund is kept in an income-yielding account. The remaining portion is disbursed to approved projects and to meet operational and administrative costs.

An external auditor conducts an annual audit of the Fund's accounts and expenses. An annual report is then prepared for circulation to the Board of Trustees, BDCP and major Donors.

4.4 Criteria for Fund Disbursement and Compensation:

The Board of Management has established a set of rules and procedures to govern disbursements and to evaluate its activities and operations. The Board will assess the relevance and sustainability of proposed projects in view of the Fund's objective and mandate. The most important factors be taken into consideration are:

- relevance to the conservation of biodiversity and the promotion of sustainable development;
- information for, or other contributions towards, the discovery of commercially viable genetic materials or drug development;

- capacity to meet the real needs of target communities, as identified through participatory processes; and
- the needs and expectations of donors which are in conformity with above ends and the underlying principles of the Fund.

4.5 Allocation of Funds

Disbursements aimed at achieving the various targets set by the Fund's mandate are made according to the following formula:

- biodiversity conservation activities/ national interests – 20 per cent;
- education – 10 per cent;
- Traditional Healer's Associations (for group projects or as micro-credit funds) – 30 per cent;
- Community Development Associations/ village projects – 30 per cent;
- women (especially widows) – 5 per cent; and,
- children's welfare – 5 per cent.

4.6 Disbursements to date

The Board of Management has approved the funds for the following projects:

- biodiversity conservation in Umubakia village, Imo State, for mapping out community forests into plots for inventory, and for providing tools, equipment, taxonomic training and security staffing;
- purchase of land in Jos, Plateau State, for a herbal clinic and garden for a co-operative of female herbal practitioners;
- funding for the Faculty of Pharmaceutical Sciences of the University of Jos, for ethnomedical surveys in the middle belt area of Nigeria;
- funds to the National Union of Herbal Medicinal Practitioners for the establishment of a national Secretariat and herbal clinic in Lagos;
- support for the establishment of a herbal clinic in Bida, Niger State;
- funds for the purchase of books for the Children Centre Library Project, University of Nigeria, Nsukka; and,
- support for a community development programme in the Owai community within the Federal Forest Reserve Area in Cross River State, specifically for securing school teachers and writing desks for the pupils.

4.7 Other activities of the Fund

The Fund has been active in soliciting the support of officials, the private sector, rural communities and medical herbal practitioners for its activities:

- The Board of Management has convened a national meeting for Herbal and Traditional Medical Practitioners, in collaboration with the Department of Planning, Research and Statistics of the Federal Ministry of Health, in order to articulate practitioners' needs and identify viable projects for assistance by the Fund. The Board aims to create a forum which traditional healers can use to address their problems and to foster further co-operative activities with the Fund. Traditional healers' acceptance of the Fund is based on its non-governmental, non-political and non-partisan nature.
- The Fund has entered into an informal agreement with the Federal Ministry of Health for the adoption of minimum acceptable standards for traditional medical practice.
- The Fund is also collaborating with the recently established Biodiversity Development Institute of Nigeria, in order to harness the latter's' advice and expertise in evaluating project proposals.

ANNEX 3: KAVA CASE STUDY

This paper offers a South Pacific perspective on indigenous innovations and practices using the kava plant as an example and discusses the implications of the TRIPS agreement on the ability of Pacific communities to retain their cultural heritage.

Peteru, C., Kava Case Study, WWF-South Pacific Programme, 1999. WWF information package to the Subsidiary Body on Scientific, Technical and Technological Advice to the Convention on Biological Diversity. (adapted)

1. NATURE OF RESOURCE

Kava is consumed throughout the Pacific. The grated, crushed or chewed roots are mixed with water to produce a mildly narcotic beverage of the same name. This looks like weak coffee and has a peppery taste numbing to the mouth and tongue. In sufficient quantities, it is mildly paralysing and creates a euphoric but clear-minded state[1].

1.1 Distribution

Kava - also known as ‘ava (Samoa), sakau (FSM), yaqona (Fiji) and by a variety of names in Vanuatu - is a domesticated woody, slow-growing perennial shrub, growing from 1 to over 4 metres in height. It is a member of the pepper family (Piper methysticum translating as “intoxicating pepper”) and is cultivated in the Federated States of Micronesia (FSM), Fiji, the Samoas, Papua New Guinea, Tonga, Vanuatu, and Wallis and Futuna. In pre-missionary times, it was cultivated in several other islands including Hawaii, where it is now enjoying a dramatic resurgence.

Of the 118 identified cultivars of kava, the number of varieties found in each country is: FSM (2), Fiji (12), French Polynesia (3), Hawaii (12), Papua New Guinea (4), Samoa (6), Tonga (7), Vanuatu (80), and Wallis and Futuna (3)[2]. Only 33 varieties, however, are recommended for consumption and chemistry purposes[3].

1.2 Origin

The number of cultivars in Vanuatu makes Vanuatu a strong candidate as the birthplace of kava. The evidence suggests that cultivated kava derives from a wild progenitor, Piper

[1] W.A. Whistler, Samoan Herbal Medicine, 1996, p59.

[2] V. Lebot, “An overview of kava production in the Pacific islands: what we do know and what we don’t know”, Journal of South Pacific Agriculture, Vol. 4, Jan-Dec 1997, p55.

[3] Vanuatu Country Paper, p2, Kava Symposium, Suva, Fiji, 1998.

Wichmannii C. DC a fertile Piper which has so far been found only in Papua New Guinea, the Solomon Islands, and Vanuatu. Although many botanists distinguish *P. wichmannii* from *P. methysticum*, there are convincing grounds for considering these two taxa of Piper to be wild and cultivated forms of the same species. The farmers in the northern islands of Vanuatu are suggested as being the first to select and develop cultivars to improve yield and the chemical composition responsible for kava's physiological effects. From northern Vanuatu cuttings from the plant were dispersed throughout the Pacific islands by voyaging canoes[4].

1.3 Innovation

Kava is a fairly young domesticate, perhaps less than 3000 years old[5]. As the kava plant is sterile it was propagated manually. The original growers would have taken cuttings from desirable plant variants so as to produce clones. They would have had to wait for at least two years before they could taste the product. Growers would obviously have exercised careful judgement in selecting only those plants exhibiting desirable characteristics in terms of potency, taste, texture, aroma, etc.

Differences in cultivation are evident today, ranging from traditional, low-tech approaches, requiring relatively little labour and capital investment, to the expensive high-tech, high yield approach seen in Hawaii.

1.4 Biochemistry

The active ingredients of kava (i.e., those ingredients responsible for giving kava its effect) are contained in its resin. The specific molecules involved are a series of compounds of related structures known collectively as kavalactones[6].

Fifteen kavalactones have been isolated from the rootstock. Nine have been fully identified. The following six are present in the highest concentrations:

- kavain
- yangonin
- methysticin
- dihydromethysticin
- dihydrokavain
- demethoxy-yangonin

For the farmer, the ideal would be to grow a variety which has a high resin content and a chemotype rich in kavain. The yield of total kavalactones also depends on the part of the plant that is extracted: percentages or dry weight are 15-20% in the lateral roots, 8-12% in the stump, 5-8% in the basal stems, 2-5% in the stems and less than 1-2% in the leaves[7].

For the beverage consumer, the effect from kava (kavalactone content and absorption) would depend on the cultivar used, its age, the part of the plant used, the method of preparation and the manner in which it is consumed. Kava's effect does not derive from a single active substance but rather from a mixture of several kavalactones, resulting in a synergistic physiological effect[8].

[4] See note 2, p55.

[5] ibid.

[6] From Lebot, Merlin and Lindstrom, Kava, the Pacific Drug. Yale University Press, 1992.

[7] See note 2, p58

[8] See note 2, p56.

2. RESOURCE HOLDERS

Kava plays a significant social and ceremonial role in the Pacific societies in which it is grown, particularly Fiji, FSM, Samoa, Tonga and Vanuatu. In Samoa, kava is relatively scarce. While there has been a small increase in public consumption, it is still reserved predominantly for ceremonial events such as chiefly meetings. In Fiji, by contrast, kava is relatively plentiful. In addition to its ceremonial role, it fulfils a significant social function and is commonly found in workplaces and offices alongside the coffee and tea. Vanuatu is different again. There, kava is consumed socially, particularly in the evenings, the emphasis being on silence and an absence of bright lights. Boisterous conversation is forbidden.

The explosion in demand for kava in recent years, resulting in significant price increases, has resulted in a predictable increase of growers who stand to earn several times more money selling kava than they would with rival crops. This has lead to kava's transition from a subsistence crop to a major cash crop. Central Bank figures for Samoa show that the export value of kava in Samoa sky-rocketed from S$47,000 in 1992 to an estimated S$3.5 million in 1998 (US$1 = SAT$2.80)[9]. There has been a corresponding increase in land area made available for kava, rising from 353 acres in 1989 to the present figure of 2,600 acres.

Growers are either subsistence farmers or larger commercial growers who grow kava plantation-style, as for example in Fiji. The crop grows well in traditional multicrop gardens, which are cut off from the forest and partly shaded by taller crops such as bananas and pawpaws. There is a concern, however, that young farmers looking for rapid income are tending towards kava monocropping, leading to susceptibility to disease and pest attacks[10]. In FSM, conservation is a major concern. Since the 1980s, growers have moved further inland to clear native forest in order to plant sakau. It has been estimated that native intact forest has decreased from 42% to 15% over the last 20 years. As a result, the government has initiated a "Grow Low Campaign" to encourage farmers to use low-lying land for planting[11].

The total area of land planted with kava in the South Pacific is around 10,000 ha, consisting of:

- Tonga 205 ha (i.e. 514 acres)[12]
- FSM 300 ha[13]
- Vanuatu 5000ha[14]
- Fiji 2000ha[15]
- Samoa 1040ha (i.e., 2600 acres)[16]

Domestic consumption is considerable, particularly in Vanuatu and Fiji. In Vanuatu, for example, of an estimated 15,000 tonnes of fresh kava produced annually, 10,500 tonnes is consumed by kava drinkers, 2,500 tonnes is absorbed by the domestic beverage market and 2,000 tonnes is exported. Samoa now exports kava to Fiji to help meet its demand for kava.

The inability of Pacific island countries to meet the quantity and quality of kava required by American and European markets has fuelled the resurgence of the kava industry in Hawaii, and has led to attempts to grow kava in Australia and Guatemala.

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[9] Samoa Country Paper, p6, Kava Symposium, Suva, Fiji, 1998.

[10] See note 2, p57.

[11] FSM Country Paper, pp2-3, Kava Symposium, Suva, Fiji, 1998

[12] Tonga Country Paper, Kava Symposium, Suva, Fiji, 1998.

[13] See note 2, p56

[14] Vanuatu Country Paper, Kava Symposium, Suva, Fiji, 1998

[15] Fiji Country Paper, Kava Symposium, Suva, Fiji, 1998

[16] Samoa Country Paper, p3, Kava Symposium, Suva, Fiji, 1998

3. TYPE OF USE AND BENEFITS OBTAINED

Research into kava has continued for well over a century. In 1860, several products (an alcohol extract, pills, essential oil, and a syrup) were prepared by the researcher Cuzent. Kava first appeared as a drug in the European pharmaceutical market in 1920 where it was used as a sedative. It was used by the Japanese prior to WWII as a treatment against gonorrhoea. Around this time medications were also being used in the United Kingdom, the United States, Venezuela and, more recently, Finland[17].

Three kavalactones (dihydromethysticin (DHM), dihydrokavain (DHK) and kavain) are responsible for several distinct effects, giving kava potential as a[18]:

- sleep inducing agent (Klohs 1959; Meyer 19622);
- pain-killer (Bruggemann and Meyer 1963);
- local anaesthetic (Meyer 1964; Kretzschmar and Meyer 1965);
- anti-convulsive agent and muscle relaxant (Meyer 1965); and
- anti-bacterial agent and food preservative (Hansel, Weiss and Schmidt 1966).

It has tremendous potential as a stress reliever because of its efficacy; the fact that, unlike anti-stress drugs such as valium, it has no side effects; and because it is non-addictive. Recent interest in kava has resulted in the world kava market segmenting into three components: the beverage, pharmaceutical and nutraceutical markets.[19]

The beverage market is comprised of Pacific island consumers who drink kava on ceremonial or social occasions.

The pharmaceutical market is centred in Germany, where kava has been studied for decades. It is categorised as a prescribable drug and is available over the counter at pharmacies. Approximately 6000-7000 tons of green kava are required each year to produce 1000-1400 tons of dry powder for an estimated 1.3 million users[20]. In the United States, by contrast, kava has not been approved as a prescribable drug.

Kava has, however, been approved in the US as a dietary supplement and has consequently taken off in the nutraceutical market (minerals, vitamins and herbal extracts). Today, most of the large herb companies in the USA include a kava product in their line[21]. Europe does not have a similar neutraceutical kava industry.

Neither kava-based pharmaceutical nor nutraceutical products are readily available in Pacific island countries.

4. WHO BENEFITS?

The export supply chain is well established. Increased demand for kava overseas may mean that overseas buyers will increase their prices in order to acquire what limited stocks are available from the Pacific. This has, in fact, happened in the past year: kava prices have shot up to record highs, with fixed term supply contracts being discarded in favour of spot buying. A plunge is, however, expected as prices fall to their usual levels.

High prices are, of course, good news for kava exporters, middlemen and farmers, as better prices are passed on down the chain of growers and suppliers. The question that should be asked is whether the price received by the country of origin is proportionate to the profits derived at the other end of the chain. It is unclear how much pharmaceutical or nutraceutical companies are prepared to pay for kava.

[17] See note 6.

[18] ibid.

[19] Fiji Country Paper, p4, Kava Symposium, Suva, Fiji, 1998.

[20] Fiji Country Paper, p5, Kava Symposium, Suva, Fiji, 1998.

[21] David R. Downes and Sarah Laird. Draft. Excerpt from: Case studies on Geographical Indications, trademarks and databases. Prepared for UNCTAD Biotrade Initiative. 1998.

Although companies in the Pacific have for many years exported dried Kava to pharmaceutical companies, questions regarding ownership are seldom asked. For example:

- can a kava plant variety be owned or protected?
- can the chemicals which gives kava its effect be owned or protected?
- can the genes in the kava plant responsible for the amount of these chemicals in the kava plant be owned or protected?
- can the name "kava" be owned or protected?

In October 1998, a Kava Symposium was held in Suva, Fiji, at which representatives from the US nutraceutical and European pharmaceutical industries were present. The representatives from nutraceutical industries insisted that they could not divulge any information about their pricing policies, given US anti-trust laws and prohibitions against price-fixing. They maintained this position throughout the meeting. No clear answer was forthcoming from the pharmaceutical representatives either. Salutary advice was, however, given against exporters insisting on high prices as this could 'kill the golden goose'.

Despite the lack of concrete figures some approximations of prices can be made. Farm gate prices for fresh kava rootstock in Vanuatu in the mid-1980s were estimated at $1/kg[22]. Current prices for kava destined for North American and European markets are reportedly in the neighbourhood of $11-22/kg[23]. A herb company was quoted as putting the wholesale price for roots at $14-20/kg but that that figure had almost doubled in recent years[24]. This appears to tally with Fijian farmgate prices of F$28-33/kg for roots, increasing to an export FOB price of F$50-60/kg ($US1 = F$1.90).

Americans spent $15 million on kava in 1996 and twice that much in 1997. The Nutrition Business Journal projected sales of almost $50 million for 1998[25].The data would suggest that kava is delivering on its promises. A typical price for a kava product in the US retail market is $10 for a bottle of 100 capsules, with a total stated kava content of 40 grams. This works out at a price of $250/kg of kava[26].

On the face of it, there is a substantial difference between farmgate prices and prices for the finished product. More information is, however, needed before it can be determined how much of this difference represents company profits.

5. *EX-SITU* COLLECTIONS OF KAVA

Kava plants or dried samples of kava are held in collections in a large number of institutions including the following:

Botanical Gardens
Royal Botanic Gardens of Sydney; Missouri Botanical Gardens; Royal Botanical Gardens, Kew; Singapore Botanical Garden; Arnold Arboretum, Massachusetts.

Universities
University of Malaysia

Research Institutes
DSIR, New Zealand

[22] See note 21.

[23] ibid.

[24] D. Grady, "Kava may soothe jagged nerves, but is it safe?" New York Times, October 13th 1998, D7.

[25] See note 24.

[26] See note 21.

Museums
Paris Museum; Bernice P. Bishop Museum; British Museum of Natural History

Who owns these ex situ samples? Samples obtained from source countries before the Convention on Biological Diversity came into force fall outside the scope of the Convention. In other words, they are not considered to be the property of the country from which they originated.

The collections are most probably the property of the State in which these institutions are located. For specimens held in International Agricultural Research Centre (IARC) genebanks, attempts are under way to bring the collections within the scope of the Convention[27]. Formerly, the genebanks held such collections in trust and distributed the germplasm from these collections to any researcher who demonstrated a legitimate interest. The IARCs made no attempt at controlling subsequent commercial uses of germplasms and associated intellectual property claims.

It is argued that ex situ collections ought to be brought within the scope of the Convention, and that the countries and communities which originally provided the germplasm should be accorded sovereign rights. This would entitle them to regulate access and to obtain benefits on the same basis as *in situ* genetic resources.

6. POSSIBLE MECHANISMS FOR A MORE EQUITABLE DISTRIBUTION OF BENEFITS

Pacific island countries may wish consider the following when examining means to obtain a larger share of the benefits derived from commercial use of Kava.

6.1 Localisation of benefits

Pacific island countries need to be more than mere suppliers of raw kava. There should be as much value addition as possible in the Pacific region before kava is exported. Indeed, a company is about to establish a multi-million dollar kavalactone extraction factory in Vanuatu. Another company plans to establish a similar facility on the island of Vanua Levu in Fiji.

It is possible to test kava at the University of the South Pacific's laboratory in Fiji for kavalactone concentration. This will be of value to local growers or exporters who wish to ascertain kavalactone concentration in their plants. Kavalactone extraction is possible on a small scale. The extract, when added to powder, is readily transportable. Such a mixture may be worth up to four times more than kava root.

6.2 Collaborative ventures

As it will be impossible to prevent research into kava, efforts should be made to undertake joint research programmes with overseas companies. An option for Pacific island countries to purchase shares in the companies using kava may be worth considering. This could ensure that both parties have shared goals.

6.3 Determining the ownership and origin of kava samples

Given that kava is currently being grown outside of the region, Pacific kava-producing countries have banned the export of green kava. Questions have arisen over the ownership of kava plants that have been taken out of the region (in addition to selling kava, one company on the internet sells kava plants for homes at US$25 per plant). It is likely that most were taken out prior to the entry into force of the Convention on Biological

[27] See Annex 6, section 1.

Diversity and may therefore be considered as the property of those currently in possession of them.

A new technology, known as genetic fingerprinting, will, however, allow scientists to determine with reasonable certainty the origin of any given cultivar of kava. If questions of compensation arise, the identity of claimants can therefore be readily ascertained.

6.4 Intellectual property rights (IPRs)

Article 27(3) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (binding on all WTO Member countries) requires the protection of plant varieties either by patents or by an effective sui generis (a class by itself) system, or by any combination thereof[28].

This provision is viewed as a threat to community rights because it forces countries to introduce protection for plant varieties either by means of patents or by means of a sui generis system - most likely one that is based on the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV). The main concern is the imposition of laws that would overturn customs of sharing planting material and that fail to understand the communal systems of innovation by which farmers select, improve and breed diverse crop varieties.

Overseas companies have readily obtained IPRs on kava products, and on processes using kava. Patents and the UPOV system of plant variety protection have, however, proved inadequate for protecting the intellectual effort of Pacific kava growers, not only in terms of qualifying criteria but also in terms of the costs of product development, and of applying for and enforcing these IPRs.

Patents[29]

Patent protection is stricter than plant variety protection under UPOV and in some countries, such as the US, is offered for plant varieties. Patents are expensive to obtain. The plant will not be considered for protection if it is already well known to the public. No Pacific island country grants patents on plants. However, even if such patents were available, it would seem no traditional variety of kava would qualify, i.e., a patentable invention needs to be "novel" (something new and not previously existing), "useful" (capable of industrial application) and "non-obvious" (there needs to be an inventive step).

Plant variety protection under the UPOV Convention[30]

Can Pacific kava-growers use plant breeders' rights to protect their varieties of kava? For the moment, this is not possible. No Pacific island country is a member of the UPOV Convention and none have plant variety protection legislation in place. Even if a Pacific island country had UPOV-consistent legislation, the intravariety genetic diversity common to traditional kava cultivars would most probably leave kava ineligible for protection given the UPOV criteria for determining new plant varieties, i.e., uniformity, stability, novelty and distinctiveness. Furthermore, kava growers would need to find the expertise and money to undertake field tests if they were to stand a chance of applying for plant variety protection with any success.

However, the possibility remains that plant variety protection could be obtained for a new variety of kava in any country with UPOV-style legislation in place, even though that variety is likely to have been based on material taken from a Pacific island country.

[28] See Chapter 3, section 3.2

[29] See Chapter 3, section 2.1 and 4.2.1

[30] See Chapter 3, section 2.2 and 4.2.2

The question of whether or not plant variety protection legislation should be enacted in Pacific island countries is likely to arise soon, given pressure to comply with the World Trade Organisation TRIPs Agreement. There is already a sense that there is pressure on developing countries to adopt the 1991 UPOV model as a sui generis system for the protection of plant varieties.

Sui generis systems for plant variety protection other than UPOV[31]

Arguably, patents and the UPOV system have failed to adequately protect traditional plant varieties from the broad claims of commercial breeders. The TRIPs Agreement does, in fact, allow WTO Member countries to implement a sui generis system of plant varieties protection other than, or only partially modeled on, UPOV and that would better serve the interests of indigenous peoples. Many developing countries are therefore seeking to implement such sui generis systems given the conviction of their farmers that they have received neither recognition nor compensation for the efforts they have expended in domesticating wild crops and in improving traditional varieties. Pacific island countries might therefore choose to seek sui generis systems appropriate to their concepts of innovation and ownership.

Although conventional intellectual property rights, trademarks and geographical indications[32] have been suggested as frameworks for sui generis protection of traditional plant varieties[33].

Trademarks and geographical indications

A trademark is a distinctive symbol that identifies particular products of a trader to the general public. The symbol may consist of a device, words, or a combination of these. Upon registration, the trader enjoys the exclusive right to use the trademark in connection with the goods for which it was registered.

Persons who manufacture or sell goods, or who provide services, may want to demonstrate a connection between themselves and the goods. The usual means of indicating this connection is the use of a distinctive mark or symbol. As the trader's reputation grows, the identifying mark becomes important to the establishment of the business. Each time a person sees such a mark, they may consciously or subconsciously make a connection between the product and the producer.

It is possible for trademarks to be held by members of a trade association. The trademark could then qualify as a form of certification mark (e.g., it can declare to the consumer that a product has been manufactured in accordance with good environmental practice).

Numerous brands of kava have been trademarked, many using the word "kava" within the brand name. For example, companies in the US and Europe have obtained trademarks such as "Kava Pure" and "Kavatril".

An opinion was sought by the South Pacific Forum Secretariat in April 1997 on whether the name "kava" could be trademarked in and of itself. It was suggested that the word "kava" is so well known, not only in the Pacific but also in the US and Europe, that it has acquired a generic meaning in much the same way as the terms sugar and coffee have. This would disqualify the word from being registerable as a trademark.

On the other hand, it was suggested that Pacific island country might together create a name, for example "Pacific kava", which could be trademarked or used as a certifica-

[31] See Chapter 3, section 4.3

[32] See appendix to this case study.

[33] See Chapter 3, section 2.3

tion mark, and which in time will come to be identified with kava and kava products originating in the South Pacific. Such indications are valuable in politically correct Northern markets.

It therefore appears that there might be significant potential for the application of registered trademarks to Kava products. It is very possible that an appropriate trademark, such a certification mark that represents standards for environmentally and socially responsible sourcing and processing of raw materials, would increase the market share of kava originating in Pacific island countries[34].

A strong argument for using geographical indications to protect kava products originating in the South Pacific is also made by Downes and Laird (1999) – an excerpt of their paper is reproduced as an appendix to this case study.

6.5 Material Transfer Agreements (MTAs)[35]

Efforts are underway to finalise an MTA contract governing the release and use of ex-situ collections of germplasm held by the University of the South Pacific (USP), in particular at the Alafua Campus in Samoa. At the international level (kava germplasm being found in ex situ collections all over the world) MTAs are also being developed for the genebanks of the FAO's Consultative Group on International Agricultural Research (CGIAR).

Conditions in the USP MTA would include a requirement to obtain the permission of the Pacific island country from which the germplasm was originally collected before it could be released. Where the country is not known, an organisation, such as the Forum Secretariat or USP itself, may be able to act as the default owner on behalf of that country.

7. RECOMMENDATIONS

Kava is a unique plant that presents Pacific island countries with unique economic opportunities. It should therefore be safeguarded against unauthorised commercial exploitation. The individual and rival interests of kava businesses in the Pacific must give way in the interests of the kava industry as a whole.

Action should be considered at:

7.1 the national level:

- strict controls over or a ban on the export of planting material; and
- establishment of national kava councils to coordinate national kava development.

7.2 the regional level:

- provide a venue to:
  - facilitate dialogue and coordination amongst the various levels of the kava industry (kava-growers, retailers, wholesalers, exporters, manufactures, etc.);
  - set industry standards and ethical guidelines; and
  - provide a regional strategy for the production and marketing of kava.

[34] See fn 21.

[35] See Chapter 4, section 4.6; Annex 4, section 3 and Annex 6 sections 1.6 and 2.

7.3 the international level:

- governments to lobby to bring ex situ collections of kava within the scope of the Convention on Biological Diversity;
- as conventional intellectual property rights are not suitable in providing the protection kava plant require, a sui generis model attuned to the conditions of Pacific island countries is required instead; and
- the maximum transition time for developing countries to implement the WTO TRIPS Agreement should be extended to allow countries to fully assess the impact of the Agreement and to devise ways in which to mitigate its worst features.

Appendix to Kava case study

Excerpt from: Downes, David R., and Laird, Sarah, Case studies on Geographical Indications, Trademarks and Databases (Draft)

Draft prepared for UNCTAD Biotrade Initiative, 1999.

Already, the secretariat of the South Pacific Forum has sought an opinion on whether the name "kava" could be trademarked; legal advice was that the term was too well known as a generic name of the substance to be registered as a trademark in relevant markets, including the Pacific, Europe and the US. However, it was suggested that Pacific Island Countries organize to create a "Pacific kava" trademark, collective mark or certification mark, which would be a distinctive term identified with kava products originating in the South Pacific (Peteru 1997).

US and European companies have trademarked a number of terms relating to Kava, including for instance the names "Kava Pure" and "Kavatril". There are also at least five kava patents on kava extracts and active compounds. At least one company has obtained a patent on a combination of kava and other herbs, "Kavatrol"[36].

Genetic resources for kava are distributed among a number of countries of origin in the Pacific, with an apparent center of diversity in Vanuatu, but additional cultivars found in a number of other islands, including Hawai'i, which is within the territory of a non-Party to the Biodiversity Convention. It appears that living exemplars of kava are also found in ex situ collections outside of the Pacific, presumably the result of collecting expeditions predating the entry into force of the Biodiversity Convention.

Options for Benefit Sharing and Sustainable Use

Kava appears to be a product with significant potential for use of trademarks or geographical indications. It is very possible that an appropriate trademark, particularly a certification mark that represents standards for environmental and socially responsible sourcing and processing of raw materials, would increase market share for its users.

Consumers, retailers and distributors of herbal products tend to be more conscious of environmental and social implications of production than the average. Increasingly, consumers and the media have criticized the herb industry's sourcing strategies. A number of companies have begun to invest in ethical sources that also guarantee control over plant material quality. For example, Madis Botanicals - one of the largest bulk ingredient suppliers of kava to the US market - has invested in a sustainable sourcing strategy for kava, a strong selling point for some of the manufacturing and marketing companies that buy Madis' products (e.g. Nature's Way, pers. comm. 1998).

At this stage, the demand is so high for kava that mediocre and adulterated material finds its way onto the market. A certification mark could represent responsible sourcing

[36] "Valley and Ventura County: Regional Roundup: Natrol Wins Patent for Plant-based Relaxant." L.A. Times, Aug. 11, 1998, Part D, p. 12A. Natrol Inc., obtained a U.S. patent for Kavatrol, a dietary supplement that serves as a general relaxant, composed of kava, chamomile, hops and schizandra.

from a quality control (e.g. preferred variety; chemical markers for kavalactone content), as well as production that meets environmental and social criteria. Although a significant outreach campaign is required to educate consumers on the standards behind any label, a number of groups have already launched programs which could assist in this effort for kava, e.g. the Rocky Mountain Herbalist Coalition (USA), United Plant Savers (USA) and the College of Phytotherapy (Herbal Medicine) (UK).

The growth in foreign demand for kava could in theory threaten to encourage less sustainable production, for instance by encouraging farmers to harvest trees earlier than usual, or to shift away from traditional methods, which frequently involve multicropping and a waiting period for the kava to reach a certain age and size, to more destructive techniques. More research is needed on the details of this point. However, the pattern is universal in the production of agricultural commodities for export, that pressure to expand exports leads to destruction of bioresources through the displacement of habitat by cultivated areas, or the intensification of cultivation techniques resulting in soil erosion, water pollution or other damage[37]. Thus, the same collective institutions that develop marks of origin should also explore basic standards for sustainable production, which may draw upon traditional techniques and customs.

Kava also appears a strong candidate for geographical indications such as appellations of origin. The production techniques for kava are based on "long histories of empirical experimentation and experience" (Moran 1993). These traditional practices continue to evolve over time, but a core of propagation, cultivation, and processing techniques combine to produce the optimally effective kava product. The four key components of appellations of origin—distinctive varieties/species; yields; production methods; and processing methods B would aptly apply in this case. Once recognised, geographical indications have the advantage over certification marks that competitors can be prohibited from using the designation unless they are authorized to use it by the association of producers in the relevant region.

With as much as 3,000 years of human cultivation and propagation, resulting in around 118 cultivars in the region, it might easily be argued that traditional production practices are distinctive, and that "true" kava products are bound to the place and the local culture. Given threats of fraudulent claims and the potential for over-production in the future from competing sources responding to the current increased market demand, kava producers in the Pacific island countries might wish to protect themselves, and the integrity of their product, through a geographical indication. However, there might be some factual question as to the inherent superiority of kava grown by traditional methods or in traditional growing areas; further research is necessary on this point.

Certification marks, collective marks and geographical indications all have the potential to increase incentives for sustainable use. Consumers may prefer to buy products with lower environmental impacts. A price premium is also possible, though the evidence is unclear whether consumers will generally pay more. Perhaps most important, the cooperative development of such marks enables producers to establish shared standards for sustainable use, and to monitor and enforce compliance with those standards. This is essential to avoid destructive competition in which producers seek to harvest resources as cheaply and quickly as possible in order to maximise short term profits at the expense of the long term sustainability of their resources.

Moving in this direction will require a number of steps. One is the creation of a framework, however flexible in the beginning, to support regional cooperation. It will also need to bring together producers with environmental groups, government officials, and

[37] Bioresources is defined here broadly to include not only to include kava itself but also the ecosystem and its components, such as soil and other plants, that support production of kava.

those involved in export, distribution and marketing. Returns will be increased to the extent that producers can add value to the commodity within the region. Ultimately, some sort of institutional structure will be needed to maintain and elaborate standards and a system for awarding certification and monitoring and enforcing compliance among producers and sellers. In addition, exporting countries will need to enact legal measures to support this system as a base for international enforcement against unauthorized use of the geographical indication.

ANNEX 4: AN OVERVIEW OF THE POLICY OF THE UNITED STATES NATIONAL CANCER INSTITUTE (NCI) ON ACCESS AND BENEFIT SHARING

Reproduced from: ten Kate, K. and A. Wells (1998), 'The Access and Benefit-Sharing Policies of the US National Cancer Institute: A Comparative Account of the Discovery and Development of the Drugs Calanolide and Topotecan', in Case Studies on Access and Benefit-Sharing Arrangements, COP 4, Bratislava, May 1998.

INTRODUCTION

The Natural Products Branch of the Developmental Therapeutics Programme (DTP), NCI, co-ordinates the screening of natural product materials derived from plants, marine macro-organisms, and terrestrial and marine micro-organisms. In its early years, screening of natural products was mainly concerned with testing fermentation products and, prior to 1960, only 1,500 plant extracts were screened for antitumour activity. However, an Interagency Agreement (IA) with the US Department of Agriculture (USDA) in 1960, for the collection of plants for screening, initiated a systematic search for anti-cancer agents from plant sources. Collections were initially made in the U.S. and Mexico, but these were expanded to sixty countries by USDA field collections and contract suppliers. By 1982, 114,000 extracts of 35,000 plant samples (12,000 to 13,000 species) in NCI's Natural Products Repository (NPR) had been tested against a range of tumour systems used as primary screens (principally the L1210 and P388 mouse leukaemias).

Given that few novel leads were emerging from the screens and that any that did emerge did not exhibit significant activity against human solid tumours, the collection programme with the USDA was terminated in 1982.

However, technological advances, including high throughput screening, and biochemical and biomolecular understanding of the mechanisms of action of diseases, led to the introduction of new in vitro human cell line screens in 1985. A new AIDS therapeutic programme was also started in 1988. These developments revitalised the NCI's work with natural products.

Plant compounds discovered by the NCI with anti-cancer and anti-AIDS properties.

Compound	Activity	Source
• Camptothecin.	• Anti-cancer.	• *Nothapodytes foetida* (India) • *Camptotheca acuminata* (South-eastern China).
• Taxol.	• Anti-cancer.	• *Taxus brevifola* (North-western USA).
• Michellamine B.	• Anti-AIDS.	• *Ancistrocladus korupensis* (South-western Cameroon).
• Conocurvone.	• Anti-AIDS.	• *Conospermum incurvum* (Western Australia).
(+)-Calanolide A & (-)-Calanolide B.	• Anti-AIDS.	• *Callophylum lanigerum & C. teysmannii.* (Sarawak, Malaysia).

In 1986, three five-year contracts were awarded for collections of plants in tropical and subtropical regions world-wide at a total cost of US$2.7million, with Missouri Botanic Gardens (MBG), New York Botanic Gardens (NYBG) and the University of Illinois at Chicago (UIC), assisted by the Arnold Arboretum and the Bishop Museum in Honolulu. The contracts with MBG, NYBG and the UIC were extended for a further 5 years in September 1991 at a total cost of $3.8 million[1].

The objectives of the NCI at the time that the UIC collected the first sample of Calophyllum lanigerum in 1987 remain the same today: to promote the discovery and development of new anti-cancer and anti-AIDS agents. To accomplish this goal, the NCI enters into a range of different partnerships.

1. NCI'S COLLABORATIVE APPROACH TO DRUG DEVELOPMENT

NCI's approach to benefit-sharing with source countries is guided by its collaborative approach to drug development. The NCI uses government funding to source, screen and isolate essential natural compounds, both through intramural research programmes and through collaborative partnerships with academia, the private sector, and other public research organisations. Development can involve preclinical and clinical studies up to the point of commercialisation, but the NCI, as a government-funded, non-profit organisation, cannot commercialise any products. Any products not selected for commercialisation by the private sector, but considered of significant therapeutic value by the NCI, would be provided to the public free of charge. The chief collaborative mechanisms for drug development are:

- Cooperative Research and Development Agreements (CRADAS);
- Small Business Innovative Research (SBIR) Grants Programme;
- National Cooperative Drug Discovery Groups (NCDDGs);
- National Cooperative Natural Product Drug Discovery Groups (NCNPDDGs); and
- NCI Liaison Office Exchange Programme.

2. BENEFIT-SHARING MECHANISMS WITH SOURCE COUNTRIES

While the majority of countries do not have detailed legislation on access and benefit-sharing, most countries have some system of regulating access to genetic resources through the issuing of permits to collectors. The experience of the NCI's contract collectors was that when source countries were aware of the drug discovery activities to which their samples were to be put, they were reluctant to grant the necessary collecting

[1] Information document on the Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI).

permits without establishing agreements to safeguard their rights in the event of commercialisation. The NCI thus developed material transfer agreements between source country Governments and the NCI's Developmental Therapeutics Program (DTP). These agreements have evolved through three distinct phases:

- **The Letter of Intent**, developed as of 1988, first used to found a formal agreement in 1990 and revised in 1991.
- **The Letter of Collection**, which replaced the Letter of Intent in 1992.
- **The Memorandum of Understanding**, initiated in 1995 and increasingly used as the model for partnerships between the NCI and qualified organisations in source countries.

Each of these three kinds of agreement has involved monetary and non-monetary benefit-sharing, although, as explained below, each successive model has involved greater benefit-sharing through stronger commitments to technology transfer and a greater emphasis on collaborative research and value addition in the source country. The agreements contain provisions on:

- intellectual property rights (involving the payment of royalties and possibilities for joint ownership of patents);
- technology transfer, training and capacity building (involving the training of source country scientists in NCI laboratories);
- confidentiality of ethnobotanical data, including prior informed consent from traditional healers prior to publication and adequate acknowledgement of their contributions;
- joint research;
- the communication of research results to source country institutions;
- resupply (collaboration over the resupply of additional material for discovery, development and scale-up for manufacture); and
- obligations on third party licensees to share benefits with the source country.

The main benefits to be shared under these three agreements are compared in Table A, whilst processes of negotiation are compared in Table B.

2.1 The Letter of Intent

The Letter of Intent was first used in a formal agreement with Madagascar in 1990[2]. There was relatively little room in the Letter of Intent for "value-addition" in the source country. Other than royalty payments, the main benefits promised to an source country were limited to the training of a scientist at the NCI and the receipt of research results (these being channelled via the Collection Contractor who had obtained field samples). No further commitments were made to involving a source country organisation in product discovery and development.

The Letter of Intent contained provisions for the commercialisation of products based on samples supplied by source countries. It stated that all licenses on patents arising out of the collaboration must refer to the Letter of Intent agreement and that all licensees must be apprised of it. When the NCI licensed any compounds derived from materials collected to third parties for further development and commercialisation, "DTP/NCI [made] its best effort to ensure that royalties and other forms of compensation [were] provided to the host country organisation and to individuals of that country, as appropriate, in an amount .....negotiated with NCI, in consultation with the host country organisation." The ambivalence of the obligation imposed by the use of the term "best efforts"[3] proved unsatisfactory to several source country partners, which were seeking

[2] Personal communication, Dr Gordon Cragg, National Cancer Institute, 9 February 1998.

[3] Ibid.

Table A: Letter of Intent, Letter of Collection and Memorandum of Understanding: benefit-sharing provisions compared

Agreement; Benefit.	Letter of Intent	Letter of Collection	Memorandum of Unde
Monetary benefits/ royalties	• Depends upon negotiation of benefits between a licensee of a patented product and the NCI, the source country having been consulted by the NCI.	• Depends upon the negotiation of benefits between a licensee of a patented product and a source country, as required by the Letter of Collection.	• Depends benefits patented country, Memorar
Intellectual property rights	• Joint patent protection is sought for all inventions developed collaboratively by NCI and source country organisation employees. • All licences on patents arising out of the collaboration refer to the agreement and all licensees are apprised of it.	• As for the Letter of Intent.	• As for Le of Intent.
Joint research	• A senior source country scientist/ technician is invited to NCI's labs for one year or gains opportunity to use technology useful in furthering work under the agreement. • Further development of compounds submitted by source country scientists to NCI for screening (as separate initiatives from submissions by the collection contractor) is conducted by NCI in consultation with the relevant source country organisation.	• During the course of the contract, the NCI (in collaboration with the source country organisation/ government), assists the appropriate source country institute with capacity building for drug discovery and research (including screening capabilities). • Once an agent has been approved by the NCI for preclinical development, the basis on which source-country scientists can participate in such development is negotiated. • With regard to source country participation in the further development of specific agents, sincere efforts are made to transfer knowledge and expertise to the source country organisation. • Otherwise, as for the Letter of Intent.	• Facilities country c house pr viral scre compour later sub with data • Once NC anti-canc the sourc undertak fractionat compour • If fraction establish organisat country s for isolati • Otherwis Collectio

Table A: continued

Technology transfer	• None is mentioned.	• With regard to source country participation in the further development of specific agents, 'sincere efforts' made to transfer technology to the source country organisation, subject to IPRs.	• The NCI necessar country c fractiona resource
Information: research results/repatriation	• NCI provides the results from screens of extracts to the source country (subject to confidentiality until the DTP has a chance to file patents).	• As for the Letter of Intent.	• The NCI its advan screens v
Rights to supply further material/who covers costs (licensees)	• NCI requires licensees to seek resupply of source material from source countries. • The Collection Contractor collaborates with the source country organisation over possibilities for mass propagation.	• As for the Letter of Intent.	• As for the Letter of
Transfer to third parties/licensing	• 3rd party recipients of material sent by the NCI must compensate the source country as appropriate.	• As for the letter of Intent.	• The NCI 3rd partie Source C organisat with such them in t
Publications	• Permission of a traditional healer is sought prior to publication of any information he/ she has contributed, and he/she is acknowledged.	• As for the Letter of Intent.	• Publicati MoU take upon by t organisat

Table B: Letter of Intent, Letter of Collection and Memorandum of Understanding: processes of negotiation compared

	Letter of Intent and associated agreements	**Letter of Collection and associated agreements.**	**Memorandum of Understanding**
Agreements and Parties	(1) Collector/NCI *[Collection Contract]* (2) Source country/Collector [*Permit*] Collector carries Letter of Intent with him to explain. (3) Source country/NCI [*Letter of Intent*].	(1) Collector/***NCI [Collection Contract***] (2) Source country/Collector [*Permit*] Collector carries Letter of Collection with him to explain. (3) Source country/NCI [*Letter of Collection*].	(1) Source country/NCI [*Memorandu* *Understanding*].
Process of reaching agreement	• (2) and (3) negotiated at the same time by the Collector as agent for the NCI.	• (2) and (3) negotiated at the same time by the Collector as agent for the NCI. • OR (3) negotiated separately by Source country and the NCI.	• The NCI and the sou negotiate directly.
Negotiation with licensees of Source Country's share in benefits.	• The licensee of a patented product agrees what benefits to share in consultation with the NCI, the source country having been consulted by the NCI.	• The NCI insists that the licensee of a patented product negotiates directly with the source country over royalties and other compensation.	• The NCI insists that t patented product neg with the source coun and other compensat of Collection).

greater involvement in research. Furthermore, the NCI's ability to enter into benefit-sharing commitments is constrained by the legal framework, which provides it with the statutory authority needed to enter into partnerships of this kind[4]. In response, the NCI revised the Letter of Intent was 1991. The new agreement was amended and was soon renamed the Letter of Collection.

2.2 The Letter of Collection

The Letter of Collection is significantly different from the old, unrevised Letter of Intent, essentially involving a shift from what was effectively a supply agreement to a more "value-added" collaboration between the NCI and a source country organisation. This is demonstrated by a commitment in the Letter of Collection's preamble to make "sincere efforts" to transfer technology to the source country[5]. Further to this, Article 3 of the Letter of Collection discusses the transfer of screening and isolation capabilities, and Article 5 contemplates collaboration between the NCI and the source country over preclinical development of selected active agents. Article 5 also outlines the transfer of knowledge, expertise and technology.

Phrases such as "in the course of the contract period" and "during such collaboration", reveal that the Letter of Collection is not specific as to exactly when in the discovery and development process the capacities of source countries in screening and isolation would be built, or information, know-how and technology transferred. With the exceptions of preclinical studies (though, even here, the precise nature of source country involvement is not specified) and opportunities to work in NCI labs or to use "technology useful in furthering work under [the] agreement", it is unclear whether the benefits shared by NCI are to support immediate work on the agents selected from source country genetic resources, or whether the benefit-sharing is intended to build source country capacities in the longer term. The presumption is still that the source country has little direct participation in the discovery and development of the drug candidate in question. The Letter of Collection does not stipulate the immediate transfer of screening capabilities for source country testing of extracts obtained under the agreement and no commitment is made to the immediate provision of bioassays to facilitate source country fractionation of those compounds found to be active.

Another significant development in the Letter of Collection, compared with the Letter of Intent, is that, in ensuring licensees deliver adequate compensation to the source country, the NCI is no longer involved in negotiating the monetary terms of the license between a licensee company and the source country, but instead insists on direct negotiations between the source country and the licensee, itself dropping out of the picture. Article 8 states that "should an agent ...be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the appropriate Source Country Government...agency(ies) or Source Country Organisation(s)...This agreement will address the concern on the part of the Source Country Government...or Source Country Organisation(s) that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation as appropriate."

Finally, Article 9 shows that the scope of the genetic resources and derivatives covered under the agreement are broader than those under the Letter of Intent, covering not just actual isolates of the natural product and any inventions structurally based upon them,

[4] For a more detailed explanation, see the 'summary of the legal context for access to genetic resources by the NCI and its practice in benefit-sharing', above.

[5] "NCI will make sincere efforts to transfer knowledge, expertise and technology related to drug discovery and development to the [appropriate Source Country Institution (SCI)] in [Source Country] as the agent appointed by the [SCG or SO], subject to provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SO], in turn, desires to collaborate closely with DTP/NCI in pursuit of the investigations of its plants, microbes and marine macro-organisms, subject to the conditions and stipulations of this agreement."

but also synthetic compounds for which the isolate was a developmental lead, and any associated methods and uses.

2.3 The Memorandum of Understanding (MoU)

As the capacities of the source country to engage in drug discovery and development increase, there is more opportunity for joint collaboration between the NCI and source country organisations. The NCI is hoping to increase the proportion of MoU-style arrangements with source countries, compared to arrangements made under the Letter of Collection.

Through greater collaboration between the NCI and the source country organisation during drug discovery and development, the MoU marks a significant shift in benefit-sharing arrangements towards more value-added source country participation in scientific research. Agreements are now based on the MoU with:

- Instituto Nacional de Biodiversidad (INBio) in Costa Rica;
- the South American Office for Anticancer Drug Development, Porto Alegre, Brazil;
- Universidad Paulista, Sao Paulo, Brazil;
- Instituto de Química, Universidad Nacional Autónoma de Mexico;
- Faculdad de Farmacia, Universidad de Panamá;
- the Research Institute of Chemistry, University of Karachi, Pakistan;
- the Kunming Institute of Botany, Yunan, China;
- the Korea Research Institute of Chemical Technology, Taejeon, Republic of Korea;
- National Institute of Water and Atmospheric Research, New Zealand.
- the Division of Food Science and Technology, Council of Scientific and Industrial Research, South Africa;
- the Zimbabwe National Traditional Healers Association (ZINATHA), University of Zimbabwe, Harare; and,
- the University of Dakar, Bangladesh[6]

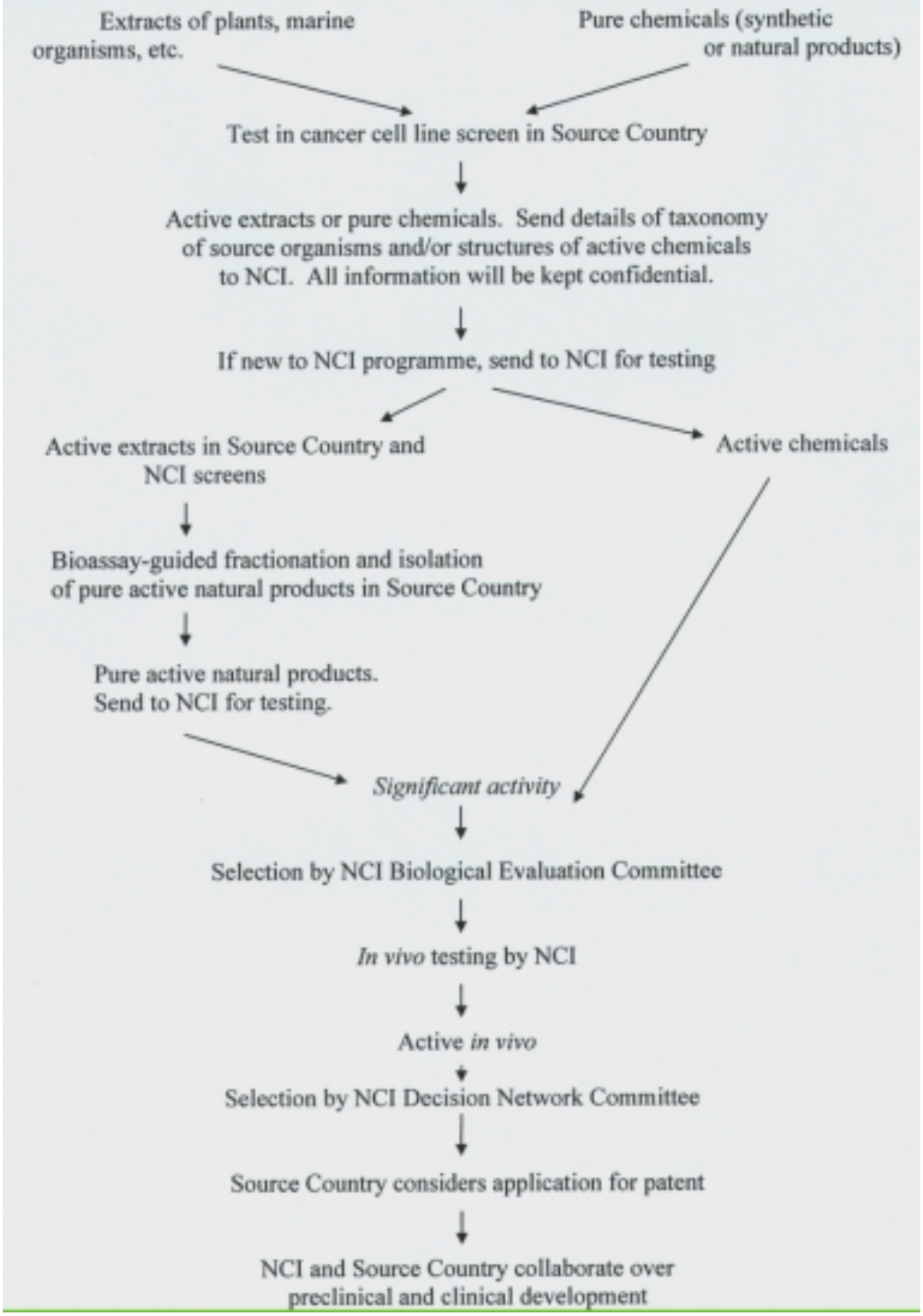
The MoU is negotiated directly between the NCI and a source country, reflected in the fact that the source country (rather than an NCI contractor) undertakes all collection work for local screening (rather than for export to the NCI).

The MoU provides for greater participation by source country facilities in screening and fractionation. More emphasis is paid to existing source country capabilities. Where these are lacking, the NCI offers to equip the source country organisation with cell lines and appropriate bio-assays, not only as part of a general commitment to capacity building, but for the specific purposes of furthering work on anti-cancer and anti-HIV therapeutics under the MoU involved. Thus, the source country organisation has a more immediate role to play. However, it is not clear if source country participation in preclinical development of selected agents is greater under the MoU itself than under the Letter of Collection, but where the expertise and capacity exist in the source country to perform one or more of the phases of preclinical development, further appropriate agreements for collaboration may be established. Also, although not explicitly stated in the Memorandum of Understanding, if a compound isolated by the source country organisation is of sufficient merit to advance into preclinical development, the source country organisation may elect to apply for patent protection using NCI test data. The NCI data is considered routine, so the NCI makes no claim to co-inventorship and the source country organisation has sole rights to the invention[7].

[6] Personal communication between Dr Gordon Cragg, National Cancer Institute, 17 April, 1998.

[7] Personal communication, Dr Gordon Cragg, National Cancer Institute, 17 April, 1998.

Flow diagram showing collaboration with NCI under the Memorandum of Understanding



Reflecting the joint responsibility of the NCI and the source country to coordinate drug discovery and development, the NCI will not distribute materials provided by the source country organisation to other organisations without written authorisation from the source country organisation. It also provides tighter requirements for the NCI to return in vitro test results to the source country organisation within 90 days, with an absolute limit of 270 days, in breach of which NCI must provide the source country with a written explanation. Finally, the MoU imposes limits on the US government's royalty-free, irrevocable, nonexclusive license to manufacture and/or use any invention claimed in a patent by a source country organisation. This license is thus restricted to work involving medical research and covers only those source country patents that rely on data generated by NCI. It does not allow for treatment of patients outside clinical trials or commercial distribution. This is sufficient to permit the NCI to continue developing a drug candidate in the long term if a private-sector licensee loses interest[8].

[8] However, NCI's right extends only to patents using data generated by DTP laboratories and only to clinical trials, rather than to commercialisation. Personal communication, Dr Gordon Cragg, National Cancer Institute, 9 February 1998.

3. THE BENEFIT-SHARING POLICY OF NCI'S NATURAL PRODUCTS REPOSITORY (NPR)

Researchers wishing to obtain samples from the NCI's Natural Products Repository (NPR), and who are deemed eligible pursuant to NCI criteria[9], are obliged to sign the NPR's material transfer agreement (the "NPR MTA") under which crude extracts and related confidential information is transferred to them[10]. The recipients are entitled to evaluate the extracts but may not use them for commercial purposes such as production or sale, for which a separate licence would be required, if such activities were to be allowed[11]. The licence could be granted either pursuant to 35 USC 207 or, if the NCI and the recipient decide to engage in co-operative research and development using the material transferred, or if the recipient wishes to licence intellectual property rights held by NCI, pursuant to a CRADA[12]. Further exchange of materials transferred by the recipient to other collaborating organisations may occur only upon execution of a copy of the NPR MTA by each such collaborator[13]. Under the NPR MTA, the recipient also agrees not to transfer materials to others without the advance written approval of the NCI, although execution of the NPR MTA would constitute such approval *per se*[14].

The terms of the NPR MTA require the recipient to acknowledge that the material it obtains from the NPR may have been acquired by the NCI under a Letter of Collection agreement with an authorised entity within the source country of such material. Whether or not this is the case, the recipient must also agree that, in the event that such material is eventually developed and marketed by the recipient, or licensed by the recipient to a third party for development and subsequent marketing, the recipient or the recipient's licensee will negotiate and enter into an agreement with the appropriate entity in the source country of such material. Under the terms of the NPR MTA, negotiations on this agreement must commence prior to the start of clinical development studies, and must be completed, and the agreement executed, prior to the commercial sale of any product based on such material. The NPR MTA further stipulates that the final agreement must address the mutual concerns of both parties, and that it must be binding upon both parties with respect to intellectual property rights[15].

In addition to this requirement that the recipient (or its licensee, as appropriate) must enter into an agreement directly with a source country organisation, the NPR MTA specifically requires the recipient to use the source country as its first source of supply and cultivation for any raw materials that may be required for the manufacture of any product based on samples of those materials transferred by NPR to the recipient under the MTA, provided such material is readily available at a reasonable price[16]. The terms of the NPR MTA also oblige the recipient to provide screening results to the NCI, a summary of which will be provided by NCI to the source country[17].

As far as ownership rights are concerned, the terms of the NPR MTA provide that the NCI retains ownership over the materials being transferred to the recipient. However, intellectual property rights on inventions made by employees of the NCI or the recipient will be allocated depending on the principle of "inventorship", as determined by governing patent law[18].

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[9] The National Products Repository (NPR) of the NCI's Development Therapeutics Program is a national resource containing materials, both those not currently under active investigation by the NCI and those, which are, which are made available to the greater research community. The research selection criteria and procedures for selecting qualified research organisations to whom to provide NPR samples are outlined in Appendix A ("Policy for the Distribution of Materials from the Natural Products Repository") to the Model Natural Products Repository Material Transfer Agreement, Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment, Diagnosis and Centres, National Cancer Institute, National Institutes of Health, Last Revised and Approved by OTD/NCI and DCTDC/NCI on August 8, 1997. For more information see: <http://epnws1.ncicrf.gov:2345/dis3d/natprod/np_open.html>

[10] Preamble, Model Natural Products Repository Material Transfer Agreement, Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment, Diagnosis and Centres, National Cancer Institute, National Institutes of Health, Last Revised and Approved by OTD/NCI and DCTDC/NCI on August 8, 1997.

[11, 13] Ibid., Clause 3; [12] Ibid., Clause 11; [14] Ibid., Clause 5; [15, 16] Ibid., Clause 9 (for the terms discussed in this paragraph); [17] Ibid., Clause 10.

[18] Clause 8, Model Natural Products Repository Material Transfer Agreement, Natural Products Branch, Developmental Therapeutics Program, Division of Cancer Treatment, Diagnosis and Centres, National Cancer Institute, National Institutes of Health, Last Revised and Approved by OTD/NCI and DCTDC/NCI on August 8, 1997.

ANNEX 5: *EX-SITU* COLLECTIONS – PLANT AND MICROBIAL GENETIC RESOURCES

INTRODUCTION TO THIS ANNEX

The Convention on Biological Diversity recognises the important role ex-situ collections have to play in the conservation of components of biological diversity and genetic resources (Article 9). However, the Convention excludes from its provisions on access and benefit-sharing genetic resources acquired prior to the entry into force of the Convention on 29 December 1993 (Article 15.3) including those now held in *ex-situ* collections.

Significant *ex-situ* collections of plant genetic resources for food and agriculture consist of 'pre-Convention' material. The issue was addressed by Resolution 3 of the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) is currently attempting to clarify the legal status of pre-Convention genetic resources in the ex-situ collections of its International Agricultural Research Centres (IARCs). It is doing so within the context of the revision of the International Undertaking on Plant Genetic Resources.

This Annex provides:

- background information on the work of the Food and Agriculture Organisation (FAO) on plant genetic resources, in particular on recent progress relating to revision to the International Undertaking on Plant Genetic Resources; and
- highlights initiatives currently being undertaken by some ex-situ collections (international gene banks, botanical gardens and microbial collections) to implement the Conventions' objectives and principles.

As noted in Chapter 2, there has been some discussion within the COP of pre-existing ex-situ collections. This issue arose again at COP 5 in the consideration of the recommendations of the Intersessional Meeting on the Operations of the Convention held in June 1999. The COP decided to continue the information-gathering exercise on pre-CBD ex-situ collections and requested the Secretariat to gather information from Parties and relevant organisations using a questionnaire annexed to Decision V/26. Parties have been invited to provide capacity-building and technology development and transfer for the maintenance and utilisation of ex-situ collections. The Secretariat will report on the implementation of this Decision at COP 6 in 2002.

1. THE FAO GLOBAL SYSTEM FOR THE CONSERVATION AND UTILISATION OF PLANT GENETIC RESOURCES

1.1 Introduction

The Food and Agriculture Organization (FAO) is the principal organisation of the United Nations system with responsibility for the global conservation of plant genetic resources. The FAO's Consultative Group on International Agricultural Research (CGIAR) oversees the world's largest ex-situ collection of plant genetic resources for food and agriculture, held by a network of 18 International Agricultural Research Centres (IARCs).

Since 1983, the FAO, through its Commission on Genetic Resources for Food and Agriculture (CGRFA), has been developing a Global System on Plant Genetic Resources aimed at promoting the conservation and sustainable utilisation of plant genetic resources. As of January 2000, 160 countries are members of the CGRFA, including the Cook Islands, Fiji, Papua New Guinea, Solomon Islands, Tonga and Vanuatu.

One of the core elements of the Global System is the non-binding International Undertaking on Plant Genetic Resources. As of January 2000, 113 countries adhere to the International Undertaking, including Fiji, Papua New Guinea, Samoa, Solomon Islands and Tonga.

In November 1993, the FAO adopted Resolution 7/93, "Revision of the International Undertaking on Plant Genetic Resources", in response to Resolution 3 of the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. Resolution 3 had requested that solutions to the issues pertaining to access to ex-situ collections not acquired in accordance with the Convention be sought within the context of the FAO's Global System for Plant Genetic Resources.

Since November 1994, the CGRFA has, at both its ordinary sessions and through extraordinary meetings, been negotiating the revision of the International Undertaking. This is considered in detail in section 1.4 below.

In June 1996, the FAO held its fourth International Technical Conference on Plant Genetic Resources (previous Conferences on plant genetic resources have been held in 1967, 1973 and 1981) in Leipzig, Germany. The Conference presented another opportunity for the international community to discuss solutions to questions of how to treat ex-situ collections not acquired in accordance with the Convention on Biological Diversity.

1.2 *Ex-situ* conservation of plant genetic resources for food an agriculture under the auspices of the FAO's Consultative Group on International Agricultural Research (CGIAR)

The principal method for *ex-situ* conservation of plant genetic resources is through gene banks, which store plants as seeds. The largest and most prominent international gene banks are those in the network of 18 International Agricultural Research Centres (IARCs) which are supported by the Consultative Group on International Agricultural Research (CGIAR).

The CGIAR was established in 1971 to co-ordinate the work of four already established research centres and to extend the scope, reach and effectiveness of agricultural research, so as to promote the "green revolution". It is an informal association of 52 public and private sector donors, research centres and non-donor representatives from developing countries. The donors consist of a consortium of countries, private foundations and regional development banks, the World Bank, UNDP and FAO. The CGIAR is chaired by the World Bank.

In 1974, the International Plant Genetics Resource Institute (IPGRI) was established. It is the IARC most concerned with the active conservation of plant genetic resources. IPGRI is located within the FAO, although constituted outside of the UN system. It is responsible for co-ordinating the activities of the other IARCs, the establishment of research centres for the conservation of plant genetic resources, and financial assistance to other non-CGIAR conservation facilities.

The CGIAR network recognises the principle of open access, and requires that genetic material held in its network should be available on a free and unrestricted basis for all bona fide users. The CGIAR describes itself as a trustee of global germplasm holdings with the whole world community as beneficiaries. Accordingly, CGIAR members state that they will not take out intellectual property protection over any germplasm in their possession. CGIAR also declares that plant genetic material will be released to private users only on the basis of agreements that require such users to negotiate with the CGIAR if derived varieties or genes isolated from the material are to be protected and used commercially.

In 1998, the CGIAR announced a moratorium on the granting of intellectual property rights for the use of materials in IARC collections. This moratorium does not, however, apply to pre-1994 transfers (see section 1.6 below).

Box 1: Definitions used by the International Undertaking on Plant Genetic Resources

Article 2 of the International Undertaking defines plant genetic resources as:

The reproductive or vegetative propagating material of the following categories of plants:

- cultivated varieties (cultivars) in current use and newly developed varieties;

- obsolete cultivars;

- primitive cultivars (land races);

- wild and weed species, near relatives of cultivated varieties;

- special genetic stocks (including elite and current breeders' lines and mutants).

Ex-situ collections refers to collections of germplasm (seeds, plants, microbes and other forms of life) held outside their natural habitat. Most major ex-situ collections of crop genetic resources are in the form of seeds held in dry, cold storage conditions, known as gene banks. *Ex-situ* collections can also include field plantings (such as botanical gardens), pollen held in cold storage, tissue cultures, or seed, pollen or tissues held under cryogenic storage conditions.

1.3 The FAO Global System for Plant Genetic Resources

As noted above, in 1983, on the recommendation of its members, the FAO began developing a comprehensive Global System for the Conservation and Utilisation of Plant Genetic Resources for Food and Agriculture (the Global System). Also in 1983, the FAO adopted the International Undertaking on Plant Genetic Resources (the International Undertaking). The Undertaking provides that it "will be further developed, and, where necessary, complemented in order to develop a Global System" (Article 7).

The FAO's Commission on Genetic Resources for Food and Agriculture (CGRFA), established in 1983 and formerly known as the Commission on Plant Genetic Resources, is the forum where the Global System and the multilateral agreements and instruments which it encompasses, have been developed. The core elements of the Global System are:

- the *International Undertaking on Plant Genetic Resources*;
- the *Global Plan of Action for the Conservation and Sustainable Utilisation of Plant Genetic Resources for Food and Agriculture*;

- an *internationally coordinated network of national, regional and international centres*, including an international network of base collections in gene banks, under the auspices of the FAO;
- a *global information system on plant genetic resources*, which includes the publication of the *State of the World's Plant Genetic Resources*;
- an *early warning system* to identify any hazards that threaten the efficient maintenance and operation of a plant genetic resource collection;
- a *Code of Conduct for Plant Germplasm Collecting and Transfer* (see Box 3); and
- a *Draft Code of Conduct on Biotechnology* (pending).

The overall aim of Global System is to coordinate a response to the issues of conservation, access and sustainable utilisation of plant genetic resources, and to address the issues of storage, ownership, and intellectual property rights in relation to ex-situ collections.

In 1998, the Commission also established an *Intergovernmental Technical Working Group on Animal Genetic Resources for Food and Agriculture*. The aim of the Working Group is to develop the *Global Strategy for the Management of Farm Animal Genetic Resources*. This is still in its early stages.

1.4 The Revision of the International Undertaking on Plant Genetic Resources

Agenda 21, adopted at the 1992 UN Conference on Environment and Development, recommended strengthening the FAO Global System on Plant Genetic Resources and its adjustment in line with the outcome of negotiations on the Convention on Biological Diversity. Also in 1992, Resolution 3 of the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity requested the FAO to provide a forum for governments to negotiate and consider, through regular and extraordinary sessions of the CGRFA:

- harmonisation of the International Undertaking on Plant Genetic Resources with the Convention on Biological Diversity;
- access on mutually agreed terms to plant genetic resources, including ex-situ collections not addressed in the Convention; and
- the issue of Farmer's Rights;

The revision of the International Undertaking began in 1994 and is proceeding in three stages:

- consolidation of the International Undertaking by the incorporation of its annexes;
- addressing the issue of access on mutually agreed terms to plant genetic resources, including *ex-situ* collections not addressed by the Convention and the question of Farmers' Rights; and
- consideration of the legal and institutional status of the revised International Undertaking.

There is a general consensus that the revised International Undertaking should be a legally-binding instrument.

Negotiations of the revised Undertaking continue. The slow pace of progress at the regular and extraordinary sessions of the CGRFA to date meant that an Informal Expert Meeting was convened by the CGRFA Chairman in January 1999. The results of that meeting (the 'Chairman's Elements' – see below) now form the basis of ongoing negotiations[1]. At the CGRFA's Eighth Regular Session in April 1999, the Chairman was authorised to convene inter-sessional meetings of the CGRFA's Contact Group to en-

[1] See: Report of the Commission on Genetic Resources, Eighth Session, FAO, Rome, 19-23 April 1999 on: http://web.icppgr.fao.org; and Composite Draft Text of the International Undertaking on Plant Genetic Resources, Incorporating: the Texts of Articles 11, 12 and 15, Negotiated at the Eighth Session of the Commission (19-24 April 1999) and the Texts of Articles 13, 14, and 16, Negotiated during the First (20-24 September 1999) and Second (3-7 April 2000) Inter-sessional Meetings of the Contact Group, on http://www.fao.org/WAICENT/FAOINFO/AGRICULT/cgrfa/DocsCG2.htm

able further progress. The first such inter-sessional meeting took place in September 1999, and the second in April 2000. Once the Contact Group achieves consensus, an Extraordinary Meeting of the Commission will be convened in 2000 to finalise the text of the International Undertaking before the FAO's Council Session in November 2000.

The *Chairman's Elements* of the revised International Undertaking, currently forming the basis of the CGRFA Contact Group's discussions, include:

- *Scope*: plant genetic resources for food and agriculture (PGRFA).
- *Objectives*: the conservation of and sustainable use of PGRFA, and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.
- *National commitments*: the integration of activities relating to the conservation, exploration, collection, characterisation, evaluation, documentation and sustainable use of PGRFA, into agricultural and rural development policies and programmes.
- *Multilateral system of access and benefit-sharing*: to facilitate access to PGRFA, and to share in a fair and equitable way the benefits arising from their utilisation as follows:
- *Coverage*:
  - A list of crops, determined according to criteria based on food security and interdependence.
  - The collections of the International Agricultural Research Centres (IARCs), on terms to be accepted by the IARCs.
- *Facilitated access*:
  - To minimise transaction costs, obviate the need to track individual accessions, and ensure expeditious access, in accordance with applicable property regimes.
  - Plant genetic resources covered by the multilateral system shall be for the purposes of research, breeding and/or training for food and agriculture only. Access for other uses shall be on mutually agreed terms in accordance with the Convention on Biological Diversity.
  - Access to non-parties shall be on terms to be specified in the Undertaking.
- *Equitable sharing of benefits*:
  - The fair and equitable benefits arising from the use of PGRFA shall be shared, *inter alia*, through:
    - transfer of technology;
    - capacity-building;
    - the exchange of information; and
    - funding, taking into account the priorities of the rolling Global Plan of Action.
- Benefits should flow primarily, directly and indirectly, to farmers in developing countries, embodying traditional lifestyles relevant for the conservation and sustainable utilisation of PGRFA.
- Support for the implementation of benefit-sharing to be provided through the use of:
  - information systems,
  - networks; and
  - partnerships in research and technology development
- *Farmers' Rights*:
  - Recognition of the enormous contribution that farmers of all regions of the world have made and will continue to make in the conservation and development of PGRFA.
  - Responsibility for realising Farmer's Rights rests with national governments. Parties are to protect and promote Farmer's Rights, including:
    - the right to use, exchange, and, in the case of landraces and varieties that are no longer registered, market farm-saved seeds;
    - protection of traditional knowledge;
    - the right to equitably participate in benefit-sharing; and

- the right to participate in making decisions at the national level, on matters related to the conservation and sustainable use of PGRFA.

· *Financial resources*: commitment to a funding strategy for the implementation of the Undertaking.

1.5 The State of the World's Plant Genetic Resources and the FAO Global Plan of Action

In 1989, the Commission recommended that a report on the State of the World's Plant Genetic Resources be prepared periodically. The report describes activities and programmes being carried out by regional, international and non-governmental organisations, with the aim of identifying gaps, constraints and emergency situations. The needs and priorities identified in the Report on the State of the World's Plant Genetic Resources provide the basis for the Global Plan of Action.

In 1991, the Commission requested the development of a rolling Global Plan of Action on Plant Genetic Resources for Food and Agriculture "with programmes and activities aimed at filling in gaps, overcoming constraints and facing emergency situations identified in the Report on the State of the World's Plant Genetic Resources". The Global Plan of Action was adopted by the International Technical Conference on Plant Genetic Resources held in June 1996, in Leipzig, Germany.

The main aims of the Global Plan of Action are:

· to ensure the conservation of PGRFA as a basis for food security;

· to promote sustainable utilisation of PGRFA, in order to foster development and to reduce hunger and poverty, particularly in developing countries;

· to promote a fair and equitable sharing of the benefits arising from the use of PGRFA, recognising the desirability of sharing equitable benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of PGRFA and their sustainable use, by:
  - confirming the individual and collective needs and rights of farmers, where recognised by national law, to have non-discriminatory access to germplasm, information, technologies, financial resources, and research and marketing systems, necessary for them to continue to manage and improve genetic resources; and
  - developing and/or strengthening policies and legislative measures, as appropriate, to promote fair and equitable sharing of benefits arising from the utilisation of PGRFA in their exchange between communities and within the international community.

· to assist countries and institutions responsible for conserving and using PGRFA to identify priorities for action.

· to strengthen, regional and international programmes, and national programmes in particular, including education and training for the conservation and utilisation of PGRFA, and enhanced institutional capacity.

The Global Plan of Action has 20 priority areas, organised into four main groupings. These address:

· *In-situ* conservation and development;

· *Ex-situ* conservation;

· Utilisation of plant genetic resources; and

· Institutions and capacity-building.

For each priority area, the Plan provides an assessment of the situation, identifies the long-term and immediate objectives, and recommends what policies and strategies governments might wish to consider, including the identification of capacity needs.

A Declaration was adopted at the FAO's Leipzig Conference which focuses attention on the importance of plant genetic resources for world food security and commits countries to implementing the Global Plan of Action. The implementation of the Plan is monitored and guided by the national governments, as well as other members of FAO, through the Commission on Genetic Resources for Food and Agriculture (CGRFA).

1.6 The International Network of Ex-situ Collections

In 1989, the CGRFA decided that an International Network of Ex-Situ Collections should be developed under the auspices of the FAO, in line with Article 7 of the International Undertaking. This was catalysed by the uncertainty of the legal situation of ex-situ germplasm in gene banks, and of the lack of appropriate agreements to ensure its safe conservation.

The International Network functions on the basis of designated germplasm that is voluntarily placed in the Network. In 1994, twelve International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) (see section 1.2 above) signed agreements with the FAO, placing some 500,000 germplasm accessions in the International Network. Under these agreements, IARCs were free to decide which germplasm in their possession would be designated for placement in the International Network. Each IARC developed its list of designated germplasm on the basis of its obligations to long-term conservation. Through these agreements with the FAO, the IARCs accepted the responsibility to hold such designated germplasm "in trust for the international community". Article 3(b) of each agreement provides that "[t]he [IARC] shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over the [designated] germplasm and related information". Article 10 of each agreement provides that "[w]here samples of the designated germplasm and/or related information are transferred to any other person or institution, the [IARC] shall ensure that such person or institution and any further entity receiving samples of the designated germplasm from such person or institution, are bound by the conditions set out in Article 3(b)" (ten Kate, K. and Collis, A. (1998), p6).

In 1998, further such agreements were concluded between the FAO and the International Coconut Genetic Resources Network, including with the Government of Papua New Guinea, as holder of the International Coconut Genebank for the South Pacific.

Material Transfer Agreements

In transferring germplasm designated under the agreements with FAO, the IARCs now use a standard Material Transfer Agreement (MTA), the text of which was agreed with FAO (see Box 2). The MTA requires that recipients do not claim ownership or intellectual property rights over the designated germplasm and related information, and that they bind subsequent recipients to the same conditions.

Intellectual property rights and the International Network

In 1998, FAO received reports that a number of applications had been filed with a national Plant Breeders' Rights Office for intellectual property rights (IPRs) over plant germplasm designated by an IARC under an agreement with the FAO, specifically accessions of chickpeas, lentils and forage crops. The application was subsequently withdrawn.

In February 1998, the CGIAR called for a moratorium on the granting of IPRs on material designated by IARCs as forming part of the International Network of *Ex-Situ* Collections under the auspices of the FAO, regardless of whether the material was distributed before or after the agreements with FAO.

Box 2: CGIAR Model Material Transfer Agreement

The material contained herein is being furnished by [IARC] under the following conditions:

"Designated Germplasm

[IARC] is making the material described in the attached list available as part of its policy of maximising the utilisation of genetic material for research. The material was either developed by [IARC]; or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made freely available for any agricultural research or breeding purposes.

The material is held in trust under the terms of an agreement between [IARC] and FAO, and the recipient has no rights to obtain Intellectual Property Rights (IPR) on the germplasm or related information.

The recipient may reproduce the seed and use the material for agricultural research and breeding purposes and may distribute it to other parties provided the recipient is also willing to accept the conditions of this agreement.

The recipient, therefore, hereby agrees not to claim ownership over the germplasm to be received, nor to seek IPR over that germplasm or related information. He/She further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the germplasm available, is bound by the same provision and undertakes to pass on the same obligations to future recipients of the germplasm.

[IARC] makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, availability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine/biosafety regulations and rules as to import or release of genetic material.

Upon request, [IARC] will furnish information that may be available in addition to whatever is furnished with the seed. Recipients are requested to furnish [IARC] performance data collected during evaluations.

The material is supplied expressly conditional on acceptance of the terms of this agreement. The recipient's acceptance of the material constitutes acceptance of the terms of this Agreement.

This does not prevent the recipient from releasing or reproducing the seed for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in the MTA are complied with."

In October 1998, the CGIAR's IARCs and FAO issued a Joint Statement, whereby the IARCs and the FAO committed themselves to taking appropriate remedial action, in accordance with agreed procedures, in cases of suspected violations of the MTAs. They also agreed on a common understanding concerning certain provisions of the MTAs, in particular regarding: (i) the size and number of samples to be made available; (ii) the health and quarantine standards to be followed; (iii) the addition of new materials to the list of designated germplasm; and, (iv) the updating and revision of that list.

1.7 The World Information and Early Warning System

The World Information and Early Warning System on Plant Genetic Resources (WIEWS) was established in conformity with Articles 7.1 (e) and (f) of the International Undertaking. Its aim is to collect, disseminate and facilitate the exchange of information that governments provide on plant genetic resources and related technologies.

The WIEWS is an important tool for the periodic updating of the Report on the State of the World's Plant Genetic Resources. Its databases contain information on: the location of over 5.5 million plant genetic resource accessions, in some 1410 ex-situ collections around the world; the structure and activities of national plant genetic resources programmes in almost all countries; some 8000 seed-supplying institutions around the world; commercial crop varieties; and, relevant non-FAO databases, including how to obtain information from them. Such information can be obtained from the WIEWS website: http://apps2.fao.org/wiews/.

The Early Warning Mechanism is being developed to draw rapid attention to hazards threatening the operation of *ex-situ* collections, and to the dangers of plant species extinction and loss of crop genetic diversity.

1.8 Codes of Conduct

The FAO's International Code of Conduct for Plant Germplasm Collecting and Transfer (see Box 3) provides a framework which countries may wish to consider in developing national access legislation or concluding bilateral agreements. It aims to regulate the collection and transfer of plant genetic resources so as to facilitate access and sustainable utilisation, prevent genetic erosion and protect the interests of both donors and collectors of germplasm. It was adopted in November 1993.

Box 3: FAO International Code of Conduct for Plant Germplasm Collecting and Transfer

Article 1 - Objectives

1.1 to promote the conservation, collection and use of plant genetic resources from their natural habitats or surroundings, in ways that respect the environment and local traditions and cultures;

1.2 to foster the direct participation of farmers, scientists and organisations in countries where germplasm is collected, in programmes and actions aimed at the conservation and use of plant genetic resources;

1.3 to avoid genetic erosion and permanent loss of resources caused by excessive or uncontrolled collection of germplasm;

1.4 to promote the safe exchange of plant genetic resources, as well as the exchange of related information and technologies;

1.5 to help ensure that any collecting of germplasm is undertaken in full respect of national laws, local customs, rules and regulations;

1.6 to provide appropriate standards of conduct and to define obligations of collectors;

1.7 to promote the sharing of benefits derived from plant genetic resources between the donors and users of germplasm, related information and technologies by suggesting ways in which the users may pass on a share of the benefits to the donors, taking into account the costs of conserving and developing germplasm;

1.8 to bring recognition to the rights and needs of local communities and farmers and those who manage wild and cultivated plant genetic resources and, in particular, to promote mechanisms:

a) to facilitate compensation of local communities and farmers for their contribution to the conservation and development of plant genetic resources;

b) to avoid situations whereby benefits currently derived from plant genetic resources by these local communities and farmers are undermined by the transfer or use by others of the resources.

The Code also addresses:

- collectors permits, including guidelines for requesting and issuing permits;
- the responsibilities of collectors, before, during and after collections;
- the responsibilities of sponsors, curators and users; and
- reporting, monitoring and evaluating observance of the Code.

The Code is based on the principle that States have sovereignty over their plant genetic resources. It calls for the participation of farmers and local institutions where germplasm is collected, and proposes that users of germplasm share the benefits derived from the use of plant genetic resources with the host country and its farmers. The Code proposes procedures for the issuance of licences for collecting missions, provides guidelines for collectors themselves, and extends responsibilities and obligations to the sponsors of missions, the curators of gene banks, and the users of genetic material.

A draft FAO Code of Conduct for Biotechnology was first discussed in detail at the Fifth Session of the CGRFA in June 1998. The draft Code aims to promote the development of appropriate biotechnologies for the conservation and sustainable utilisation of plant genetic resources, the promotion of biosafety standards, and the equitable sharing of the benefits between the developers of the technology and the donors of the germplasm (see also Chapter 4 on Biosafety).

Further work on and revision of both Codes of Conduct awaits the outcome of the revision of the International Undertaking.

The Eighth Session of the CGRFA, in April 1999, requested that a report on the status of the draft Code of Conduct on Biotechnology as it relates to Genetic Resources for Food and Agriculture be presented at its Ninth Session in 2001, as the negotiations for the revision of the International Undertaking are expected to be completed during the year 2000.

2. BOTANICAL GARDENS

A database maintained by Botanic Gardens Conservation International (BGCI) - an international network organisation linking over 500 botanical gardens in 120 countries - indicates that, globally, botanical gardens maintain living collections representative of as many as 80,000 plant species. This constitutes over 4 million individual living plant accessions. More that 90 per cent of these were obtained prior to the entry into force of the Convention on Biological Diversity, and are hence excluded from the Convention's provisions on access and benefit-sharing (see Chapter 2, section 2.1).

Botanical gardens have traditionally enjoyed virtually free and open access to plant materials for their collections for scientific research, conservation and educational purposes. Increasingly, however, botanical gardens are being approached by commercial entities, such as pharmaceutical companies, to obtain plant material for product development. To address this situation some countries are attempting to regulate access to ex-situ collections within their territory, including to the *ex-situ* holdings acquired prior to the entry into force of the Convention. An example is the "Common System on Access to Genetic Resources" adopted by the Member Countries of the Andean Community (see Annex 1).

An increasing number of botanical gardens only distribute plant material subject to material transfer agreements (MTAs), which set out the terms and conditions of access and benefit-sharing. A number of botanical gardens are also adopting official policies on the collecting, acquisition and supply of plant material in order to bring management of their collections in line with the objectives of the Convention.

Botanic Gardens are also in the process of developing international Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing (see Box 5).

Box 4: Policy on Access to Genetic Resources and Benefit-Sharing of the Royal Botanic Gardens (RBG) Kew, United Kingdom

RBG Kew's Policy on Access to Genetic Resources and Benefit-Sharing came into effect in January 1998. Elements of this policy are outlined below:

- Acquisition: the Policy states that acquisitions of genetic resources by RBG Kew requires the prior informed consent (PIC) of source countries and stakeholders, and the conclusion of material acquisition agreements (MAAs).
- Supply: RBG Kew will only supply genetic resources in its possession under material transfer agreements (MTAs), the terms of which are consistent with those under which it acquired the resources. RBG Kew may chose not to supply material if it is not satisfied that the prospective recipient is acting in accordance with the Convention, and other national laws and agreements.
- Benefit-sharing: RBG Kew's material transfer agreements require the fair and equitable sharing of any benefits arising from the utilisation of genetic resources it supplies to recipients. Such benefit-sharing shall be consistent with the terms under which RBG Kew acquired the resources concerned.
- Commercialisation: the material transfer agreements also prohibit the commercialisation of material by recipients without RBG Kew's written consent. Commercialisation of RBG Kew's post-Convention material will be subject to the prior consent of the source country, stakeholders and suppliers. Also, RBG Kew will negotiate with recipients over benefit-sharing with source countries should they wish to commercialise Kew's pre-Convention material.
- Review: the Policy is periodically reviewed to suit the wishes of the UK government, source-country governments and overseas partners, as well as changes in law and 'best practice'

Source: ten Kate, K. and Laird S.A., (Earthscan, 1999), p 311.

Box 5: Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing

The Royal Botanic Gardens, Kew, in the United Kingdom, is currently co-ordinating a project to develop a harmonised approach for participating botanical gardens on access to genetic resources and the sharing of benefits.

The project involves seventeen botanical gardens from Australia, Brazil, Cameroon, Canada, China, Colombia, Malaysia, Germany, Ghana, Mexico, Morocco, Russia, South Africa, the UK and the US. In May 1999, at a meeting held in Beijing, China, representatives of botanical gardens in the participating countries agreed on Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing.

Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing (Extracts)

Section 1. Objectives

a) to ensure that the activities of the Participating Gardens involving access to genetic resources are consistent with the provisions of the Convention on International Trade in Endangered Species, the Convention on Biological Diversity and other international, regional, national and sub-national laws and policies concerning biodiversity;

b) to promote co-operation between botanic gardens, individuals, organisations, groups and other Stakeholders dealing with genetic resources;

c) to establish conditions that facilitate access by others to the genetic resources within the collections held by the Participating Gardens and that may help each Participating Garden to access the genetic resources worldwide, whether found in in-situ or ex-situ conditions;

d) to promote the fair and equitable sharing of the benefits arising from the use of genetic resources, their progeny and derivatives, with the country of origin that provided the genetic resources and with other Stakeholders, as appropriate. The benefits to be shared arise both from the use of genetic resources, their progeny and derivatives, by the Participating Gardens and from the use by others of genetic resources, their progeny and derivatives, provided by Participating Gardens; and

e) to encourage other botanic gardens to become Participating Gardens and follow a harmonised system of access to genetic resources and benefit-sharing.

Contents of box continue to next page

Box 5: Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing (continued from previous page)

Section 3. Principles

Participating Gardens subscribing to the Common Policy Guidelines will, as far as possible and as appropriate:

- Obtain prior informed consent for the acquisition of genetic resources from in-situ conditions from the government of the country of origin and other Stakeholders;
- Obtain prior informed consent for the acquisition of genetic resources from ex-situ conditions from the body governing the ex-situ collection concerned, and such other consents as that body indicates are required;
- Acquire and supply genetic resources, their progeny or derivatives under material acquisition and material supply agreements which satisfy these principles;
- Maintain records and mechanisms to track the acquisition and supply of genetic resources, their progeny and derivatives, and the benefits that arise from their use; and
- Share the benefits arising from the use of genetic resources, their progeny and derivatives fairly and equitably with the country of origin and other Stakeholders.

Section 4. Acquisition

4.1 Prior informed consent

When it collects or otherwise gains access to genetic resources, each Participating Garden will abide by applicable law and best practice. When obtaining access to genetic resources from in-situ conditions, each Participating Garden will obtain the prior informed consent of the government of the country of origin, in accordance with its applicable legislation, and will make reasonable and sincere efforts to obtain the prior informed consent of other Stakeholders, as appropriate. When obtaining access to genetic resources from ex-situ conditions, each Participating Garden will obtain the prior informed consent of the body governing the ex-situ collection, and such other consents as the body governing the ex-situ collection requires.

4.2 Material acquisition agreements

When obtaining access to genetic resources from documented ex-situ collections, each Participating Garden will:

a) obtain, in writing, prior informed consent from the officer authorised to agree terms of access on behalf of the ex-situ collection, and such other consents required as indicated by that officer for access to the genetic resources concerned and for their use;

and will make reasonable and sincere efforts to:

b) obtain from the authorised officer of the ex-situ collection a written undertaking that the genetic resources were acquired and are being supplied in accordance with all applicable law and that the ex-situ collection is entitled to supply them to the Participating Garden;

c) ensure that the export of the genetic resources, their progeny or derivatives, from the country where the ex-situ collection providing them is based, and import to the country where the Participating Garden is based, are in accordance with all applicable law; and

d) clarify, in writing, the terms and conditions under which the materials are acquired and can subsequently be used, particularly whether the materials, their progeny or derivatives may be supplied to third parties and/or commercialised.

Section 7. Benefit-sharing

7.1 Commitment to share benefits

Each Participating Garden will make reasonable and sincere efforts to share the benefits arising from the use of genetic resources, their progeny and derivatives, fairly and equitably with the country of origin and other Stakeholders, as appropriate.

To the extent possible, each Participating Garden will share the benefits arising from the use of materials acquired prior to and after the entry into force of the Convention on Biological Diversity in the same manner.

Source: Convention on Biological Diversity Document UNEP/CBD/ISOC/Inf.2, 15 June 1999 - Submission by the Government of the United Kingdom

3. MICROBIAL CULTURE COLLECTIONS

3.1 The Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC).

In 1996, the World Federation for Culture Collections (WFCC) recommended the development of a voluntary code of conduct specifying access and benefit-sharing procedures for microbial culture collections in keeping with the Convention on Biological Diversity. The recommendation was made in response to the growing use of micro-organisms in product development and industrial processes across a variety of sectors, including the health sector, agriculture, the food industry, environmental remediation, energy production and other industries.

Procedures for better regulating the collection, transfer and use of micro-organisms for the purposes of the Convention are currently under development by an EU-funded project, 'Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)' (see Box 6 below). MOSAICC represents a consensus reached between its 14 project partners, representative of governments, culture collections, academics, non-governmental organisations and the private sector, from developed and developing countries.

Box 6: Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)

MOSAICC aims to assist microbiologists:

- in obtaining prior informed consent (PIC) for access to microbial genetic resources; and
- in establishing, on mutually agreed terms:
  - material transfer agreements (MTAs) for the transfer of microbial genetic resources;
  - access to and transfer of technology, including biotechnology;
  - fair and equitable benefit-sharing; and
  - technical and scientific cooperation.

The Code also aims to assist the source countries of microbial genetic resources:

- in issuing prior informed consent (PIC) for access to microbial genetic resources; and
- in tracking the path and utilisation of microbial genetic resources, with a view to enable a fair and equitable sharing of benefits arising from their utilisation.

MOSAICC's recommendations are designed to provide microbiologists and ex-situ culture collections with guidelines on implementing the Convention on Biological Diversity, and to complement other existing national and international rules. The Code makes suggestions to source countries and provides definitions, and model documentation and certificates.

MOSAICC's scope spans both in-situ and ex-situ microbial genetic resources. It recognises that source countries may or may not have designated national authorities with competence to grant PIC for access, and may have implemented an access framework more stringent than required by the Convention. The Code also takes into account the diversity of providers, recipients and end-uses of microbial genetic resources.

Source: Philip Desmeth, 'Code of Conduct for Accessing Microbial Genetic Resources (MOSAICC Project)', World Federation for Culture Collections (WFCC) Workshop, 'The Economic Value of Microbial Genetic Resources', Eighth International Symposium on Microbial Ecology, Halifax, Canada, August 12th 1998.

3.2 The deposit of samples in *ex-situ* microbial culture collections for the purposes of patenting biological inventions

Ex-situ microbial culture collections are of particular significance in terms of the deposit of samples of microbiological inventions for the purposes of patent applications. It may be impossible for a patent applicant to describe his claimed invention in a manner 'sufficiently clear and complete for it be to carried out by a person skilled in the art', if it involves biological material which is not available to the public.

In lieu of a full written description, a number of jurisdictions, including the US, Japan and the Contracting States of the European Patent Convention (EPC), permit a patent applicant to deposit a sample of his claimed invention in an ex-situ culture collection. Relevant culture collections include International Depository Authorities (IDAs), as designated by the WIPO pursuant to the 1977 Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure. Under the EPC Implementing Regulations, an applicant for a patent on a microbiological invention must deposit a sample in an IDA no later than the filing date. The European Union's Directive 98/44/EC on the legal protection of biotechnological inventions specifies that a description in any patent application which 'involves the use of or concerns biological material which is not available to the public', and which cannot be described in the manner stated above, is only to be considered complete once a deposit has been made at a recognised culture collection. Around 35,000 microbial cultures have been deposited in this way and IDAs may hold material for up to 30 years after the date of deposit.

Sources of Information

Convention on Biological Diversity Document UNEP/CBD/ISOC/Inf.2, 15 June 1999 - Submission by the Government of the United Kingdom

Composite Draft Text of the International Undertaking on Plant Genetic Resources, Incorporating: The Texts of Articles 11, 12 and 15, Negotiated during the Commission's Eighth Regular Session (19-24 April 1999), and the texts of Articles 13, 14 and 16 Negotiated during the First and Second Inter-sessional Meetings of the Contact Group http://www.fao.org/WAICENT/FAOINFO/AGRICULT/cgrfa/DocsCG2.htm

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ten Kate, K. and Lasen Diaz, C., (1997) "The Undertaking Revisited: a commentary on the Revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture", in Review of European Community and International Environmental Law (RECIEL), Vol. 6, Issue 3, 1997.

Useful website:

www.fao.org/ag/cgrfa	Commission on Genetic Resources for Food and Agriculture

ANNEX 6: CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) “Exporter” means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) “Import” means intentional transboundary movement into one Party from another Party;

(f) “Importer” means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) “Living modified organism” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) “Living organism” means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) “Modern biotechnology” means the application of:

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

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) “Regional economic integration organization” means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) “Transboundary movement” means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of

import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of

import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism 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 such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is re-

sponsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding 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;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it 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, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer

of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27

LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and

technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties

serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this 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

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

General principles

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

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

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified 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 risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

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

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

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

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

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

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

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

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

Points to consider

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

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

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

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

(d) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

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

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

(g) *Information relating to the intended use*. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

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

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ANNEX 7: IMPLEMENTATION OF THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD) IN THE PACIFIC ISLANDS REGION

WORKSHOP REPORT: 30 MARCH- 3 APRIL 1998, NADI, FIJI

Opening Session

1. The regional workshop "Implementation of the Convention on Biological Diversity (CBD) in the Pacific Islands-Region" was held in Nadi, Fiji from the 30 March–3 April 1998. Participants included:

- 22 government representatives from the 11 Pacific Island CBD Parties,
- six government representatives from the three Pacific island countries not party to the CBD (Palau, Tonga, Tuvalu)
- eight participants from six Intergovernmental Organisations (IGOs)
- ten participants from eight Non Governmental Organisations (NGOs)

The workshop was organized by SPREP in partnership with FIELD and WWF. Government representatives included participants from national conservation/environment agencies and from national planning or foreign affairs agencies. The workshop organisers believed that this combination of government representation was key to working on CBD implementation. A full list of participants is annexed to this report.

Opening Prayer

2. An opening prayer was given by Mr. Kosimiti Latu (Commonwealth Secretariat) to welcome participants to the workshop.

Official Opening

3. The Workshop was officially opened by the Honourable Vilisoni Cacgimaivei, Minister of Local Government, Housing and Environment. In his opening remarks the Minister emphasised that with eleven Pacific Island Parties the CBD forms a critical legally binding agreement for the conservation and sustainable use of biological diversity in the Pacific islands region. He briefly outlined Fiji's progress with implementing the CBD noting that the assistance provided from the Global Environment Facility (GEF) through the United Nations Development Programme (UNDP) has resulted in Fiji completing its first national report to the Convention and support for the preparation of a National Biodiversity Strategy and Action Plan. Minister Cagimaivei noted that the meeting provided an excellent opportunity for Pacific Island Parties to the CBD to prepare for the forthcoming Fourth Meeting of the Conference of the Parties (COP4) and to recommend priorities for regional support to national implementation of the CBD. The Honourable Minister thanked the workshop organisers and wished participants a successful and productive meeting.

Welcome from workshop organisers

4. Welcoming remarks were then expressed by the Workshop Organisers, Mr. Joe Reti on behalf of SPREP, Ms. Ruth Mackenzie on behalf of FIELD, and Mr. Cedric Schuster on behalf of WWF.

Election of Chairperson

5. Mr. Epeli Nasome, Director of the Environment (Fiji) was unanimously elected as Plenary Chairperson for the Workshop.

Plenary session I

6. The Chairperson opened the Plenary by welcoming all the participants and pledging his full commitment to achieve a successful meeting with agreed outputs by Friday. He invited SPREP to outline the Workshop's Objectives, Outputs and meeting arrangements.

7. SPREP introduced the Workshop Facilitator Team; Ms Sue Miller (SPREP), Ms Ruth Mackenzie (FIELD), Ms Ruth Khalastchi (FIELD), Mr. Cedric Schuster (WWF-SPP), Mr Bernard Moutou (SPREP) and Mr Clark Peteru (SPREP Consultant). The documentation for the meeting, including workshop papers and information papers, was also outlined.

8. The Objectives and Outputs for the meeting were:

Objective 1

To build capacity for implementation of the Convention on Biological Diversity (CBD) in the Pacific Islands region by providing an overview of the Convention and its obligations and focusing on current key legal and institutional issues of:

- relationship between the CBD and other regional/international agreements and institutions and the coordination of existing national legal and institutional arrangements relevant to the CBD,
- biosafety and the development of a protocol,
- regulating access to genetic resources and benefit sharing, and
- intellectual property rights.

Output 1: Regional Information Package on these key issues (to be completed after the workshop).

Objective 2

To identify priority areas, issues and actions needed for regional support to Pacific Island Parties in their implementation of the Convention.

Output 2: Recommendations and key issues.

Objective 3

To assist Pacific Island Parties to prepare for the Fourth Conference of the Parties to the Convention on Biological Diversity.

Output 3: COP4 Actions and associated recommendations

Objective 4

To provide an introduction to the CBD for Pacific Island non-Parties and opportunity to assist them in their consideration of joining this Convention.

Objective 5

To provide a forum for Pacific Island countries, including non government organisations, to share experiences and information in the implementation of the Convention.

9. It was noted that Output 2 and 3 could be amalgamated into a Participants' Statement. SPREP emphasised the importance of participants' input and participation during the workshop and the structure of Plenary and Working Group Sessions to achieve these objectives and outputs. In addition two Pacific Island Committees would be established to finalise drafting of outputs from the meeting: one focused on recommendations for regional support and one on needed COP 4 actions. It was also emphasised that this meeting was part of a larger project initiative between SPREP and FIELD and should be seen as the start of a process and network to support CBD implementation in the region. Finally, there were further opportunities for participants to form issue-based groups to progress work further on areas of key concern.

10. The Workshop adopted the draft Agenda, without amendment (annexed).

Pacific Island CBD implementation issues

11. All workshop participants were requested to make summary presentations on issues relevant to implementation of the CBD in their country. Participants gave an overview of their country's biodiversity; governmental institutional infrastructure, including the relationship between national and local government; national legislation relevant to biodiversity conservation; and provided information on policies, programmes and other activities that have been or are intended to be taken to implement the CBD. Non Parties to the CBD (Palau, Tonga, Tuvalu) also updated the meeting on their progress in assessing the merits of joining the Convention. Palau noted that they were seriously considering acceding to the CBD. Participants' reports emphasised the growing number of threats to biodiversity in their respective countries.

12. Participants also reported on progress with developing national biodiversity strategies and action plans, and whether or not they had received GEF funding to prepare their first national reports. Few participants had attended the COP meetings, and many experienced difficulties in receiving funding to attend CBD-related international meetings. NGOs and IGOs present also gave presentations related to their involvement in CBD implementation in PICs. All participants highlighted some of their concerns and key obstacles to effective CBD implementation, which included:

- lack of effective coordination among government departments,
- lack of understanding of some of the core issues such as intellectual property rights,
- lack of access to information; and
- insufficient sharing of information in the region.

Other issues that were highlighted included the need for capacity building, funding and scientific and legal drafting assistance. Presentations also focused on country and NGO key priorities and needs, including the need:

- to increase understanding of key issues and how to implement the CBD at national level,
- for capacity building,
- to review existing laws and training of legal drafters,
- to collect baseline data,
- to increase public awareness,
- for mechanisms to protect genetic resources and traditional knowledge, and
- to have worked together prior to COP4 to develop as far as possible common positions and negotiating strategies.

Some presentations were also delivered during subsequent Plenary Updates, however, for the sake of brevity they have all been summarized together in this agenda item.

Opening Statement by the Secretariat to the Convention on Biological Diversity

13. Mr Claude-Georges Ducret of the CBD Secretariat gave an opening statement and provided an overview of the objectives and institutions of the Convention (Annex 2). He highlighted some of the issues of relevance to the Pacific region which are on COP4's agenda, and noted that the international CBD process was moving into a new phase which focused much more on national implementation. Mr Ducret also reported on some of the discussions at the Asian Regional meeting. This regional meeting had considered the implementation of the CBD at the national level and had discussed ways and means to develop regional cooperation, including through better use of existing instruments, increasing information exchange through a clearing house mechanism and increasing South-South cooperation and use of local expertise.

Working Group Session I - CBD Overview

14. Workshop Facilitators gave an overview of the CBD which emphasised the objectives and scope of the Convention. In particular it was noted that the CBD breaks new ground by taking a comprehensive, ecosystem approach to the conservation and sustainable use of biological diversity, and by explicitly coupling biodiversity conservation with the right to control access to genetic resources and share benefits deriving from their utilization. It was further emphasized that the CBD represents a framework that adopts a country-driven approach and allows for further development of its provisions through decisions taken at meetings of the Parties and through further elaboration of annexes and protocols. It was noted that the CBD places few precise binding obligations on Parties, but rather provides goals and guidelines. Key provisions were outlined including those relating to; national strategies and plans, identification and monitoring of biodiversity, conservation and sustainable use, and ex situ conservation. Benefits were also noted including benefit sharing, technology transfer and financial resources. Institutional arrangements were briefly introduced including; COPs. SBSTTA, Secretariat role, Convention Trust Funds, Open-ended Ad hoc Working Group on Biosafety and the Financial Mechanism. Finally, the importance of national implementation through addressing the cross-sectoral inputs from government agencies and NGOs needed to achieve the goals of the CBD in countries party to the convention was emphasised.

15. After a brief discussion participants formed smaller working groups to look at key priorities for regional support to national implementation of the CBD and the key constraints or common concerns they had in implementing its provisions.

16. Participants then formed two committees (Pacific Island Committee I and II) whose mandates were to draft results of Working Group Sessions into issues, priorities and recommendations firstly for regional support of CBD implementation in Pacific island countries (PIC I) and secondly for issues and recommended actions to be taken by Pacific island delegations at COP4 (PIC II). PIC I and PIC II then met briefly to organise their work for the week. The compiled results of the smaller working groups were given to PIC I and PIC II to develop recommendations for consideration by Plenary.

Tuesday 31 March1998

Plenary Update

17. A brief Plenary Update was held to continue presentations and update delegates on workshop arrangements.

Working Group Session II- COP 4 draft brief

18. Workshop Facilitators gave a brief presentation on the upcoming COP 4 meeting, based on the draft SPREP COP4 briefing paper. Three key points relating to the COP 4 meeting for PICs were noted:

- that recognition of the CBD's noting of the 'special needs and considerations of least developed countries and small island states' needs to be fully realised in the work programmes and operations of the Convention,
- the need to find ways and means to increase effective PIC participation in the international meetings and processes of the Convention and the associated need for adequate in-region preparation for these, and
- to ensure that decisions made at COPs for GEF Enabling Activities (e.g. under biosafety, NBSAPs, CHM) and other forms of support (e.g. from the CBD Secretariat, NGOs and SPREP etc.) are effectively accessed by PICs and result in improved national implementation of the convention.

The importance of PIC delegates at COP 4 organising themselves so as to cover the discussions taking place in two concurrent working groups and the likely numerous contact groups was also noted and other logistics were briefly outlined. The opportunity to attend the Global Biodiversity Forum held immediately before the COP meeting was also mentioned. The types of decisions COP4 may take on key items such as CHM, biosafety, programmes of work (freshwaters, forests, agriculture, marine and coastal biodiversity) were introduced. Finally, it was stressed that the SPREP briefing paper was in draft form, and would be finalised once all COP papers were available from the CBD Secretariat and that input from workshop delegates would be extremely useful.

19. Participants then briefly discussed COP4 arrangements and the need to work together. SPREP was asked to ensure that the importance and use of the Barbados Programme of Action was reflected in the final COP4 briefing as a key framework for Small Island Developing States and as a lobbying tool.

Working Group Session III–National Coordination

20. Workshop Facilitators gave brief presentations on the issues of national and regional coordination of implementation of the CBD, and participation of NGOs and local communities. It was noted that many of the country reports given so far at the workshop had revealed that in each country a number of different government departments and agencies had responsibilities relevant to implementation of the Convention. The need for coordination at a number of levels to ensure integration of biodiversity considerations into other sectoral areas was also highlighted. Some possible areas for regional coordination were outlined including the importance of the SIDS Programme of Action adopted at the Barbados Conference of the Sustainable Development of Small Island Developing States in 1994. The importance of ensuring that PICs were represented on technical panels formed under the CBD to address specific issues was noted. WWF also emphasized the importance of the participation of NGOs in the implementation of the CBD at the national level.

21. The Working Group then divided into small groups to discuss these issues in more detail and to share information on national experiences to date. The small groups reported back their discussions, with recommendations, to PIC I and II. The key conclusions drawn from the small working groups were that :

- resource owners need to provide inputs into national policy, through "participatory" processes and that local communities should be involved from the beginning of the process – e.g. in project document formulation
- multi-agency/cross-sectoral approaches should be endorsed – e.g. through issue-based committees/subcommittees, including NGOs, organized through the national environment agency.

- cross-sectoral approaches should include the Foreign Affairs Ministry
- there was limited capacity within institutions/budgetary restraints.
- government/NGO co-ordination should be improved – e.g. through umbrella NGOs with formal government recognition
- the legal basis of sustainable development committees, including NGO representation, should be formalized at the national level.
- there was a need to ensure effective participation in COPs and related meetings.

The draft synthesized results of these smaller discussion groups were directed to PIC I and PIC II for drafting of issues, priorities and recommendations arising out of this session for the Workshop to consider in Plenary.

22. A lunchtime session was held for follow up on participants' questions to the CBD Secretariat on the Convention.

Plenary Session II

23. The CBD Secretariat addressed the workshop on a number of key issues:

- COP4 Bureau,
- biosafety,
- convention administration, budget and additional funding,
- focal point designation, and
- regional meetings

24. On biosafety it was noted that the COP4 would not deal with substantive issues as these were for negotiation within the Ad hoc Working Group. However, COP4 would decide on arrangements and budget considerations for Biosafety Working Group 5 and 6 and the ordinary or extraordinary COP to immediately follow BWSG 6 for adoption of the Protocol. Information on the staffing and funding of the CBD Secretariat and how the Secretariat may in future be organized into four divisions (Science and Technology, Implementation and Communication, Administration and Resource Mobilization, Biosafety) was also given. The role of Focal Points and associated issues for Parties to consider were also briefly mentioned. Finally, participants were updated on the recent Asian Regional Meeting in China. Questions from participants further clarified bureau representation, focal point arrangements, participation by PICs in the Asian Regional Group and rules on regional meetings.

Working Group Session IV – Biosafety

25. Workshop Organizers introduced the issue of biosafety. In essence 'biosafety' is about taking measures to ensure that any risks to the environment or to human health from living modified organisms (LMOs) are properly managed. COP2 established the Ad hoc Working Group on Biosafety to negotiate a protocol by the end of this year. It was noted that the term LMO is not specifically defined in the CBD and it generally refers to living organisms (whether plants, animals or microbes) whose genetic material has been altered through modern biotechnological processes in such a way that does not occur naturally. It was noted that modern biotechnology excludes traditional breeding and cross-fertilization techniques. To date there has been little experience with field testing making it difficult to know how LMOs will interact with different ecosystems. It was also noted that many similar issues associated with alien species arise when considering biosafety issues. The aim of the Protocol is to regulate the transboundary movement i.e. the transfer from one country to another of LMOs that might have an adverse effect on biological diversity. So far the Ad hoc Working Group on Biosafety has met four times and will meet twice more to finish its work, once in August and then a final meeting in February 1999. A draft protocol text (80 pages) which consolidates the proposals from governments now exists. While the general structure of the protocol is in

place, there is still much to negotiate at the next two meetings. Parties have until 1 June 1998 to submit any further proposals.

26. The basis of the Protocol is likely to be the Advanced Informed Agreement (AIA) procedure - the idea is that a Party which might be receiving an LMO should be in a position to decide whether or not it will allow the transfer, based on information it would have received about the LMO. In other words, any transfer of LMOs will be subject to the prior and informed consent of the receiving Party. In practice AIA would work through a notification process so that any State (or a legal or natural person) wishing to transfer an LMO will need to notify the receiving country and provide certain information on the LMO. This means that a national competent authority would need to be designated to receive and process any notifications. Other core elements of the protocol are; risk assessment - the purpose of which is to identify the nature and characteristics of the LMO in order to determine what hazards, if any, are associated with the LMO and the likelihood of these hazards being realized; and risk management - having the means and infrastructure to regulate the risks associated with LMOs.

27. Contentious issues in protocol negotiations currently include the types of LMOs and the scope of the protocol. As a result of limited field testing there is little knowledge on the risks associated with LMOs. This is why some Parties are arguing that the Protocol should cover all LMOs. Others argue that coverage should be limited to LMOs known or suspected of posing specific risks. As regards the scope of the protocol, the CBD and subsequent COP decisions provide that the scope of application is the "safe transfer, handling and use" of LMOs. To date, the BSWG has focused principally on the "transboundary movement" of LMOs and it is unclear whether this will include the handling and use of the LMO once transferred. Other particularly contentious biosafety protocol issues are related to; funding, socioeconomic considerations, and liability.

28. Regional biosafety issues were then briefly outlined emphasizing that this was largely a new and emerging issue to be addressed by PICs and as such awareness raising and capacity building were likely to be of high priority. It was noted that to deal with trans-boundary issues of LMOs would in many respects necessarily involve the same agencies that deal with alien species e.g. Customs, Quarantine, Fisheries, Agriculture. A short briefing on the GEF/UNEP Biosafety Project was also given, highlighting the need for Pacific Island Parties to the CBD to ensure that they were involved in UNEP's regional training workshops on biosafety and to explore possible in-country initiatives in Component 1 of this initiative. Finally, SPREP outlined likely issues under COP4 Agenda Item 9 on Biosafety.

29. our smaller groups were then formed to discuss and clarify:

· questions related to biosafety

· issues and recommendations for regional support (PIC I)

· possible COP4 actions (PIC II)

· possible issues for the BSWG negotiations

Results of these smaller discussion groups were directed to PIC I and PIC II for drafting of issues, priorities and recommendations arising out of this session for the Workshop to consider in Plenary.

Wednesday 1 April 1998

Plenary Update

30. The Workshop welcomed Edgar Cocker (Forum Secretariat), Tom Osborn (SPC-Agriculture) and, Lopeti Senituli (PCRC) to the meeting. Country and NGO presentations were completed and arrangements for the week updated, including the day's agenda.

Working Group Session V: Access and Benefit Sharing

31. Workshop Organizers introduced the meeting to the key international aspects of Access to Genetic Resources and Benefit Sharing. One of the CBD's objectives is to promote the sharing of benefits derived from products developed using genetic resources with the country that has provided those resources. Bioprospecting, or the search for genetic resources (i.e. samples of plants or animals), which might potentially be used to develop medicines and other products has long been practiced in many parts of the world, including in the Pacific Islands region. The CBD is the first international agreement to specifically acknowledge that a country has sovereignty over its genetic resources and as a result a right to control access to those resources and derive benefits from them. The CBD specifically links controlling access with a right to share in the benefits that might be derived from the use of those resources. The CBD also gives some guidance on what these benefits might include. However, it is up to the parties to a bioprospecting agreement to negotiate terms within the framework of any relevant national laws or regulation. Benefits can include fees to collect genetic resources, technology transfer (e.g. screening), royalties from product sale etc.

32. According to the CBD access should be based on PIC (Prior Informed Consent) of the country providing genetic resources. It is generally accepted that PIC should be extended to resource owners and local and indigenous communities responsible for conserving the resources in question. Participants were directed to information papers which provide examples of access regimes in the Philippines Executive Order (national) and Andean Pact (regional). In practice countries have sought to control access to genetic resources in various ways such as through:

- contractual bioprospecting arrangements
- adopting new laws
- adapting existing laws
- a combination of the above

It was noted that the advantage of legislative action is that the government can set the standards within which bioprospecting arrangements could then be negotiated. It is important to note that the CBD's provisions on access to genetic resources do not apply to:

- *ex situ* genetic resources (e.g. collections, seed banks, gene banks) collected before the Convention came into force
- human genetic resources
- genetic resources beyond the limits of national jurisdiction (EEZs) i.e. the high seas

It was finally noted that access issues are linked with traditional knowledge associated with these resources. Often the knowledge associated with the resources is just as important to bioprospectors when they are searching for potentially economically valuable resources. These issues would be raised in the next Working Group Session on Intellectual Property Rights (IPR).

33. A number of key regional considerations for access and benefit sharing were then outlined, including the importance of controlling access so to not lose opportunities for revenue through bioprospecting and through the possible commercialisation of any products that might be developed from these initiatives. Furthermore, it was important to link these revenue generating activities to support environmental protection. It was noted that there will be a variety of options for PICs to develop access regimes and they will need to consider the rights of local resource owners, and differing approaches needed to be taken for biological resources that are found in more than one country and those that are only found in one country.

34. Fiji's Department of Environment briefly outlined their progress with bioprospecting provisions within the draft Sustainable Development Bill. Fiji has formed a committee of agencies relevant to the use of biodiversity (Department of Environment, Ministry of Fijian Affairs, Ministry of Agriculture, Fisheries and Forests, National Trust for Fiji, Native Land Trust Board, Museum of Fiji and Ministry of Education) to address bioprospecting. The proposed process in Fiji for bioprospecting is consistent with the CBD's provisions and is based on an open consultative process.

35. Mr Bill Aalsbersberg (University of the South Pacific) followed this presentation by giving background on specific Fijian bioprospecting or 'bio-partnership' initiatives. This has concentrated on developing access agreements with agencies e.g. in joint proposals between USA universities, USP, private companies, Biodiversity Support Programme (BSP), Biodiversity Conservation Network (BCN) and others. The BSP's BCN project has focused on enterprise development as an incentive for conservation and sustainable development. Bioprospecting or bio-partnership initiatives could be one of these enterprises and a USP/Fijian community initiative is currently being funded by BCN. At the time of project development it became clear for the need for national policy in Fiji. Partnerships can be a way to generate more benefits, including revenue or enterprise development, and documentation of biodiversity and monitoring through participatory techniques by the local community for improved resource management. Key points were transparency (information available to Fiji Government agencies, NGOs etc.), and development of expert groups to access input on proposed contracts. The USP contract has a sub agreement with the community for benefit sharing. He stated that the contract includes provisions such as: samples are licensed to be studied for one year and full information disclosure within material transfer agreements (MTAs). He noted that MTAs can be useful as you can put things into them that are not in law and they are contractually binding. MTAs need to be supported by a permitting system so that samples cannot easily be taken out of the country. For the USP contract the governing law is English Law,with international tribunals for dispute resolution (at the cost of the company). He concluded that the region needs to develop these access/benefit sharing polices and laws and will likely need to access outside expertise to assist this. He supported a regional agreement on benefit sharing for those resources that are found in more than one country. Mr Aalbersbeg finally noted that SPREP's proposed Biodiversity Trust Fund may be able to assist benefit sharing from regional arrangements.

36. In discussing this issue the Workshop heard a report from a participant on an example of an American drug company that markets kava pills. The 50 capsule box sells at US$7.50, and he was interested to know the profit breakdown (producer, purchaser, company) and if there were any benefits coming back to the Pacific islands region. Discussion noted that kava is being widely developed and marketed by non Pacific island countries e.g in Germany, Australia and USA. Bill Aalbersberg also reported on Forum Secretariat kava meeting in 1997 to address these issues however, noting that these uses of kava were prior to the CBD entering into. It was strongly noted that we need to learn from these examples and protect our resources. PNG noted that there is a range of bioprospecting approaches, not those that just include traditional use of species and that royalty distribution is a key issue. Royalties are generally less than

1-5% of sales and depend on whether traditional knowledge was used and the compound(s) themselves. PNG also noted that a national workshop on IPR and access regimes had recently been held. The Workshop discussed the key issue of need for regional policy and guidelines on benefit sharing. The Workshop also noted that it is still important to discuss ex situ collections as these collections were done without consent and we need to seek repatriation of ownership of these ex situ resources.

37. Four smaller groups were then formed to discuss:

- the need to regulate access to genetic resources and benefit sharing , and if so, what sort of approaches and elements might work
- issues and recommendations for regional support (PIC I)
- issues and recommendations for COP4 action (PIC II)

The draft synthesized results of these smaller discussion groups were directed to PIC I and PIC II for drafting of issues, priorities and recommendations arising out of this session for the Workshop to consider in Plenary. In reporting back it was noted that kava is currently being grown in both Australia (Brisbane) and Mexico. USP also informed the Workshop of its assistance to countries in training on legal drafting (currently 22 participants).

Working Group Session VI - Intellectual Property Rights

38. Workshop Organizers presented a brief introduction to Intellectual Property Rights relevant to the CBD. It was noted that IPRs are a legal mechanism to protect use or applications of ideas and information, and allow the holders of the right to stop others from using or copying those ideas and information for a defined period of time. The different types of IPRs include:

- patents
- plant breeders rights
- trademarks
- trade secrets
- copyrights
- geographical indication

39. Kosimiti Latu (Commonwealth Secretariat) outlined the relevance of the General Agreement on Tariffs and Trade (GATT), the Agreement on Trade Related Intellectual Property Rights (TRIPs) and the World Trade Organization (WTO) to CBD/IPR issues He first introduced aspects of the history of the TRIPs agreement, which was concluded at the end of the Uruguay Round of GATT. The presentation highlighted importance of TRIPs with regards to IPRs as it is seen as the dominant international forum determining IPR Article 27 of the TRIPs agreement was also highlighted with regard to country obligations to make available patents and plant variety protection.

40. SPC Agriculture then updated the Workshop on the current Regional Working Group on IPRs focusing on plant issues. It was noted that plant breeding research in the region is mostly done by the national agencies rather than the private sector as is seen in developed countries. The concern on the ownership of regional tissue culture samples was noted as these materials have moved freely around the laboratories around the region. The results of the 1997 Regional IPR Workshop were also outlined. This meeting discussed bioprospecting, the need for wider participation by countries and agencies, report production, germplasms, development of policies for contractual agreement, kava councils; and assistance to the region on IPR work with countries in the region.

41. Workshop organisers then presented case studies of IPR issues in the region with a special focus on kava of which extracts are being patented and sold overseas, and the

mamala plant from Samoa which was taken out of the country by an American ethnobotanist. Prostratin, a chemical found in mamala has now been patented with no clear technology transfer and benefit sharing mechanisms, even though these potential uses were identified on the basis of the knowledge of Samoan traditional healers. Key conclusions on IPR from this experience were:

- that current IPR laws rewards inventors and protecting inventions,
- current IPR laws are not suitable for rewarding PIC inventors nor protect PIC inventions; but protect applicants from the north, and
- suitable IPR laws should be designed to protect PICs' inventions and inventors.

Discussion revolved around the need for a regional approach to addressing the IPR issues, linkages to regimes needed for access and benefit sharing, and the importance of the WTO agreement to the national sovereignty issue of the CBD.

42. Four smaller groups were then formed to discuss

- examples of biodiversity related IPR use in Pacific island countries
- forms of customary control over traditional knowledge and use of genetic resources
- issues and recommendations for COP4 action (PIC II) and regional support (PIC I)

The draft synthesised results of these smaller discussion groups were directed to PIC I and PIC II for drafting of issues, priorities and recommendations arising out of this session for the Workshop to consider in Plenary.

Thursday 2 April 1998

Plenary Update

43. A brief Plenary Update was held to update delegates on workshop arrangements. In addition, new difficulties with COP4 logistics were outlined. After hearing Participants' views, the CBD Secretariat representative agreed to follow this matter up urgently with the CBD Secretariat.

Working Group Session VII Article 8j Traditional Knowledge

44. Presentations were made on Article 8(j) by Workshop Organisers, Adi Litia Qionobaravi (Fijian Affairs Board), and Victor Kaisiepo (PCRC). Article 8(j) of the Convention was introduced and in particular outcomes of the Workshop on Traditional Knowledge held in Madrid, Spain in November 1997. COP4 will likely establish a work plan for Article 8j based on reviewed options and recommendations from the Madrid Workshop. It will be important for PIC delegations at COP4 to input their priorities to such as work plan and to support the establishment an open-ended inter-sessional working group that allows for the representation of indigenous peoples and local communities' views on Article 8(j) and other relevant Articles. With regard to intellectual property rights, it was noted that although there was some scope to work within the present system, there was a sense that Pacific island countries should be developing an alternative body of IPR laws more suited to indigenous people and their knowledge. Various sui generis models have been suggested. The importance of networking with NGOs and indigenous peoples' organisations on these issues was emphasised, and the links to the protection of traditional knowledge. The need for Pacific Island representation on any body which might be established under the Convention to address Article 8(j) was stressed.

45. Following this presentation there was some discussion of the importance of Pacific island representation in the negotiations for the revision of the FAO International

Undertaking on Plant Genetic Resources. Until now, this has not been possible. A participant from the Marshall Islands noted that he had approached FAO for funding to attend these meetings, and that FAO had indicated that it would attempt to address this for future meetings. In the meantime the FAO had indicated that concerned countries might submit position papers expressing their views.

46. Adi Litia Qionobaravi (Fijian Affairs Board) outlined the areas of concern relating to Article 8(j) which had been identified by the Pacific caucus at the Madrid meeting. These were:

- how to develop the required national IPR-related legislation according to the TRIPs Agreement;
- the need for guidelines for the development of the required IPR law in conjunction with biodiversity/plant resource protection/access legislation;
- how to recognise and protect the collective ownership of biological resources, folklore and knowledge related to the sustainable use of biological diversity under existing customary regimes, and the continuing customary uses of biological resources;
- the relationship to implementation of Article 8(j) and related articles of the CBD and other international instruments and initiatives in the area of the protection and maintenance of biodiversity and traditional knowledge relating to biodiversity; and
- the need to develop a mechanism to facilitate the control of patent applications and the confirmation of prior informed consent of local and indigenous communities to the use of their knowledge and/or resources at the regional, multilateral and inter-jurisdictional level, to address continuing biopiracy activities in the region.

Adi Litia Qionobaravi then described the ways in which Article 8(j) is being addressed in Fiji. Discussion set the question of Article 8(j) in its broader context, highlighting the preparation within the United Nations (UN) of the Draft Declaration on the Rights of Indigenous Peoples. General discussion supported the need for an open-ended working group on Article 8(j) under the CBD.

47. The Workshop established a small group to formulate outputs of the session for PIC I and PIC II to consider.

Working Group Session VIII National Biodiversity Strategies and Action Programmes (NBSAPs) (Art. 6) and National Reporting (Art. 26)

48. The objectives of this Working Group Session were to clarify the processes and answer any questions regarding NBSAPs and National Reports to the Convention. A key output of the session was also to obtain an up to date picture of where countries were with NBSAPs and National Reports including their achievements, constraints and next steps. Finally, the session looked at any issues and recommendations for regional support (PIC I) and COP4 action (PIC II).

49. The background, development and opportunities available for the preparation of NBSAPs and for the preparation of National Reports to the CBD were outlined. Decision II/66 of COP2 requested GEF to make financial resources available to developing country parties to assist implementation of Article 6. This was linked by Decision II/7 to national reporting. Subsequently under the GEF Enabling Activities financial resources were made available through the implementing agencies (UNDP, UNEP, World Bank) of up to US$300,000 dollars

50. per developing country Party for Article 6 and preparation of the first National Reports (Article 26). Article 6 focuses on developing, or adapting existing, national strategies, plans or programmes for the conservation and sustainable use of biodiversity. It also promotes the integration of the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies. It was

suggested that in the Pacific Island context the existing National Environment Management Strategies (NEMS) or their equivalents should be seen as a key basis for NBSAP development. However, newer issues such as access and benefit sharing, intellectual property rights, biosafety and others should be reflected, as appropriate, in these strategies. In addition, countries were strongly urged to use the draft Action Strategy for Nature Conservation in the Pacific Islands Region (1999-2002) as this provides a key framework and actions developed through region-wide government and NGO input. It was emphasised that the key challenge for PICs was really Article 6b which promotes integrating biodiversity conservation and sustainable use issues into national planning and related cross-sectoral initiatives. Under National Reporting it was outlined that the form and interval of these reports was decided in Decision II/17 of COP2 and that these reports were due to the CBD Secretariat on 1 January 1998. To date Fiji, Vanuatu and Marshall Islands have submitted national reports.

51. UNDP (Suva office) Sustainable Development Adviser then outlined UNDP's involvement in supporting countries to access resources for NBSAPs. It was noted that the PNG was covered by its own UNDP office and the UNDP Samoa Office covered four other Pacific Island countries. To date UNDP Suva Office has supported NBSAP projects for Marshall Islands and Fiji. Furthermore, Kiribati's proposal had just been approved and FSM's proposal was in development. These were nationally executed projects and the basic provisions of approval (GEF Council), payments, reporting and support available from UNDP were outlined. It was noted that the experience gained in the Marshall's had been shared to assist Fiji's NBSAP proposal and that this information sharing was very useful. Supporting work on Article 6b was also of great interest and priority in the region to achieve the linkages in national planning. WWF's programme to support CBD implementation in Pacific island countries was also introduced. This has focused on supporting NBSAP work in Fiji and Samoa, however, WWF was also interested in working with other countries in the region.

52. Each Pacific Island Party then outlined how far they had progressed with NBSAPs, key achievements, issues and next steps. A summary table of this information is produced in the following page.

53. Non Parties and IGOs/NGOs were also invited to comment on this issue. Tonga, Tuvalu and Palau noted that they had been through a NEMS process and had also had a number of other related initiatives. These non Party delegates all indicated firm interest in following up CBD membership. The following NGOs indicated that they were directly involved in PIC NBSAPs: WAINIMATE (Fiji), USP (Fiji), PIANGO members in some countries, and ECOWOMAN (Fiji).

54. In discussions the Workshop identified the following priority issues and items for follow up:

- the need to encourage Pacific Island Parties to quickly move ahead the NBSAP proposal process through the relevant implementing agency (UNDP, UNEP, World Bank)
- concern at more strategising and the need to ensure that there are resources to implement strategies
- the need to share information, with requested countries, and for UNDP, SPREP, and the WWF to assist with sharing NBSAP information and National Reports, and noting that the CBD Secretariat web site has those national reports which countries have made publicly available
- noted the importance of multi government agency and NGO involvement in NBSAP process, however, it was also noted that significant capacity problems exist as the NBSAPs adds to existing full workloads of government and NGO officers
- the need to emphasize local expertise and broad based expertise (scientific, social, economic, sectoral etc.)

Status of National Biodiversity Strategies and Action Programmes development and National Reporting

Pacific Island Party	NBSAP progress	Supporting Agency	Comments
Marshall Islands	Strategy in development, national report completed	UNDP (Suva)	1. emphasized process of information gathering and consultation at the community level, followed by workshops to develop elements of NBSAPs and consultations to finalize this strategy
Fiji	Strategy in development, national report completed	UNDP (Suva)	2. four phases of work; establishment, stocktaking using technical groups, consultative workshops, national workshops with final NBSAP approval by government. 3. NGOs involved
Vanuatu	Strategy in development, national report completed, 2 year time frame	UNEP	4. establishment has increased staff capacity including a trainee in the programme for capacity building, 5. reviews of existing information have also provided an opportunity for information repatriation 6. NGOs involved 7. provincial workshops to develop their strategies will be followed by a national workshop and then further consultation to finalize strategy 8. limited resources has resulted in approaches to other donors 9. building in fund raising for strategy implementation during strategy development 10. approach is supporting traditional practices as a key part of the strategy
Cook Islands	draft proposal	UNDP (Samoa)	11. proposal format difficult to meet in-country needs
Kiribati	Proposal just approved	UNDP (Suva)	
FSM	draft proposal for completion		
Solomon Islands	Proposal completed and taskforce established, workplan	UNEP	12. concern at over strategising and focus needs to be for implementation 13. using a consultative process 14. currently working on sectoral reports
Nauru	Proposal to be developed	UNDP (Suva)	
Niue	Proposal developed awaiting approval	UNDP (Samoa)	
PNG	Reviewing of formulated draft proposal	World Bank	15. acknowledge large amount of strategising carried out n this are over the last 20 years 16. NBSAP process moving forward contingent on other institutional changes 17. the NBSAP is expected to be completed in 1998
Samoa	draft proposal developed, currently finalizing national report	UNDP (Samoa)	18. working on national report even though funding has not come through yet 19. using existing NEMS and policy committees

- noted the importance of participatory and consultative process in NBSAP development
- the need for all NBSAP development pay particular attention to addressing CBD Article 6b
- noted that information and processes for national reports need to be useful at national level to assist CBD implementation in the Parties, the planned key uses of information in National Reports should be carefully considered, designed and agreed in deciding on the form and interval of any future reports

Additional Agenda Item - Accessing GEF Finds for the Clearing House Mechanism (CHM) of the Convention on Biological Diversity

55. UNDP (Suva Office) briefed delegates on the newly announced opportunity for support for CHM establishment. The principal objective of the CHM is to facilitate global access and exchange of information regarding biodiversity conservation, sustainable use and benefit sharing of biological resources. Key points noted in the GEF CHM funding were:

- CHM proposals can be submitted in conjunction with a GEF enabling Activity proposal or as a module of already existing NBASAP programmes
- countries need to nominate a CHM focal point and need to complete a Technology Evaluation Form to be sent to the CBD Secretariat
- support includes provision of hardware, software, training and access to Internet

In discussions it was also noted that UNDP (Suva office) also has a programme of support for Internet access for those countries who presently have no access (Nauru, Tokelau, Tuvalu). It was also confirmed that Non Parties to the CBD were not eligible for this support.

56. Delegates also briefly discussed other opportunities under the GEF including; medium sized projects. Support is available for up to US$750,000 dollars (US$1,000,000 dollars maximum) for governments, NGOs and institutions. The process can be simply initiated through preparation of a one page concept proposal which requires endorsement from the country GEF focal point. Several proposals from the region were already been supported under this programme including projects on; traditional medicine and a alternative energy project. Summary information of the GEF Medium Sized Projects was provided and further information is available from the GEF Secretariat.

Working Group Session IX

57. Participants broke up into two working groups to prepare texts for the Workshop's 'Nadi Statement' based on the outputs of previous working group sessions. These two groups were; Pacific Island Committee I (PIC I) which focused on issues, priorities and recommendations for regional support to national implementation of the CBD, and Pacific Island Committee II (PIC II) which focused on issues, recommendations and actions needed for COP4.

Friday 3 April 1998

Plenary Update

58. The CBD Secretariat informed the session on recent updated information with regard to the organizational arrangements set up for COP4. Copies of relevant details were made available to participants. The CBD Secretariat offered to take back completed registration forms for COP4. However, he reminded the participants that these forms were not meant to be a substitute for the requested credentials. He also reminded the participants that such credentials are only required from party representatives. On the specific question of the possibility of availability of advance funding from the Secretariat of CBD to assist the delegates from PICs to attend COP4, no specific response was made.

59. PCRC reported on a recent development on a Food and Agricultural Organization (FAO) initiative on transfer of germplasm samples. It was noted that there had been recent attempts to obtain protection for plant variety resources obtained from the CGIAR system and there will be a meeting in June 1998 to address this issue and for PICs to participate.

Working Group Session X

60. Following brief presentations on some remaining items of priority to PICs the Workshop broke into smaller groups for discussions on:

- work programmes under the CBD on marine and coastal biodiversity and forest biodiversity
- approaches to implementation of the CBD in national law in the region
- biodiversity in EEZs and high seas
- CGIAR and patenting issues

The groups on biodiversity in the EEZ and high seas, and the group on CGIAR and patenting issues reported back to the session with draft recommendations for inclusion of text in the Nadi Statement. The other groups reported back for the general information for the meeting.

Closing Plenary Session

61. Workshop Report. Workshop Organizers presented the draft Workshop Report for the meeting to consider. After some amendments and clarifications the Workshop Report was officially adopted and the Workshop Organizers entrusted to complete the remaining sessions from the Closing Plenary. Vanuatu and PNG delegations thanked the Secretariat for the report and called on SPREP and its workshop partners to organize regular CBD meetings in the region, with at least one regional meeting being organized before each COP. PNG further added that regional trade issues be discussed at such future meetings in relation to provisions of the CBD.

62. Participants' Nadi Statement. The draft Participants'Statement from the workshop was presented containing recommendations drafted by PIC I (regional support) and PIC II (COP 4 action) based on the results of the Working Group Sessions. It was noted that this combined outputs for Objective 2 and 3 of the Workshop. After some discussion, amendment and clarification the 'Nadi Statement' (annexed) was adopted by the Workshop.

63. Workshop Evaluation: Participants evaluated the workshop programme, structure, content, arrangements and outcomes using a form to assist Workshop Organizers plan any future initiatives.

64. Closing Statements: Participants thanked Workshop Organizers for a successful and productive meeting and recommended that such workshops were needed on a regular basis to assist PICs implement the CBD and to prepare for key meetings such as COPs. It was suggested that future meetings should include a focus on the implications for trade of implementing certain CBD provisions. NGO delegates especially appreciated the open, participatory style of the Workshop. Participants noted that all Workshop objectives had been achieved and they were pleased with the outcomes. Participants also thanked the Chairperson for his able leadership during the Workshop and the Government of Fiji for hosting the Workshop.

65. Workshop Organizers (SPREP, FIELD and WWF) also gave brief closing statements which outlined the process for finalizing the CBD information package (Objective 1) and further noted the key outcomes and mechanisms for follow up from the

Workshop in the organizers' work programmes, including the joint SPREP/FIELD project. They thanked participants for their hard work during the sessions, the Chairperson for his able leadership during the week's sessions and the Government of Fiji for hosting the meeting. Workshop Organisers acknowledged the support of donors which made the Workshop possible including the; United Kingdom (UK) Department of the Environment, Transport and the Darwin Initiative; UK Department for International Development (DFID), Government of Australia, WWF, South Pacific Biodiversity Conservation Programme, and the Conservation, Food and Health Foundation (USA).

66. The meeting was officially closed by the Chairperson at 6pm on Friday, 3 April 1998.