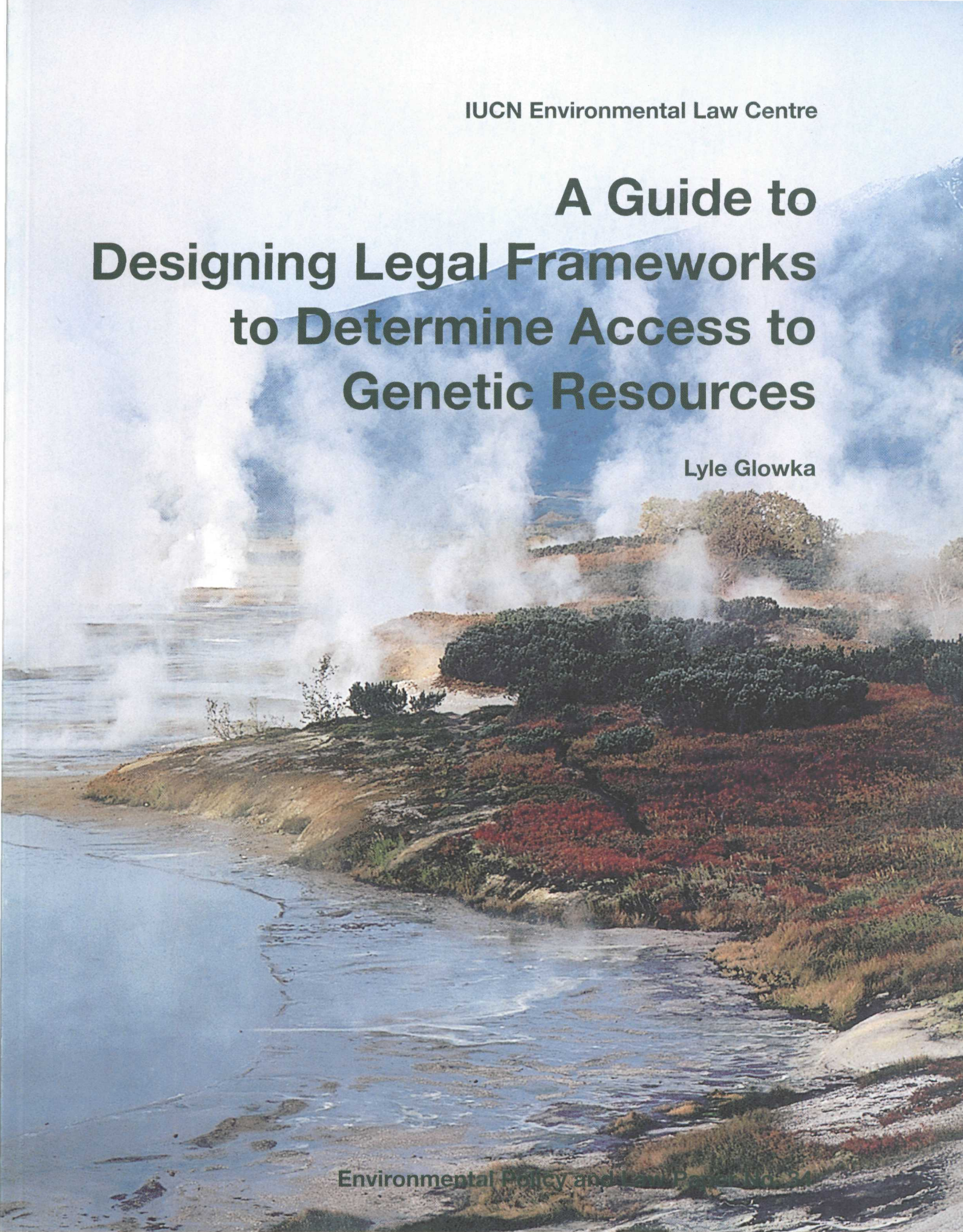
IUCN Environmental Law Centre

A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources

Lyle Glowka



Environmental Policy and Law Paper No. 34

IUCN
The World Conservation Union

A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources

IUCN - The World Conservation Union

Founded in 1948, The World Conservation Union brings together States, government agencies and a diverse range of non-governmental organizations in a unique world partnership: over 913 members in all, spread across some 136 countries.

As a Union, IUCN seeks to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable. A central secretariat coordinates the IUCN Programme and serves the Union membership, representing their views on the world stage and providing them with the strategies, services, scientific knowledge and technical support they need to achieve their goals. Through its six Commissions, IUCN draws together over 6,000 expert volunteers in project teams and action groups, focusing in particular on species and biodiversity conservation and the management of habitats and natural resources. The Union has helped many countries to prepare National Conservation Strategies, and demonstrates the application of its knowledge through the field projects it supervises. Operations are increasingly decentralized and are carried forward by an expanding network of regional and country offices, located principally in developing countries.

The World Conservation Union builds on the strengths of its members, networks and partners to enhance their capacity and to support global alliances to safeguard natural resources at local, regional and global levels.

A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources

Lyle Glowka

Environmental Policy and Law Paper No. 34

IUCN - Environmental Law Centre

A Contribution to the Global Biodiversity Strategy

IUCN -The World Conservation Union
1998

Published by: IUCN, Gland, Switzerland and Cambridge, UK in collaboration with IUCN Environmental Law Centre, Bonn, Germany.

IUCN
The World Conservation Union

Citation: L. Glowka (1998), *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources.* IUCN, Gland, Switzerland Cambridge and Bonn. xii + 98 pp.

ISBN: 2-8317-0428-6

Cover design by: IUCN Environmental Law Centre

Cover photograph: Geothermal vents of the Uzon Caldera, Kamchatka, Russia: Nikolai Smelov

Layout by: Barbara Weiner, Desktop Publications Co-ordinator

Printed by: Daemisch Mohr GmbH & Co.KG, Siegburg, Germany

Available from: IUCN Publications Services Unit
219c Huntingdon Road, Cambridge CB3 0DL, United Kingdom
Tel: +44 1223 277894, Fax: +44 1223 277175
E-mail: iucn-psu@wcmc.org.uk
www: http://www.iucn.org
A catalogue of IUCN publications is also available

Table of Contents

Editorial Note

The primary goal of A *Guide to Designing Legal Frameworks to Determine Access to Genetic Resources* is to highlight some of the principles which should be considered by planners, legislative drafters and policy-makers as they work to develop legal frameworks on access to genetic resources in their countries. Contextual information on the Convention on Biological Diversity and examples of how countries have thus far approached the issue are provided.

This publication supplements IUCN's *A Guide to the Convention on Biological Diversity* and draws on lessons learned from one component of a four year IUCN Environmental Law Centre project to provide technical legal assistance to implement the Convention on Biological Diversity. The overall project, which commenced in 1994, was funded by the German Bundesministerium für Wirtschaftliche Zusammenarbeit (BMZ), and additional funds for this publication were also provided for by the Dutch Ministry of Development Cooperation.

The genetic resources component of the project was initially conceptualised (and budgeted) to provide technical legal assistance to only one country to implement article 15 of the Convention (Access to Genetic Resources). In 1994 the Council of the Cartagena Accord (the Andean Pact), a regional economic integration organisation whose member states are Bolivia, Colombia, Ecuador, Peru and Venezuela, requested technical legal assistance from the IUCN Environmental Law Centre (IUCN-ELC).

The Council asked IUCN's assistance in preparing a report aimed at providing elements for a common regime on access to genetic resources. The report would be subsequently considered in a governmental drafting phase. In a break from the usual process, the Council was particularly interested in gaining the views of civil society prior to the governmental drafting phase.

With the support of the Sociedad Peruana de Derecho Ambiental (SPDA), an IUCN member, a legal team was created consisting of Patricia F. Moore and Lyle Glowka from IUCN-ELC and Brendan Tobin and Manuel M. Ruiz from SPDA. Special advisors were Jorge Caillaux (SPDA) and Françoise Burhenne-Guilmin (IUCN-ELC).

A process was designed to solicit comments from interested groups within the five country region. Two workshops were organised by IUCN and SPDA.

The first workshop took place in Lima, Peru. It was attended by a representative from each Andean Pact member state, acting in a personal capacity, and a representative from Coordinadora de las Organizaciones Indigenas de la Cuenca Amazonica (COICA), Estudios de Estructure y Administracion del Estado (ESTADE), the International Potato Centre of the Consultative Group on International Agricultural Research, the Food and Agriculture Organisation of the United Nations and the United Nations Environment Programme. Participants were asked to comment on principles and criteria prepared by the legal team which could then provide the conceptual basis for possible substantive elements of an Andean Pact common regime.

The second workshop took place in Villa de Leyva, Colombia. It was attended by over eighty people from non-governmental organisations, indigenous peoples' organisations and governmental and intergovernmental organisations. Participants were asked to comment on a discussion document prepared by the legal team which suggested possible elements for a common regime on access to genetic resources.

The final report to the Andean Pact Council was written by Francoise Burhenne-Guilmin and Manuel M. Ruiz. Entitled *Toward a Legal Framework to Regulate Access to Genetic Resources in the Andean Pact*, it was submitted to the Council in October 1994. Governmental technical experts then began an intergovernmental process which subsequently led to the adoption of Decision 391 in July 1996.

Foreword

During the negotiations of the Convention on Biological Diversity, and in the subsequent years since its entry into force in December 1993, perhaps no other subject has been as contentious as article 15 (Access to Genetic Resources). Controversy stems from the implications article 15 has for State sovereignty, economic development, indigenous and local communities, scientific research, the industries dependent on genetic resources and, above all, the conservation of biological diversity and the sustainable use its components. Nevertheless, the compromise reflected in article 15 marks an historic commitment by the contracting parties of the Convention to direct benefit flows from the utilisation of genetic resources back to the countries providing genetic resources. Legislation will play a central role in nearly every country's approach to implementation particularly those countries which provide genetic resources.

There has been a flurry of activity around the world aimed at creating or modifying legal frameworks in response to the access provisions of the Convention. The emerging legal frameworks are bold first steps to capture the benefits of genetic resources and they manifest the new relationship between the providers and users of genetic resources which is reflected in the Convention.

They are remarkable in many ways. For example, many of the legal frameworks have been or are being developed in consultation with a variety of interest groups, including indigenous and local communities. In addition, some legislation promotes transparent and participatory decision-making processes to determine access to genetic resources. Local benefit-sharing is also being promoted.

The advent of participatory processes to develop and implement legal frameworks on a very specialised, complex and political issue such as access to genetic resources bodes well for the future development of other biodiversity-related laws. Not surprisingly developing countries, which because of their biodiversity are targets for bioprospecting activities, have been some of the first to create legal frameworks on access to genetic resources. While it is too early to tell how successful the innovative work of these countries will be in actually capturing benefits from genetic resources, there is no doubt that the precedents set and lessons learned in the legal development process will influence their work in other areas important to the implementation of the Convention.

A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources is the culmination of four years of work by the IUCN Environmental Law Centre (IUCN-ELC) on the legal and institutional aspects of the access issue. It is the first in a series of focused supplements to IUCN's *A Guide to the Convention on Biological Diversity* and demonstrates the continued commitment of IUCN to the conceptual development and practical implementation of the Convention.

This new guide combines lessons learned from the field with desk-based research and comparative analysis of the emerging legal frameworks on access to genetic resources. It aims to provide planners, legislative drafters and policy-makers with a source-book of contextual information and real world examples which can be drawn upon to tailor a country's legal and institutional approach to this complex issue. We also hope this guide will be useful to all those people interested in implementing article 15 of the Convention, as well those interested generally in the access issue.

A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources is a publication of the IUCN Environmental Law Programme. We are very grateful to the German Bundesministerium fur Wirtschaftliche Zusammenarbeit (BMZ) for generously providing the financial support which made the entire four year project possible, and to the Dutch Ministry of Development Cooperation for the support to this publication.

Frangçise Burhenne-Guilmin
Head, IUCN Environmental Law Centre
Bonn, Germany

Acknowledgments

Many people have assisted with *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources.*

Patti Moore, my colleague at the IUCN Environmental Law Centre, sat with me for many hours and interpreted Spanish language legal instruments.

Some of the text in this publication has been generously provided by others, and adapted by me, including Box 4 (Manuel M. Ruiz, Lima, Peru) and Box 6 (Sam Johnston, Montreal, Canada, Brendan Tobin, Lima, Peru and Joseph H. Vogel, Quito, Ecuador).

Finally, a number of people from all around the world, some of whom I have yet to meet face to face, took time out of their busy schedules to provide me with thoughtful verbal or written comments, answers to my questions, legislation, documents or photographs. I would like to acknowledge especially William Aalbersberg (Suva, Fiji), Wale Ajai (Lagos, Nigeria), Eugenio Arcanjo (Brasilia, Brasil), Jim Armstrong (Geneva, Switzerland), Alfonso Ascencio (Tlatelolco; Mexico), Marc Auer (Montreal, Canada), P. Balakrishna (Madras, India), John Barton (Palo Alto, United States of America), Julian Burger (Geneva, Switzerland), Dubravka Bojic Bultrini (Strasbourg, France), Mary Jean Caleda (Quezon City, Philippines), Juanita Castano (Quito, Ecuador), Richard Castenholz (Eugene, USA), Graham Dutfield (Oxford, United Kingdom), Jan Engels (Rome, Italy), David Farrier (Wollongong, Australia), Chris Gakahu (Nairobi, Kenya), Mary Garson (Brisbane, Australia), Kodzo Gbewonyo (Somerset, USA), Naigzy Gebremedhin (Asmara, Eritrea), Anil Gupta (Ahmedabad, India), David Hathaway (Rio de Janeiro, Brasil), Andre Heitz (Geneva, Switzerland), Anwarul Islam (Dhaka, Bangladesh), Veit Koester (Copenhagen, Denmark), Ashish Kothari (New Delhi, India), Sarah Laird (Waterbury Center, USA), Antonio La Vina (Quezon City, Philippines), Bob Lindstrom (Yellowstone, USA), Anni Lukacs (Bonn, Germany), Patricia Madrigal (San Jose, Costa Rica), Arturo Martinez (Buenos Aires, Argentina), Sue Miller (Apia, Western Samoa), Vladmir Moshkolo (Moscow, Russia), John Mugabe (Nairobi, Kenya), Heather Paull (Adelaide, Australia), Rosario Ortiz Quijano (Bogota, Colombia), Ruth Raymond (Rome, Italy), Walt Reid (Washington DC, USA), Monica Rosell (Lima, Peru), Manuel M. Ruiz (Lima, Peru), Anna Sittenfeld (San Jose, Costa Rica), Nikolai Smelov (Petropavlovsk-Kamchatsky, Russia), Reed Smith (New York City, USA), Vivienne Solis (San Jose, Costa Rica), Alfred Soons (Utrecht, the Netherlands), Clive Stannard (Rome, Italy), Jessica Suplie (Bonn, Germany), Johanna Sutherland (Canberra, Australia), M.S. Swaminathan (Madras, India), Pedro Tarak (Buenos Aires, Argentina), Kerry ten Kate (Kew, United Kingdom), Jim Thorsell (Gland, Switzerland), Joseph H. Vogel (Quito, Ecuador), Michael von Websky (Bonn, Germany), Xue Dayuan (Nanjing, China) and A.H. Zakri (Selangor, Malaysia).

Barbara Weiner, despite my German language skills, worked closely with me on the layout for this publication, as well as an abridged version entitled *The Next Rosy Periwinkle Won't Be Free: Emerging Legislative Frameworks to Implement Article 15 of the Convention on Biological Diversity* which was distributed in Montreal at the Third Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity in September, 1997.

I would also like to extend my deep appreciation to Françoise Burhenne Guilmin, Head of the IUCN Environmental Law Centre, who was firm when she needed to be, understanding when I needed it most and always gave me wide latitude to shape this publication as I saw fit.

My thanks go to all of these people, and others, for their assistance in making this publication possible. I, however, remain responsible for any weaknesses that remain.

Lyle Glowka
Bonn, Germany
February 1998

1.0 Introduction

Innovation based on genetic diversity has always relied on having physical access to genetic material. Many States have historically controlled access to biological resources directly through their regulatory powers or more indirectly through property laws. With few exceptions, they have not controlled access to the genetic material that biological or other materials may contain. Consequently users who gained access to genetic resources have not been required to share benefits derived from their use with the country of origin or those individuals or communities who may have been the ultimate providers.

The failure to capture the benefits of genetic resources derived primarily from the fact that the genetic material had neither a clear legal status, nor an obvious market value. It was *de facto* usable by anyone for any purpose once it was obtained physically.

In the last twenty-five years, some governments have perceived this situation as inequitable. Recently, it has become more widely recognised that the situation may also eliminate a potential incentive for conserving biological diversity and using its components sustainably.

A major aim of many developing countries in the intergovernmental negotiations which led to the Convention on Biological Diversity was to redefine historical benefit flows from the use of genetic resources. Article 15 of the Convention on Biological Diversity defines the rights and obligations of Contracting Parties regarding access to genetic resources and the fair and equitable sharing of benefits derived from their use. Encompassing only 7 paragraphs, it is a far-reaching and complex article which attempts to define in international law a new relationship between the Parties of the Convention which provide and use genetic resources: access to genetic resources in exchange for a share of benefits derived from their use.

The Convention provides the general contours of the new relationship. But the details of the practical implementation of article 15 will be defined primarily at the national and sub-national levels by creating or adapting legislation, administrative procedures and institutions.

Drawing on existing examples, this document highlights some of the legislative and institutional approaches that Parties to the Convention on Biological Diversity could consider as they strive to implement article 15 and attain the third primary objective of the Convention: fair and equitable benefit-sharing from the use of genetic resources. Part 2 provides a contextual overview of the relevant articles of the Convention. Part 3 discusses legal and institutional considerations for States providing genetic resources. International issues, fora and instruments relevant to implementation of article 15 are addressed in a number of boxes throughout the text.

2.0 Convention on Biological Diversity

The legislative and institutional considerations for implementing the access and benefit-sharing provisions of the Convention on Biological Diversity begin naturally with the provisions of the Convention itself.

Article 1 (Objective) states the objectives of the Convention and covers its main themes. The objectives of the Convention are:

- the conservation of biological diversity;
- the sustainable use of its components; and
- the fair and equitable sharing of benefits arising from the use of genetic resources.

The latter part of the article then indicates three means by which the sharing of benefits could occur. Paraphrased they are:

- appropriate access to genetic resources, taking into account all rights over those genetic resources;
- appropriate transfer of relevant technologies, taking into consideration all rights to technologies; and
- appropriate funding.

The first phrase foretells article 15. The word "appropriate" relates to the terms or conditions of access to genetic resources. They can be determined by a Party providing genetic resources. The reference to rights over genetic resources foreshadows that the legal status of genetic resources is a major consideration that the Convention leaves to each Contracting Party to clarify.

The second phrase foretells article 16. It reflects the need for balancing a series of factors including legal rights over the technologies transferred which may incorporate genetic material provided.

The third phrase looks forward to the financial provisions of the Convention in articles 20 and 21. The negotiators of the Convention envisioned that some Parties may need assistance from the financial mechanism of the Convention to make benefit-sharing a reality. For example, developing countries could seek funding from the Convention's financial mechanism for enabling activities such as a planning process on access and benefit-sharing or developing access and benefit-sharing legislation. The word "appropriate" envisages a degree of negotiation as the financial mechanism covers only the agreed full incremental costs of the activity proposed.

Article 1 provides an overall sense of direction to the Convention. It is then supplemented by the more substantive provisions of the Convention. As an approach is developed to implement article 15, other relevant articles will also need to be drawn on.

2.1 Access to Genetic Resources (article 15)

A primary objective of the Convention, and the basis for article 15, is to ensure the equitable sharing of benefits derived from the use of genetic resources with the Parties providing them. These are Parties that are (1) countries of origin (possessing genetic resources *in-situ)* or (2) Parties which have acquired them in accordance with the Convention (article 15(3)).

The access and benefit-sharing provisions of the Convention do not apply to genetic resources collected prior to the Convention's entry into force in a particular State. Therefore, Parties with collections of genetic resource which were collected originally from other Parties before the entry into force of the Convention are not obliged to share the benefits derived from their use with the latter. They can, however, choose to do so.

The Parties with these pre-existing collections do have the sovereign right to control access to them to ensure benefit-sharing, but have no legal claim under the Convention to invoke the benefit-sharing provisions of articles 15, 16 and 19 because these genetic resources were technically not acquired in accordance with the Convention.

Furthermore, the Convention left outstanding the situation with regard to access to *ex-situ* collections of plant genetic resources. In its third resolution (see appendix 1), the intergovernmental conference which adopted the draft convention in May 1992 recognised the need to seek a solution to this matter within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture. Governments meeting within the Food and Agriculture Organisation of the United Nations' Commission on Genetic Resources for Food and Agriculture are addressing this within the context of the renegotiations of the International Undertaking on Plant Genetic Resources (see box 1).

The Convention defines genetic resources as genetic material of actual or potential value. Genetic material means "any material of plant, animal, microbial or other origin containing functional units of heredity" (article 2). Functional units of heredity include all genetic elements containing DNA (deoxyribo-

nucleic acid) and, in some cases, RNA (ribonucleic acid). Under the Convention, therefore, "genetic material" would include, for example, a seed, cuttings, semen, or an individual organism because they contain functional units of heredity. It also includes DNA extracted from a plant, animal or microbe such as a chromosome, a gene, a plasmid or any part of these such as the promoter region of a gene.

Under the Convention, genetic material would not include a biochemical extract if it did not contain functional units of heredity (Glowka *et al.,* 1994). Interpreting strictly the term "genetic resources" would therefore limit the implementation of the Convention to genetic material.

State practice, however, will likely be more expansive. For example, the scope of legislation will likely cover biomolecules found within biological materials which are the direct result of the expression of individual genes or gene groups, or which are the indirect result of the metabolic processes that these genes may orchestrate. These biomolecules could be used directly or they could be modified or synthesised. If they are proteins, they could be used to "reverse engineer" or synthesise a genetic sequence.

The scope of the Convention also does not include access to human genetic resources (COP, 1996), although, again, State practice may differ. States may choose to regulate access to human genetic resources after taking into consideration the bioethical dimensions of the issue (a subject which will not be addressed in this publication).

Finally, the phrase "or other origin" has not been defined. However, it could be interpreted to include environmental samples such as soil, sediments or liquids which either include (1) plant, animal or microbial material containing functional units of heredity or (2) functional units of heredity unassociated with plant, animal or microbial material, in other words, "naked functional units of heredity" (Glowka, 1996a).

To overcome the inequity perceived by developing countries which have not shared directly in the benefits derived from their genetic resources, and to provide a possible incentive for biological diversity conservation, the Convention on Biological Diversity attempts to create a new relationship between the providers and users of genetic resources (de Klemm *et al.,* 1995). The new relationship only applies between the Contracting Parties of the Convention.

The basic idea is to create a *quid pro quo* between the Parties of the Convention: access to genetic resources in exchange for sharing the benefits derived from their use. While the Convention applies only between its Parties (States and regional economic integration organisations (REIOs) such as the European Community), legal and institutional measures used to define the new relationship will likely apply to other potential users such as governmental actors from States which are not Parties to the Convention as well as natural and legal persons.

Article 15 provides the foundation for the new relationship. It outlines the rights and obligations of each Contracting Party regarding access to genetic resources and their subsequent use. It is premised on four fundamental concepts:

- sovereignty over genetic resources (article 15(1));
- facilitating access between Parties (article 15(2));
- access subject to mutually agreed terms (article 15(4)); and
- access subject to prior informed consent (article 15(5)).

In addition, each Contracting Party is to take legislative, administrative or policy measures which aim to achieve benefit-sharing (article 15(7)).

2.1.1 Sovereign Rights over Genetic Resources (article 15(1))

Article 15(1) establishes clearly the authority of a government to determine physical access to genetic resources in areas within its jurisdiction. This derives from the sovereign rights States have over the natural resources in areas within their jurisdiction.

Even before the Convention on Biological Diversity, States had this power over the genetic resources in areas within their jurisdiction (de Klemm, 1993). The Convention reaffirms this. Prior to the Convention on Biological Diversity this power was probably rarely exercised to ensure benefit-sharing however.

While reaffirming the sovereign rights of a State over genetic resources in areas within their jurisdiction, article 15 does not grant the State a property right over these resources (Glowka *et al.,* 1994). In fact, ownership of genetic resources is not addressed by the Convention at all. It is a function of national or sub-national law.

Resolving questions about the legal status of genetic resources, such as who may have an ownership interest in them, is especially relevant to designing effective access and benefit-sharing legislation (Glowka *et al.,* 1994) (see section 3.2.1.1). Clarity will eliminate uncertainty especially with

regard to who is entitled to share in the benefits derived from the use of genetic resources.

Article 15(1) goes on to state that the authority to determine access to genetic resources rests with national governments and is subject to national legislation. The phrase "subject to national legislation" reaffirms the power of a State to legislate on this issue. Depending on the legal system the control-oriented provision of article 15 — prior informed consent — may or not may not be viewed as self-executing. The article is not self-executing if it does not create the necessary rights and obligations at the national or sub-national level for it to be implemented without further legislation. If this is the case, the authority to control access will need to be clarified in legislation.

2.1.2 Facilitating Access To Genetic Resources between Parties (article 15(2))

The authority of a government to determine access to genetic resources is qualified by article 15(2). Article 15(2) requires Parties to (1) endeavour to create conditions to facilitate access to genetic resources by other Parties for environmentally sound uses and (2) not to impose restrictions which run counter to the objectives of the Convention.

What this means in practice remains to be seen. However the provision implies that Parties are to extend special treatment to each other. But depending on the interpretation of article 15(2) this might apply only when access to genetic resources is for environmentally sound uses. Determining when a use is sound environmentally is left to the discretion of the Party providing genetic resources. A Party may want to consider its practical meaning in the context of legislation (see sections 3.4.3 and 3.4.3.1).

The obligations to facilitate access and to eliminate or minimise restrictions derive in part from the recognition in the Convention that the conservation and sustainable use of biological diversity, and access to and sharing of both genetic resources and technology, are "of critical importance for meeting the food, health and other needs of a growing world population" (preambular paragraph 20). This is supported, for example, by the realisation that no State today is completely self-sufficient in the genetic resources of the major food crops such as maize, rice or wheat. Whether from *in-situ* or *ex-situ* sources, all States are interdependent in their need to have access to plant genetic resources for food and agriculture (PGRFA). Consequently, access to PGRFA may need to be facilitated to ensure the food security of the world. The challenge is to do this while the ability of the providers of genetic resources to obtain benefits — either directly or indirectly — is maintained.

Finding the right balance between determining access to PGRFA and ensuring benefit-sharing is the central issue in the renegotiations of the International Undertaking on Plant Genetic Resource (see box 1). Reaching a solution is complicated by the fact that large collections of PGRFA exist in *ex-situ* conditions outside of the countries of origin. Therefore, access to these collections is not subject to their control.

Box 1. Renegotiation of the FAO International Undertaking on Plant Genetic Resources

The Food and Agriculture Organisation of the United Nations (FAO) created the Global System for the Conservation and Utilisation of Plant Genetic Resources for Food and Agriculture (the "Global System") in 1983 to coordinate the conservation and use of plant genetic resources at the molecular, population, species and ecosystem levels primarily for food and agriculture production. As of late 1997, one hundred and seventy-three States and the European Community participated in the Global System. The System has two institutional components: the Commission on Genetic Resources for Food and Agriculture (CGRFA) (formerly the Commission on Plant Genetic Resources renamed in 1995 (Resolution 3/95)) and the International Undertaking on Plant Genetic Resources (the "Undertaking") (Resolution 8/83).

The CGRFA is a global intergovernmental forum of State donors and users of plant genetic resources, technology and funds. As of late 1997, one hundred and fifty-nine States and the European Community were members.

The International Undertaking is presently a non-binding agreement whose objective is "to ensure plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes" (article 1). The Undertaking, as originally adopted, was premised on the "principle that plant genetic resources are a heritage of mankind and consequently should be

continued on the next page

Box 1. Renegotiation of the FAO International Undertaking on Plant Genetic Resources

continued from the preceding page

available without restriction" (article 1). It followed from this that governments and institutions adhering to the Undertaking were to allow access to plant genetic resources under their control "free of charge, on the basis of mutual exchange or mutually agreed terms", but only "for the purposes of scientific research, plant breeding or genetic resource conservation" (article 5). As of late 1997, one hundred and twelve States and the European Community have adhered to the Undertaking.

Over the years since the Undertaking was first completed, a number of agreed interpretations of, and annexes to, the International Undertaking were negotiated by the Commission on Plant Genetic Resources. These were adopted by resolutions of the FAO Conference and are now an integral part of the International Undertaking.

The Undertaking and its annexes presently recognise that:

- nations have sovereign rights over their plant genetic resources (Annex III, Resolution 3/91);
- both farmers and breeders have the discretion to make their breeding lines and breeding materials available to others (Annex III, Resolution 3/91);
- plant breeders' rights are not incompatible with the Undertaking (Annex I, Resolution 4/89);
- a State adhering to the Undertaking may impose only those minimum restrictions on the free exchange of plant genetic resources as are necessary for it to conform to its national and international obligations (Annex I, Resolution 4/89); and
- "free access" does not necessarily mean access free of charge (Annex I, Resolution 4/89).

The concept of Farmers' Rights was created in 1989 (Annex II, Resolution 5/89) as a complement to plant breeders' rights in order to provide the basis for recognising the contribution of farmers to plant genetic resource stewardship. Farmers' Rights are defined as:

> rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions (Annex II, Resolution 5/89).

The Resolution went on to provide more specifically that Farmers' Rights were vested in the international community in order to:

- ensure that the need for conservation is globally recognised and that sufficient funds for these purposes will be available;
- assist farmers and fanning communities, in all regions of the world, but especially in the areas of origin/diversity or plant genetic resource, in the protection and conservation of their plant genetic resources, and of the natural biosphere;
- allow farmers, their communities and countries in all regions, to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources, through plant breeding and other scientific methods.

Farmers' Rights were intended to provide "legal and economic symmetry to the global system governing access to and development of plant genetic resources" (Cooper, 1993). In other words, the Farmers' Rights concept was intended to promote a more equitable relationship between the providers and users of germplasm by creating the basis for farmers to share in the benefits derived from germplasm they have developed and conserved over generations (Glowka *et al.,* 1994).

The International Fund for Plant Genetic Resources, envisaged in Resolution 3/91 (Annex III), was in part designed to create the means to implement Farmers' Rights. The International Fund would support plant genetic

continued on the next page

Box 1. Renegotiation of the FAO International Undertaking on Plant Genetic Resources

continued from the preceding page

conservation and utilisation programmes, particularly, but not exclusively, in developing countries. Since conservation and sustainable utilisation of plant genetic resources at the time were viewed "as a pressing and permanent need ... the resources for the international fund as well as for other funding mechanisms should be substantial, sustainable and based on the principles of equity and transparency". Through the Commission on Plant Genetic Resources, the donors of genetic resources, funds and technology were to have determined and overseen the policies, programmes and priorities of the fund and other funding mechanisms, with the advice of the appropriate bodies. For a variety of technical and political reasons, however, the fund has yet to be established.

To complement the Undertaking within the Global System, international agreements have been negotiated by the Commission on Plant Genetic Resources or are being negotiated by the CGRFA. One is relevant to access to genetic resources.

The International Code of Conduct for Plant Germplasm Collecting and Transfer, was adopted by the FAO Conference in November 1993 (Resolution 8/93). It provides guidelines for collecting and transferring plant genetic resources to facilitate access and promote their equitable use and development. It is a rich source of information for countries contemplating access legislation and provides an ethical framework for collectors and institutions which handle plant genetic resources.

Agreements have been and are currently being negotiated with various States and institutions, such as the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR), to place their base or active *ex-situ* collections of plant genetic resources under the auspices of FAO as part of an international network of *ex-situ* collections pursuant to article 7 of the Undertaking.

The primary goal of the International Network of *Ex-situ* Collections under the Auspices of FAO is to provide a clear legal framework for the material included and to resolve the problems associated with the legal status of the materials. It is hoped that this will better ensure the accessibility and proper management of *ex-situ* collections of plant genetic resources particularly important to global food security. Over thirty States originally expressed their willingness to participate in the network[1], including 12 IARCs of the Consultative Group on International Agricultural Research[2].

Strictly a voluntary decision, participation in the international network entails an agreement to ensure the safe conservation of designated germplasm and its availability for plant breeding and research purposes, while respecting the rights of the providers of germplasm.

Resolution 3 of the Nairobi Final Act, the instrument by which governments adopted the Convention on Biological Diversity in May 1992, recognised the need to seek solutions to outstanding matters concerning plant genetic resources within the FAO Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture, in particular (1) access to *ex-situ* collections not acquired in accordance with the Convention; and (2) the question of Farmers' Rights (see appendix 1).

The FAO Conference subsequently initiated an intergovernmental process within the Commission on Genetic Resources for Food and Agriculture to (1) harmonise the International Undertaking with the Convention, (2) regulate access to plant genetic resources for food and agriculture and (3) realise Farmers' Rights.

---

[1] Argentina, Bangladesh, Chile, Costa Rica, Czech Republic, Denmark, Ethiopia, Finland, France, Germany, Indonesia, India, Italy, Japan, Iraq, Madagascar, Netherlands, Norway, Pakistan, Philippines, Russia, Senegal, Spain, Sweden, Switzerland, Syria, Togo, Tunisia, United Kingdom, Uruguay and Yemen.

[2] These are CIAT, CIMMYT, CIP, ICARDA, ICRAF, ICRISAT, IITA, ILCA, INIBAP, IPGRI, IRRI and WARDA.

continued on the next page

Box 1. Renegotiation of the FAO International Undertaking on Plant Genetic Resources

continued from the preceding page

FAO has regularly informed the Conference of Parties (COP) to the Convention on the progress made in the negotiations and the COP has given its support. For example, COP Decision 11/15 recognised the "special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions". COP Decision III/11 noted that the "various options for the legal status of a revised International Undertaking on Plant Genetic Resources, which include a voluntary agreement, binding instrument, or protocol to the Convention on Biological Diversity, have not been decided upon by the [FAO]." The FAO was requested by the COP to inform it of the outcome of the negotiations. The COP also affirmed its willingness to consider a decision by the FAO Conference that the renegotiated International Undertaking should take the form of a protocol to the Convention once it is revised.

The COP has repeatedly called for the speedy revision of the International Undertaking. The re-negotiations of the International Undertaking began in November 1994 within the Commission on Plant Genetic Resources and have continued within the CGRFA.

In a broad sense, facilitating access and eliminating or minimising restrictions to all genetic resources imply that a Party should consider:

- clarifying the legal status of genetic resources;
- developing a uniform policy on access to genetic resources and benefit-sharing; and
- adapting existing legislation and administrative procedures or, where appropriate, creating new laws and procedures, to establish clear jurisdictional and administrative competencies and efficient access procedures.

In addition, the negotiation of multilateral international agreements with other States, such as the International Undertaking, could facilitate access to genetic resources while ensuring benefit-sharing.

Bilateral agreements could establish a more detailed access and benefit-sharing relationship between two or more States. They might be useful especially to build a framework of trust, cooperation and reciprocity between States. For example, the rights and obligations of natural and legal persons providing and using genetic resources might be defined clearly, regardless of whether the States are "providers" or "users" of genetic resources (see section 2.1.5).

The most immediate indirect benefit of facilitating access and minimising or eliminating restrictions will be to increase the probability that genetic resources within areas under a State's jurisdiction will be used. This should increase the likelihood that benefits will be created and these can then be shared. In other words, benefits can be created only if genetic resources are used sustainably. Facilitating access to genetic resources and minimising restrictions should facilitate their use. The critical factor is finding a balance which ensures that the benefit-sharing interests of a Party are protected while encouraging access and subsequent sustainable use.

2.1.3 Access Subject to Mutually Agreed Terms (article 15(4))

Article 15(4) conditions access to genetic resources on reaching "mutually agreed terms" between the Party providing genetic resources and a potential user. "Mutually agreed terms" implies a negotiation between the Party granting access to genetic resources and an entity which wants to use genetic resources. A successful negotiation, in other words reaching mutually agreed terms, could result in an "access agreement".

Access agreements — sometimes called contracts (Laird, 1993), material transfer agreements (Barton and Siebeck, 1994) or research agreements (Reid *et al.*, 1993) — will likely become the primary means to (1) authorise access to genetic resources, (2) control subsequent use and (3) establish the return of benefits from their subsequent use.

Access agreements could be negotiated for access to *in-situ* and *ex-situ* genetic resources. In fact, they could be simply appended to other permits or authorisations related to obtaining biological resources or to their subsequent use. A good example are permits required for research, collecting or export.

The Convention on Biological Diversity uses the phrase "mutually agreed terms" exclusively in rela-

tion to the States and regional economic integration organisations party to it. This, in combination with the call in other Convention articles for benefit-sharing with the Contracting Parties providing genetic resources, makes it easy to overlook the fact that access agreements could be negotiated with providers other than the State, such as communities, individuals and private institutions (see sections 2.3 and 3.4.2.2.1). The subtle ambiguity created by the Convention may require clarification where all genetic resources are not owned by the State itself (Glowka, 1997).

In almost all cases, the State is sovereign over the genetic resources in areas within its jurisdiction, even though it will not always be the owner. Where it is the owner the State could enter into an access agreement for genetic resources in areas within its jurisdiction.

The sovereign rights of a State over genetic resources in areas within its jurisdiction also allows it to subject to review private or communal agreements granting access to genetic resources which are not owned by the State. Furthermore, it implies that the government could then reach mutually agreed terms with the potential user in addition to any private or communal conditions negotiated. This could be reflected in a separate agreement between the State and the potential user, or in a tripartite agreement between the private or communal provider, the potential user and the State.

The situation may be complicated especially in federalised or regionalised States with potentially conflicting jurisdictional competencies over genetic resources, or where there are conflicting public, private or communal property regimes over biological resources (see section 3.2.1.1).

2.1.4 Access Subject to Prior Informed Consent (article 15(5))

According to article 15(5), access to genetic resources is also subject to the prior informed consent (PIC) of the Party providing the genetic resources. This means that *prior* to a potential user gaining access to genetic resources under the jurisdiction of the State, it must obtain the *consent* of the government based on *information* provided by the potential user, such as how the genetic resources will be used subsequently (Glowka *et al.*, 1994).

In effect, reaching mutually agreed terms could be part of a larger access determination process (Glowka, 1997) (see section 3.4 and figure 2). The process could be overseen by a designated competent authority and would lead the authority to make an access determination — a decision to grant or deny access to the genetic resources within its competency.

When determining its approach to implementing article 15(5), a Party providing genetic resources may want to take into consideration four things. First, and most importantly, the Convention on Biological Diversity establishes PIC as the norm "unless a Party provides otherwise" (see article 15(5)). However, it is important to consider that achieving benefit-sharing will be difficult without the adaptation of existing laws and administrative procedures, or the creation of new laws and administrative procedures, which regulate access to genetic resources, the source of genetic material.

Many States may already have in place legislation which subjects legal or natural persons to a regulatory procedure to obtain a permit to collect, undertake research on or export *biological resources.* A major consideration is whether this legislation, and the institutions which implement it, is sufficient to control access to *genetic resources* and to ensure subsequent benefit-sharing via an access agreement.

Second, all uses of biological resources can potentially lead to gaining access to genetic material. However, it will not be possible to subject all uses of biological resources to the PIC process. Therefore, discretion must be exercised to determine to which materials, suppliers and uses the PIC procedure will apply (see section 3.2). For example, a distinction could be made between *in-situ* and *ex-situ* genetic resources, public and private or communal suppliers or commercial or non-commercial uses.

Third, it is not enough to simply regulate access. While it may seem self-evident, this is not the purpose of article 15. In fact, the Convention does not require restrictions on the use of genetic resources *per se.* Instead, it merely affirms that a government has authority to determine access.

To take full advantage of article 15(5), a Party providing genetic resources must link regulating access to benefit-sharing. An access agreement will ensure this link but the direct and indirect benefits sought from the potential user need to be identified. The benefits sought might be part of a larger plan for benefit-sharing developed during a planning process (see section 2.4.1).

Fourth, simplicity of process will be critical to successfully linking access to benefit-sharing. This is not only implicit in article 15(2) (facilitate access to genetic resources), but it may make good business

sense as well. Except perhaps in the case of valuable endemic species, potential users will almost always be able to find other sources (though not necessarily of the same quality). Future benefits could be outweighed easily by heavy transaction costs created by an inefficient bureaucratic procedure.

In addition, many States which could supply genetic resources potentially have limited capacity to create new regulatory processes. Therefore, it will be important for them to consider how to ensure benefit-sharing by the most cost effective and efficient means possible.

2.1.5 Legislative, Administrative or Policy Measures to Share Benefits (article 15(7))

Article 15(7) may be the most overlooked provision in the Convention on Biological Diversity and all Contracting Parties will need to consider carefully its implementation. *Each* Contracting Party is to take legislative, administrative or policy measures which aim to achieve fair and equitable benefit-sharing, subject to mutually agreed terms, with the Parties providing genetic resources.

Article 15(7) is interesting because its implementation raises important policy and practical considerations for developed and developing country Parties with regard to their responsibilities to support the implementation of the Convention's access and benefit-sharing provisions in other Parties. There has been little discussion within, and no decision by, the Conference of Parties to the Convention on this issue.

This particular issue is important to address because, overall, the access debate has been defined primarily in North-South terms: genetic resources originating in the South benefit the North with little direct benefit returning to the South. The Convention on Biological Diversity demonstrates the commitment of the international community to remedy this inequity.

In some cases, however, southern genetic resources have benefitted the south. Northern genetic resources have benefitted the north. In addition, northern genetic resources have benefitted the south. In these instances, who should benefit and how is far from clear. This is the case for plant genetic resources for food and agriculture (PGRFA) used in plant breeding. The issues surrounding benefit-sharing for PGRFA are being addressed multilaterally by the FAO Commission on Genetic Resources via the renegotiations of the International Undertaking on Plant Genetic Resources (see box 1) primarily because of the interdependency of the world on a handful of major food crops.

A strict reading of the text indicates that as a "user" of genetic resources, a Party is obliged by article 15(7) to take action aimed at fair and equitable benefit-sharing. Furthermore, in order to give full effect to PIC and to ensure benefit-sharing, sole action by the Party from which genetic resources are provided — the primary focus of article 15 and upon which the primary burden of implementation falls — will probably not be sufficient (Hendrickx *et al.*, 1993).

This is due to the relative ease with which genetic resources can be obtained illicitly, exchanged and used, particularly for environmental samples taken to obtain microbial genetic resources. High transaction costs for States from which genetic resources are provided may result as they try to enforce prior informed consent and mutually agreed terms and ensure benefit-sharing. In many cases these countries simply will not have the capacity to do this.

Therefore, measures in both Parties from which genetic resources are provided *and* Parties within which genetic resources are used will be necessary. In fact, as any Party can be both a provider and user of genetic resources, measures taken to give effect to article 15(7) should best address both situations and apply to nationals and non-nationals alike (Glowka *et al,* 1994).

The important point is that for the benefit-sharing provisions of the Convention to work properly, actions tailored to support States from which genetic resources are provided, and consequently the ultimate providers of genetic resources such as indigenous and local communities, will be required. In other words, what is needed is more equitable *bur*cfeft-sharing between Parties from which genetic resources are provided and those within which they are used (Glowka, 1997). This would promote an atmosphere of good will, reciprocity and equity between the key providers and users of genetic resources.

A first step might be to develop a combination of policy, legal and economic actions targeted at commercial and non-commercial users of genetic resources. This will catalyse the process of crystallising the new global ethic represented by the access and benefit-sharing provisions of the Convention and more clearly define the responsibilities of non-commercial and commercial users of genetic resources.

The success of article 15 will very much depend on the professionalism of scientists, collectors, *ex-situ* conservation facilities and industry to ensure that

their work lives up to the spirit of the Convention, even if genetic resources originate from one of the States which has not yet ratified the Convention (Glowka, 1996). Consequently, in the policy area, for example, education and awareness campaigns could be established by States with commercial and non-commercial user communities to foster among them a better understanding of the need to seek prior informed consent and negotiate mutually agreed terms.

Dialogues between private sector genetic resource users and stakeholders from provider States could be a useful means of undertaking education and awareness. Dialogues have already taken place in the European Union (ERM, 1996), Germany (BMU, 1996) and Spain (EC and BMU, 1998). Well conceived and facilitated dialogues could establish a clearer understanding of the needs of commercial and non-commercial users of genetic resources and the providers of genetic resources, while building good will and lowering uncertainty. Such dialogues could provide the basis for subsequent elaboration of professional or industrial best practices or codes of conduct. These would not only heighten awareness among users of genetic resources, but would create a standard against which the conduct of users could be judged.

Professional or industrial best practices might one day provide the basis for end-users to voluntarily police themselves, and their suppliers, thereby avoiding "biopiracy", in other words, the removal and subsequent use of genetic resources without prior informed consent and mutually agreed terms. For example, a multinational company might require a local supplier, or an intermediary such as a botanic garden, to demonstrate that the genetic resources to be supplied have been acquired with the prior informed consent of the State from which the genetic resources are provided. States with commercial and non-commercial users of genetic resources could provide economic or other incentives to encourage the appropriate behaviour of the user community operating within their jurisdiction.

To make voluntary measures feasible, States from which genetic resources are provided must do their part by making it easy for those seeking access to navigate any regulatory process in force especially by making it clear from whom they must seek and obtain prior informed consent (see sections 3.3 and 3.4.2.2.1). It is especially important that the legal status of genetic resources within the country is also clear (see section 3.2.1.1). To support this States with commercial and non-commercial user communities could cooperate with provider States by providing financial and other resources for enabling activities in the areas of planning, legislation and institutions.

But while it may tempting for States with commercial and non-commercial users to rely solely on voluntary measures to ensure PIC and MATs, because there is typically a hesitancy to regulate the private sector, legislation will always be required to fill-in gaps and provide a margin of safety when users stray.

On the legal front, States with commercial and non-commercial users of genetic resource could require them to develop a policy on the acquisition of genetic resources and subsequent benefit-sharing. Legislation could provide indicative criteria for developing a policy. These could draw on international best practice. Economic incentives could be provided to support this.

Measures on subsequent use could be contemplated which ensure prior informed consent. For example, genetic resource users might be required by legislation to maintain registers of sources from which genetic resources were obtained and which were used subsequently (Hendrickx *et al.*, 1993). *Ex-situ* conservation facilities could be required to establish that genetic resources accepted for deposit have been obtained with the prior informed consent of the State providing them (Glowka, 1996).

Other legal measures might require potential users of genetic resources operating within the jurisdiction of a State, whether they are legal or natural persons, to obtain prior informed consent prior to acquiring genetic resources. Penalties and remedies for importation and subsequent use without prior informed consent could be provided.

More complicated measures might include legal requirements for importers to demonstrate export has been pursuant to the prior informed consent of the exporting State. Import controls could coincide with existing customs and biosecurity controls (such as quarantine regulations for plants and animals). Bilateral or multilateral agreements could be negotiated between States to establish the basis for cooperation in this area. For example, within the OECD Germany proposed in 1996 the negotiation of a code of conduct on the illegal transfer and use of genetic resources without prior informed consent (von Websky, 1998). The proposal was subsequently rejected however.

The existence of prior informed consent could also be established through application processes to grant intellectual property rights (IPRs) or product approval and licensing. Ideally, an application would not be accepted, or an approval would not be granted, until prior informed consent and mutually agreed terms had been confirmed. There would be at least three practical effects from this.

First, the origin of the genetic resources upon which the intellectual property or product is based could be established, something which current IPR systems or licensing systems do not require presently. Evidence of PIC could be supported ultimately through an international certificate of origin system (Tobin, 1997c). Second, an incentive would be created for genetic resource users to comply with the spirit of the Convention on Biological Diversity and the letter of existing access laws. Third, the need for overly burdensome regulatory regimes in States from which genetic resources are provided could be eliminated, consequently access to genetic resources would be facilitated.

States which provide genetic resources, and which are reviewing their IPR regimes for compliance with the rules of the World Trade Organisation under the Agreement on Trade-related Aspects of Intellectual Property Rights, could catalyse action by the international community on the issue by modifying their IPR application procedures to support the Convention's implementation.

Finally, the effectiveness of all of these proposed measures would depend on the States from which genetic resources are provided, or the legal and natural persons within their jurisdiction, having access to the court system of the State in which the genetic resources are used.

2.2 Benefit-sharing (articles 15(6), 15(7), 16 and 19(1) and (2))

The ability to ensure benefit-sharing is the primary advantage which accrues from controlling access to genetic resources. In fact, the primary rationale for article 15 is to create the broad international legal and policy framework for benefit-sharing to take place between the Parties of the Convention.

Access and subsequent use of genetic resources provide indirect and direct benefits. An example of the former include the benefits individuals, communities and nations receive from the use of their genetic resources, such as those from enhanced food security created by the sharing of plant genetic resources for food and agriculture. More direct benefits include those provided by targeted technology transfer in joint ventures or renumeration (cash or in-kind) from the commercial development of a particular end-product developed from the genetic resources provided. Indirect and direct benefits can be characterised as short-term (or up-front), medium-term and long-term (King *et al.,* 1996).

The extent to which indirect and direct benefits can be generated, captured and allocated may be related to (1) the nature of the resources at issue, (2) the end use (3) the particular mechanism employed to guarantee benefit-sharing and (4) the transaction costs involved.

The Convention lists some examples of benefits which could be shared. For example, article 15(6) provides for participation in scientific research. Article 15(7) provides for sharing fairly and equitably research and development results and commercial and other benefits derived from genetic resource use. Access to and transfer of technology making use of genetic resources is provided for in article 16(3). Article 19(1) provides for participation in biotechnological research activities based on genetic resources. Article 19(2) provides for priority access to results and benefits arising from biotechnological use of any genetic resources provided.

Unfortunately, none of the benefit-sharing provisions of the Convention require actual benefit-sharing. This probably reflects the political reality that most benefits contemplated for sharing will be generated by the private sector, even though public or governmental actors may also use genetic resources. While the benefit-sharing provisions of the Convention apply only between its Parties (States and REIOs), Parties will need to organise their approach to benefit-sharing for genetic resources in conjunction with the private sector. This is made clear by article 16(4).

Article 16(4) requires *each* Contracting Party to apply appropriate legislative, administrative or policy measures whose aim is for the private sector to facilitate "access to, joint development and transfer of technology...for the benefit of both governmental institutions and the private sector of developing countries". The paragraph refers back to article 16(3) which deals with access to and transfer of technologies making use of genetic resources provided by a Party. The "private sector" is not defined. In general, access is to be on mutually agreed terms (article 16(3)). Terms for technologies subject to intellectual property rights (IPRs) protection are to recognise and be consistent with the adequate and effective protection of IPRs (see box 2).

In all cases benefit-sharing is to be on mutually agreed terms. This implies case by case negotiation typically between a provider and potential user (or an intermediary). Depending on the circumstances the parties negotiating the agreement could be a government, a community, an individual or industrial user. Where foreign users of genetic resources are involved, bilateral or multilateral cooperation agreements between the States at issue could provide a framework of principles within which negotiations could take place for benefit-sharing.

Box 2. Intellectual Property Rights Relevant to Technology Transfer

Intellectual property rights (IPRs) are private legal rights which apply to the intangible human contribution that goes into producing a particular technology. Legislation and case-law create the legal right and define its scope. In its most basic form, an intellectual property right allows its holder to control others' commercial use of the intellectual information embodied in the technology during the life of the IPR. In effect, the holder has a legal monopoly over the commercial exploitation of the intellectual property for a specified period of time and, therefore, the technology which embodies it. As a result, potential users must seek the holder's permission before commercially using the intellectual property. Permission is typically granted, and technology transfer effected, pursuant to a licensing agreement.

There are many forms of intellectual property rights which are relevant to the Convention. Copyrights, for example, are extended to scientific publications, computer software and databases. This box focuses on three which are particularly relevant to technology transfer pursuant to the Convention: patents, trade secrets and plant breeders' rights. The scope of the holder's right varies with each.

Patents

Patents can be granted for any process, machine or composition of nature which is novel, useful and embodies an inventive or non-obvious step. An inventor is given a private monopoly of fixed duration to restrict others from making, using or selling the invention. In exchange for the patent, the patent's subject matter must be published.

The international treatment of patents has been through the Paris Convention for the Protection of Industrial Property which is administered by the World Intellectual Property Organisation (WIPO). The Paris Convention does not create an internationally enforceable patent right. Rather, patent protection remains a phenomenon of national legislation and case law. Therefore, the extent of patent protection varies by State. For example, as matters of public policy many States do not allow living organisms to be patented. The United States first confirmed the extension of utility patent protection to living organisms in 1980. In so doing, it initiated a debate in other OECD countries as to whether they should offer similar protection. In addition to the moral questions which extend to the patenting of life-forms is the issue of restricted access to modified genetic material which has been patented.

The term, scope and enforcement of international patent protection was discussed in the negotiations which led to an Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). The TRIPs Agreement stipulates that the term of patent protection in GATT member States shall be no less than twenty years from the filing date of the patent application (article 33). In a separate part which applies to all forms of intellectual property covered by the agreement, general enforcement obligations (article 41), civil and administrative procedures and remedies (articles 42-49), provisional measures (article 50), special requirements related to border measures (articles 51-60) and criminal procedures (article 61) are also specified.

Trade Secrets

Trade secrets are used to protect subject matter which is either unpatentable because it does do not fit the criteria for a patent or because the holder does not want to publicly publish the subject matter for fear that a commercial competitor will use the information to the holder's disadvantage. Once information is publicly disclosed, the holder can no longer claim the information secret and the ability to control others' use could be lost. For example, the ability to subsequently apply for and be granted a patent may be affected by the public disclosure of the information.

Trade secrets can be applied to a wide range of information. For example, scientific information or a traditional healer's knowledge could be protected (see box 6). Biological materials subject to material transfer agreements can also be protected through trade secret law. In general, trade secret protection is only against acquisition, disclosure or use of information or materials in a manner contrary to honest commercial practices. Unlike a patent, trade secret protection does not prevent others from developing and using the same information by other independent means, for example by reverse engineering. Their existence and enforcement vary from State to State. In some States, the unauthorised disclosure and subsequent use of trade secrets is linked to unfair competition laws.

continued on the next page

Box 2. Intellectual Property Rights Relevant to Technology Transfer

continued from the preceding page

Trade secret protection as a means against unfair competition is recognised at the international level in article l0bis of the Paris Convention. The TRIPs Agreement (article 39) requires member States to protect trade secrets (known in the agreement as "undisclosed information") as well.

Plant Breeders' Rights

Plant breeders' rights (PBRs) are recognised internationally through the 1961 International Convention for the Protection of New Varieties of Plants as amended in 1978 and 1991 (UPOV). Member States are expected to grant and protect breeders' rights at the national level for plant varieties which are new, distinct, uniform and stable (article 6(1)). In contrast to the 1978 text, the amendments adopted in 1991, expand the scope of the breeder's right in two instances.

In the first instance, the original minimum scope of the PBR gave the breeder the right to exclude others from commercially marketing or selling the protected variety's propagating material (seed, for example) (article 5(1)). This had the effect of implicitly creating a "farmer's privilege". The privilege allowed a farmer who buys the protected variety's seed to save the seeds from the resulting crop for subsequent use the following year without paying additional royalties to the plant breeder. The 1991 text extends the PBR to all production — commercial or otherwise — theoretically eliminating the farmers' privilege (article 14(1)). The 1991 text, however, allows UPOV members in their national legislation to limit the scope of the PBR and, therefore, recognise a farmer's privilege after all (article 15(2)).

In the second instance, the 1991 text, as does the 1978 text, recognises a breeder's or research exception (article 15(l)(iii)). Within the research exception, the protected variety can be used by other breeders as the basis for creating new, protectable varieties without prior authorisation. Therefore, unlike patenting genetic material, the PBR does not limit others' access to the plant variety's genetic material to create new plant varieties. Consequently, the UPOV Convention helps ensure unrestricted access to modified genetic material.

The scope of the research exception, however, has been limited in the 1991 text by the introduction of a new concept: essential derivation. Under the 1991 text, the exploitation of new varieties developed from a protected variety is subject to the original breeder's right when the new variety is very closely related to the protected variety and, therefore, contains virtually all of the protected variety's genes (article 14(5)).

The concept of essentially derived varieties was created to close a loophole in the breeders' right which is likely to widen with the use of genetic engineering in plant breeding, and to improve the breeders' position in relation to the owner of a patent on a product or process for transformation of plants. It was felt improper that the breeder of a variety, on the one hand, should be deprived of fair renumeration for his efforts by another person who would add but one useful characteristic to the variety and exploit the resulting new variety, while the patent owner has, on the other hand, a right to exclude the breeder (or any other person) from using the patented product or process. The new concept will enable the breeder to exclude the patent owner (or any other person) from exploiting the transformed variety, if it falls within the narrow limits of essential derivation. Authorisation to use or exploit will be given through licenses, with payment of a royalty being a likely term of the license.

By whatever means, the end result should be an arrangement, manifested in an access agreement, which is fair and equitable. What is fair and equitable will change with the circumstances. But it could be measured by the relative contributions to the partnership of each party to the agreement based on the genetic resources provided, any associated knowledge or information, investment capital or labour.

The terms of benefit-sharing are likely to be different in each case. In some cases it may not be possible to determine at the time of the access agreement negotiation either the genetic resources involved, since they have yet to be collected, or the types of subsequent use contemplated, since end-products have yet to be determined. A final user, whether commercial or non-commercial, may not yet be evident. Even with this uncertainty effective benefit-sharing can be ensured and provided for in the access agreement.

For example, technology transfer can be sought without knowing how genetic resources will be used. This could take the form of research participation and

sharing research results or hard technology transfer. The providing State could be acknowledged in publications and local scientists could be co-authors.

Advanced payment or per sample fees could also be established. Minimum royalties as a percentage of sales of a future end-product could be provided for, while keeping in mind that the probability of receiving direct financial benefits is very small for plant genetic resources for food and agricultural used in traditional plant breeding and relatively low for other uses of genetic resources.

Future unforeseen end-products, applications or other contingencies could be provided for an access agreement. For example, it is standard practice in industry to transfer biological and genetic materials for research purposes pursuant to a material transfer agreement. This is typically on the condition that prior to commercialisation the user is to return to the provider to negotiate, in good faith, a benefit-sharing arrangement with the latter. Reporting requirements could be incorporated into an access agreement to track subsequent use. Third party transfers could be controlled in the same manner, perhaps by being subject to PIC. Finally, the access agreement could include a clause whereby the user of genetic resources is required to recognise or list sites or countries of origin when applying for intellectual property protection.

In summary, the access agreement should at minimum aim to establish and protect the commercial and non-commercial interests of those who are entitled to provide genetic resources.

2.3 Indigenous and Local Communities (articles 8(j) and 10(c))

The access provisions of the Convention, and its more detailed provisions on benefit-sharing, are directed to the Parties providing genetic resources. Depending on the legal system of the State, and from where genetic resources are to be acquired, providers other than the State, such as indigenous and local communities, may be entitled to claim a fair and equitable share of benefits derived from genetic resources. Some of the same principles outlined in article 15 — such as prior informed consent and reaching mutually agreed terms — could be applied to facilitate this, although this is not required explicitly by the Convention.

In many parts of the world, indigenous and local communities are the grass-roots stewards of genetic diversity. They actively conserve, manage and use wild genetic resources. They may have also developed over many generations new plant varieties, animal breeds and strains of micro-organisms through informal, but scientifically valid and economically valuable, techniques.

Innovative human-manipulated genetic resources, as well as a rich library of innovative knowledge and practices related directly to the use of biological resources, have been valuable especially in modern agriculture, industry and medicine. Few direct benefits have gone back to the communities in exchange (Posey, 1996a).

Article 8(j) requires, *inter alia*, Contracting Parties to:

- respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles;
- promote their wider application with the approval and involvement of their holders; and
- encourage equitable sharing of benefits derived from their use.

The provisions of article 8(j) are directed to the individual home State of indigenous and local communities referenced (Wolfram and Stoll, 1996). Their implementation is subject expressly to national legislation. This qualification was introduced to preserve the legal relationships some States had established with indigenous peoples prior to the completion of the Convention (Chandler, 1993). The qualification may mean that the provisions of article 8(j) will not be self-executing in some States. Therefore, new or existing legislation must be implemented or relied upon to bring the provisions of article 8(j) into effect.

Indeed, depending on the circumstances, some of the options to implement article 8(j) may need to be implemented in conjunction with policies or legislation which provide individuals and communities — whether indigenous or local — certain rights under the law. Among others, these could be associated with ownership of genetic and biological resources, rights of use, land and sea tenure, intellectual property, cultural identity, legal recognition, legal personality and the right to associate. The explicit guarantee of these rights will help individuals and communities maintain their knowledge, innovations and practices, clarify rights over access and benefit-sharing and help ensure that those who profit from using their knowledge and innovations share equitably and fairly the benefits from that use. Because the scope of article 8(j) is greater than article 15 which focuses only on genetic resources, separate comprehensive legislation guaranteeing these rights should be the starting point for any future access and benefit-sharing legislation to address the knowledge, innovations and practices associated with genetic resources.

Even though its language is perhaps not as strong as many activists would have liked, especially because of the proviso regarding national legislation, article 8(j) signals an important acknowledgement by the international community that the knowledge, innovations and practices of indigenous and local communities are valuable, especially to "modern" society. And, as holders of knowledge, innovations and practices, indigenous and local communities have a right of consent prior to their wider application and are entitled to share equitably and fairly in the benefits derived from their use by others.

The challenge will be for Parties to develop appropriate policies and legislation to ensure consent and encourage benefit-sharing for genetic resources and associated knowledge, innovations and practices, while minimising the tendency to simply see these as just another resource to appropriate easily (see section 3.2.5.1.2 and box 6).

Work being currently undertaken at the global level can guide the process of implementing article 8(j) as it relates to genetic resources and associated knowledge, innovations and practices of indigenous and local communities. Relevant fora include the Conference of Parties to the Convention on Biological Diversity, the United Nations Working Group on Indigenous Populations, the intergovernmental process initiated by the United Nations Commission on Human Rights mandated to consider the Draft United Nations Declaration on the Rights of Indigenous Peoples (see box 3) and the on-going renegotiations of the International Undertaking on Plant Genetic Resources, where the concept of Farmers' Rights is being addressed (see box 1). Human rights processes and instruments may also may also be useful sources of guidance.

In addition, work focusing on indigenous communities should draw on the aspirations of indigenous peoples themselves. A number of declarative statements made by indigenous people before and after the entry into force of the Convention on Biological Diversity have been reviewed. The main rights demanded by indigenous peoples with regard to genetic resources and associated knowledge include those related to self-determination or control, territory, prior informed consent, cultural rights and the recognition or renegotiation of existing treaties with States (Posey, 1996a).

Access policies and legislation can empower indigenous and local communities by giving them greater control over genetic resources located in areas that they inhabit or use and associated knowledge, innovations and practices. But policy-makers should keep in mind that imprecise and insensitive drafting and implementation could provide the basis for further disempowerment by, for example, affecting adversely the customary use and exchange of genetic resources within and between communities. Indigenous and local communities have customarily used and exchanged genetic resources for a variety of economic, cultural and religious purposes, and they still do.

Article 10(c) requires Parties to protect and encourage traditional cultural practices involving customary use of biological resources (provided they are compatible with conservation and sustainable use requirements). This provision is a natural corollary to article 8(j). It requires Parties to consider customary use as they develop their future policies and legislation on access to genetic resources. For example, measures taken to control access to genetic resources to ensure benefit-sharing should not impede customary use and exchange of genetic resources.

Box 3. Fundamental Principles for Indigenous and Local Community Control Over Genetic Resources and Associated Knowledge

In many instances, indigenous and local communities may be the ultimate providers of wild or domesticated genetic resources because the genetic resources sought are located in *in-situ* or *ex-situ* conditions within the areas that they inhabit or use. These communities may also be the ultimate providers of knowledge associated with a particular genetic or biological resource which is targeted for collection.

Article 8(j) of the Convention on Biological Diversity (see section 2.3) does not distinguish between indigenous and local communities. Posey (1996b) notes however that indigenous and local communities are distinguishable from each other and have different political needs and aspirations: "Indigenous peoples want separate political and ethnic identities from the state within which they live. Traditional societies, local communities and farmers do not seek these rights." Nevertheless, Posey points out that indigenous and local communities share some characteristics in common as well. For example, genetic resources and associated knowledge are not privately owned, but are typically shared within the communities.

continued on the next page

Box 3. Fundamental Principles for Indigenous and Local Community Control Over Genetic Resources and Associated Knowledge

continued from the preceding page

Indigenous and local communities also have common concerns with regard to genetic resources and associated knowledge. For example, based on the principles of prior informed consent and equitable benefit-sharing they seek:

- the right to control the physical access of outsiders to the land and sea areas that they inhabit or use and where genetic resources are located; and
- the right to control access to and subsequent use of genetic resources and associated knowledge.

Existing international legal instruments provide an important source of fundamental principles upon which legal frameworks can be premised. The instruments from the United Nations Conference on Environment and Development, such as the Convention on Biological Diversity, Agenda 21 and the Forest Principles, provide few references to local control over biological or genetic resources and associated knowledge. They reaffirm State sovereignty over natural resources (Shelton, 1995; Posey, 1996a). International human rights instruments, however, can provide a supplemental "bridge" by supplying fundamental principles for legislation (Shelton, 1995).

For example, the right of peoples to freely dispose of their natural wealth and resources, found in the 1966 International Covenant on Economic, Social and Cultural Rights (article 1)) and the 1966 International Covenant on Civil and Political Rights (article 1 (2)) is fundamental to the ability to control access to genetic resources. This right can be interpreted as a basis for establishing a right of prior informed consent. Furthermore, the right of peoples to freely dispose of their natural wealth and resources is especially important for the indigenous peoples because this right derives from the broader right of self-determination, a "cornerstone" right indigenous peoples are trying to achieve worldwide (Posey, 1996b).

For the knowledge associated with genetic resources, the most important basic human right may be the right to recognition of interests in scientific production found in the 1948 Universal Declaration on Human Rights (article 27(2)) and the 1966 International Covenant on Economic, Social and Cultural Rights (article 15). This right could encompass protection of and control over individual and communal scientific achievement or intellectual property (Shelton, 1995).

Rights over genetic resources and associated knowledge also need to be supported by other rights for indigenous and local communities including those related to culture, legal recognition, legal personality, the ability to associate and contract, legal standing and the right to information and participation in decision-making.

From international environmental and human rights law, including International Labour Organisation Convention 169 Concerning Indigenous and Tribal Peoples in Independent Countries (1989), a "bundle of integrated rights" related to both genetic resources and associated knowledge have been delineated within a United Nations forum in collaboration with indigenous peoples. This bundle of rights has been drawn together and reflected in the Draft United Nations Declaration on the Rights of Indigenous Peoples (1993).

The draft Declaration was developed within the Working Group on Indigenous Populations of the UN Sub-Commission on Prevention of Discrimination of Minorities. It was submitted to an open-ended inter-sessional working group of the UN Commission on Human Rights for negotiation by member States of the United Nations. It was created by indigenous peoples within a United Nations forum for governments ultimately to adopt and implement. The Draft Declaration exemplifies an integrated approach to the rights and aspirations of indigenous peoples.

Among other things, the Draft Declaration recognises that the rights of indigenous peoples must also extend to ownership and control over genetic resources and associated knowledge. For example, article 26 confirms that "Indigenous peoples have the right to own, develop, control and use the land and territories, including the total environment of the lands, air, waters, coastal seas, sea-ice, flora and fauna and other resources which they have traditionally owned or otherwise occupied or used." In addition, article 29 states "Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property ... They

continued on the next page

Box 3. Fundamental Principles for Indigenous and Local Community Control Over Genetic Resources and Associated Knowledge

continued from the preceding page

have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts."

The principles the draft Declaration embodies, as well as those in a subsequent document adopted by the Working Group which provides principles and guidelines for the protection of the heritage of indigenous peoples (UN Sub-Commission on Prevention of Discrimination and Protection of Minorities, 1994), could provide the basis for legislation even before the Draft Declaration is adopted by States.

2.4 Other Relevant Convention Articles

Articles 6, 7, 8, 9, 11, 13 and 14 of the Convention on Biological Diversity provide the basis for a comprehensive approach to genetic resource access and benefit-sharing. The policies and goals reflected in these provisions should be considered in any comprehensive approach to ensuring benefits from access to genetic resources.

2.4.1 National Biodiversity Strategies, Plans or Programmes (article 6)

Article 6 relates to national biodiversity planning (Miller and Lanou, 1995). Parties are required to develop national strategies, plans or programmes to conserve and use sustainably biological diversity or adapt existing ones for this use (article 6(a)). The conservation and sustainable use of biological diversity is also to be integrated into relevant sectoral and cross-sectoral plans, programmes and policies (article 6(b)).

Whether through a comprehensive treatment of all aspects of the conservation of biodiversity and the sustainable use of its components, or through a more focused sectoral plan, a planning process will help to organise and implement an approach to genetic resource access and benefit-sharing (Glowka, 1995). Initiating a planning process on access and benefit-sharing issues could lead to appropriate comprehensive policies and legislation in these areas.

A salient point that should not be overlooked is that the process is just as important as the access and benefit-sharing plan that results. It will be critical to the effective implementation of the plan. A critical criterion is making the planning process highly participatory by involving the people, institutions and economic sectors — sometimes called stakeholders — which will be most affected by the plan. Participation then becomes a mechanism for building the political and social consensus needed to implement policies and, where necessary, legislation.

Indeed, the very nature of genetic resources — in particular their wide availability and distribution, ease of dissemination and replication — may demand that national policies, legislation and institutions reflect a consensus for action among the various constituencies which are knowledgable about, control or use genetic resources. A consensus of action will be crucial particularly where genetic resources are available from a number of different sources within a State (see box 5).

The list of possible stakeholders will vary with the country but may include:

- governmental agencies (e.g., environment, natural resource, agriculture, technology, health and customs agencies);
- industry (e.g., pharmaceutical, agricultural or other biotechnology-oriented businesses);
- the scientific and academic communities;
- animal and plant breeders;
- botanic gardens, zoos and microbial culture collections and other *ex-situ* conservation facilities such as gene banks;
- indigenous and local communities or their representative organisations;
- private land owners; and
- relevant non-governmental organisations and concerned citizens.

Because many genetic resources may be shared, the planning process should ensure the participation of neighbouring communities and regions within the country. Genetic resources may also transcend territorial boundaries between States. A planning process might even provide the basis for initiating regional cooperation with other States (see box 4).

All of these stakeholders have useful information and perspectives to contribute. They will help shed light on the practical realities of determining access to genetic resources and ensuring benefit-sharing.

When stakeholders are identified, goals can be clarified. Goals should be a primary output of the process, keeping in mind that they may vary depending on the type of genetic resource. Important issues to consider might include:

- linking access and benefit-sharing to the country's conservation, technological and development goals;
- ensuring national food security;
- reviewing mechanisms to ensure genetic resource use is linked to benefit-sharing;
- linking conservation measures to access agreements to avoid unsustainable use of biological resources which are targeted as genetic resources;
- determining where benefits generated should be directed, such as back into conservation;
- identifying where capacity building may need to take place in terms of benefit-sharing or administering any subsequent regulatory programme;
- ascertaining the economic viability of various access and benefit-sharing options;
- considering and providing for the particular needs and aspirations of indigenous and local communities;
- identifying and minimising the transaction costs of access determinations and associated benefit-sharing;
- identifying the scope of access legislation; and
- identifying public, private or communal property issues and the legal status of genetic resources.

It is also important to consider the supply strategy for genetic resources. In other words, will the country be a low cost/high volume supplier of "raw" genetic resources, or a value added supplier offering not only samples, but information as well (Reid *et al.,* 1995)?

Mechanisms to attain the goals can be then identified. At this point, a legal and institutional profile could be undertaken to ascertain which laws and which institutions' portfolios intersect with, and apply to, genetic resources (Glowka, 1998). International obligations should also be identified. Once this is completed new legal and institutional arrangements can be contemplated and devised if appropriate.

In the meantime, existing law and institutions might be used as "stop-gaps" until more specific policies, legislation and institutions can be established. Legislative stop-gaps could be combined with administrative measures, such as modifying the terms of reference of a relevant agency if need be. Stop-gap measures are especially important to consider because the planning process and implementing comprehensive new measures may be time consuming and expensive. Stop-gap measures can also be used to regulate access, ensure benefit-sharing while establishing a planning process for more in-depth treatment of the issues later.

2.4.2 Identifying and Monitoring the Components of Biological Diversity (article 7)

A cornerstone of any strategy to provide genetic resources and ensure benefit-sharing is identifying and monitoring the components of biological diversity, the processes which affect them and organising the information collected as required by article 7 of the Convention. The information collected will contribute to the overall efforts to conserve biological diversity and use its components sustainably. Furthermore, the ability to negotiate mutually agreed terms prior to granting PIC might also be strengthened as the ability to ascertain independently the potential use or value of a particular genetic resource increases.

In the context of access to genetic resources the information generated could be used in a number of ways. One application may involve establishing the conservation and sustainable use parameters for collecting. Parties to the Convention are to take steps not only to identify possible threats to biological diversity (article 7(c)), such as collecting, but also take steps to regulate or manage them (article 8(1)).

The Convention identifies collecting for *ex-situ* conservation purposes as an activity which could require regulation and management if it poses a threat to ecosystems or *in-situ* populations of species (article 9(d)). The information gathered could contribute to the conservation and sustainable use of target organisms collected from *in-situ* sources, as well as the non-target species which may depend upon them.

Other applications for information generated by identification and monitoring activities include adding value to genetic resources and identifying new uses for genetic resources. By developing its capacity to characterise the genetic resources within its jurisdiction, a State will develop a better understanding of their potential uses. The information collected could also contribute to processes designed to add-value to genetic resources supplied from *in-situ* and *ex-situ* sources. In short, information can increase the chances that genetic resources are used. Increased use might then actually strengthen the ability of a

State to conserve biological diversity by providing an additional economic incentive to support conservation and sustainable use (WRI, IUCN and UNEP, 1992).

For these reasons, legislation on access to genetic resources should either contain provisions on identification and monitoring, or support other legislation implementing the Convention which provides for identification and monitoring (see section 3.7).

2.4.3 *In-situ* Conservation (article 8), Sustainable Use (article 10) and Environmental Impact Assessment (article 14)

Access to genetic resources intersects with a number of *in-situ* conservation and sustainable use issues both for a target organism, the particular habitat in which it resides as well as associated organisms. Underlying these issues is the need to determine the environmental impact of a proposed activity which would be in keeping with the article 14 of the Convention.

There are two points in time when collecting activities may endanger the conservation status of a target organism. The first is at the point of initial collection. The second is after researchers discover that materials collected have interesting properties, and need to collect more materials for further study.

Collecting for genetic material will probably not threaten the conservation status of an organism because only small amounts of biological materials are needed and genetic material is easily replicated. In contrast, collecting for interesting biomolecules, such as secondary metabolites, may present a different situation when initial exploratory collecting yields interesting compounds and more source material is required. For example, intense collecting may endanger the conservation status of a target organism where an interesting compound it produces is not synthesisable or the organism itself cannot be cultivated or farmed. This may especially be the case for plants (Leaman *et al.*, 1997) or animals with medicinal properties. Marine organisms are potentially threatened because those targeted tend to be slow growing (Paine, 1996).

The problem is potentially compounded if the target organism is already threatened or endangered. The trade provisions of the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) may become relevant if the materials collected are for export.

Micro-organisms provide interesting additional situations to consider when considering the potential conservation threats collecting might present. For example, it appears that the use of a micro-organism may not diminish a fixed stock of that organism, especially if the micro-organism is readily culturable. However, there may be instances where the use of a micro-organism is unsustainable because of the impact of the use on its habitat or the impact on other mutualistic or non-mutualistic organisms it is associated with it.

For instance, sampling in extreme or unique environments may be an unsustainable use without precautions to minimise the introduction of alien or non-indigenous micro-organisms (Nadis, 1997; Castenholz, 1996; Holmes, 1996; Noble Wilford, 1996). In addition, sustainability may need to be considered where collectors need large quantities of a macro-organism to obtain useful quantities of a secondary metabolite produced by a mutualistic micro-organism as is typical in many marine situations (Paine 1996; Glowka, 1996). If the secondary metabolite is not readily synthesisable and the micro-organism is not culturable, then harvesting the macro-organism at unsustainable levels could threaten both it, the micro-organism as well as the particular ecosystem (Garson, 1996; Paine, 1996; Anderson, 1995).

Because of the threats collecting may present, proposed access legislation should be generally harmonised with the legislation or regulatory provisions to maintain the conservation status of biological resources (see CBD article 8(c)). Legislation required by article 8(k) of the Convention on Biological Diversity for the protection of threatened species and populations should also be considered. Articles 8(k) and (l) of the Convention focus on minimising impacts to the target organism itself.

Measures may also need to be taken relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity overall (article 10(b)). In other words, the impacts on other organisms of taking the targeted material need to be considered and minimised or eliminated. This reflects one aspect of the Convention's "ecosystem approach" to conserving biodiversity and use sustainably its components (Glowka *et al.*, 1994).

Finally, access legislation may also need to be harmonised with legislation on habitat protection including that for protected areas. Protected areas are attractive particularly for collecting because their protected status may provide collectors with a reliable and continuous source of genetic and biochemical resources. In some cases protected areas have an infrastructure which allows readily repeatable collecting opportunities (Laird and Wynberg, 1997). Harmonising access legislation with the habitat protection and protected area goals of a State will better ensure that collecting activities will not threaten

unique habitats or conflict with the management objectives of a protected area.

In all three instances, environmental impact assessment (article 14(a)(l)) may help identify the possible impacts of a particular collecting activity before it occurs. Environmental impact assessment could be used to identify situations which could lead to over-exploitation as well as unsustainable practices. It may be most useful to apply progressively EIA requirements as the level or intensity of collecting activities increases to minimise the regulatory burden. The effective application of EIA will require an application for access to genetic resources to include such basic information as species targeted, collecting and storage methods (see sections 3.4.1 and 3.8).

2.4.4 Incentive Measures (article 11)

Parties to the Convention on Biological Diversity are to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of biological diversity. In addition to overcoming the inequities between providers and users of genetic resources, negotiators of the Convention envisioned fair and equitable benefit-sharing as an important incentive for conserving biodiversity and using biological resources sustainably at the national and sub-national levels.

Access and subsequent use of genetic resources provide indirect and direct benefits (see section 2.2). To create incentives for conservation and sustainable use, indirect and direct benefits must be identified and a balance must be found in their appropriation and distribution (Reid *et al.,* 1995).

The first steps toward delineating such a balance, and thereby creating appropriate incentives, may depend on initiating a planning process (see section 2.4.1) for access to genetic resources and benefit-sharing. Among other things, the planning process could identify areas where benefit-sharing could be targeted to satisfy certain needs within the country.

For example, a government may want to target benefit-sharing to bolster capacity in biotechnology. Therefore research participation, training and hard and soft technology transfer may be sought as a condition of access.

Other constituencies may have their own particular needs. For example, indigenous or local communities may have concerns and priorities different, but no less important than, those of the government. In other words, indigenous and local communities may want to use their rights over genetic resources and associated knowledge, innovations and practices to capture benefits more relevant to their immediate needs. These might include, for example, establishing a local development fund for a new school, health facility or the acquisition of farming aids.

The important point is that the planning process can be used to identify the priority areas where benefits could be directed, as well as identify and avoid potential conflicts in the allocation of benefits well in advance of the initiation of the PIC process by a potential user. In both cases, access to genetic resources will be facilitated (see section 2.1.2) because a clear vision, premised on a set of priorities, will have already been identified. It can be articulated to the potential user and then tailored to the particular request for access.

2.4.5 Public Education and Awareness (article 13)

It should come as no surprise that the success of the access and benefit-sharing measures will depend on public education and awareness. The "public" in this case could be providers of genetic resources within the country, as well as users both within and outside the country.

Steps towards education and awareness start early in the planning process when major stakeholders come together to discuss a way forward. In addition to being a very good exercise in the building of public awareness in its own right, the planning process should uncover appropriate target groups and mechanisms to ensure their education and awareness in this area. Possible target groups might be governmental administrators, industry, professional bodies, institutions such as botanic and zoologic gardens, aquaria and other *ex-situ* conservation facilities and indigenous and local communities.

Indigenous and local communities, in particular, may benefit from public education and awareness activities related to access to genetic resources and benefit-sharing. For example, public education and awareness through outreach programmes to educate communities on their rights within the country with regard to their genetic resources and knowledge and how to negotiate benefit-sharing agreements will help ensure a "level playing field" when access is sought by others. Community individuals may benefit from

"parataxonomist" training and subsequent employment to collect biological materials when undertaken in conjunction with a long term identification and monitoring effort or bioprospecting initiative within their region (Reid *et al.,* 1993).

Because many Parties may not have the financial, technical or human resources to develop and execute a full fledged educational programme, developing a public education and awareness campaign in this area may need to be linked to other important aspects of biodiversity conservation and sustainable use. The planning process could identify the possibilities for this. In addition, possible partnerships with the schools, local NGOs, local scientific institutions, such as botanic gardens and zoos, as well as the private sector could be identified. They could provide a cost-effective way to achieve public education and awareness goals in this area.

Education and training will also be necessary to start the regulatory machinery in motion once appropriate legislation and institutional structures are in place and applications for access to genetic resources are submitted. A regulatory programme cannot implement itself automatically. Therefore, the different actors overseeing any future access determination procedure will need to learn how to operate the procedure early on. Proper education and training will ensure that these people know what to do when a particular situation presents itself. This will minimise delays. This is an especially important point for applicants when they can choose any number of other States to fulfil their genetic resource needs.

3.0 The Content of National Access Legislation for States Providing Genetic Resources

Worldwide there has been a significant amount of planning and legislative activity at the regional, national and sub-national levels dealing with access to genetic resources since the Convention on Biological Diversity entered into force. An informal survey indicates activities in the Andean Pact States of Bolivia, Colombia, Ecuador, Peru and Venezuela (both regionally and nationally), Argentina, Australia (at the Commonwealth level and in the states of Western Australia and Queensland), Brazil (including the state of Acre), Cameroon, Costa Rica, Eritrea, Ethiopia, Fiji, The Gambia, Ghana, India, Indonesia, Kenya, Laos PDR, Lesotho, Malawi, Malaysia (including the state of Sarawak), Mexico, Mozambique, Nigeria, Philippines, Seychelles, South Africa, Republic of Korea, Tanzania, Turkey, United States of America and Zimbabwe.

A comparative analysis of existing and draft access legislation indicates that access provisions are being incorporated into five groups of legislation. The first group comprises general environmental framework laws. Examples include The Gambia (National Environmental Management Act (1995)), Kenya (Draft Environmental Management and Coordination Bill (1995)), Malawi (Environmental Management Bill (1996)), Republic of Korea (National Environmental Preservation Act (1991) as amended (1994)) and the Uganda (National Environmental Statute (1995)).

These tend only to be enabling in nature. As enabling laws, they all merely charge a competent national authority to examine the issue in order to provide more specific guidelines or regulations sometime in the future. The draft and final African laws are based on a standard model developed by the United Nations Environment Programme. They charge a national authority to develop measures on regulating the export of germplasm, benefit-sharing and access fees. However, with the exception of Malawi, they do not clearly establish the principles that access to genetic resources shall be on mutually agreed terms (MATs) and subject to prior informed consent (PIC).

The second group includes framework sustainable development, nature conservation or biodiversity laws. These include laws in Costa Rica (Wildlife Conservation Law (1992)), Eritrea (Second Draft Eritrean Proclamation on the Conservation of Biological Diversity (1996)), Fiji (Draft Sustainable Development Bill (1997)), Mexico (Environmental Act (1996)) and Peru (Law for the Conservation and Sustainable Use of Biodiversity (1997)). A 1993 FAO Technical Report (TCP/SEY/2253) provided recommendations and drafting instructions for possible conservation and national parks legislation and regulations in Seychelles with a component on bioprospecting.

Generally, the access provisions in this group tend to be more detailed than the framework enabling environmental legislation described earlier. In all cases they clearly establish the MAT and PIC principles. The biodiversity laws are particularly interesting because they are intended to comprehensively implement the Convention on Biological Diversity.

A third group consists of dedicated or stand-alone national laws or decrees on access to genetic resources. This group is characterised by the most comprehensive pieces of access legislation surveyed. The only finalised example identified is the Philippines Executive Order 247 (1995) and Department of Environment and Natural Resources Administrative Order 96-20 (Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources) (1996).

A fourth group is characterised by the modification of existing laws and/or regulations to better reflect genetic resource access and benefit-sharing issues. Only two examples have been identified at the national level both regarding national parks. In Nigeria, there is a proposal to modify the National Parks Act of 1991 (Draft National Parks Decree (1996)) to establish prior informed consent prior to bioprospecting in Nigerian national parks. In the United States of America there is a proposal to revise Code of Federal Regulations Title 36(2.5) which deals with research specimens removed from national parks.

At the sub-national level two examples have been identified. In Western Australia legislation has been enacted to explicitly clarify the authority of the state government under the Wildlife Conservation Act (1950) and the Conservation and Land Management Act (1984) to enter into exclusive agreements for the removal of forest produce (including soil) or flora to promote the use of flora for therapeutic, scientific or horticultural purposes (Part 3, Conservation and Land Management Amendment Act (1993)). In Malaysia, the state of Sarawak amended its Forest Ordinance to require written approval from the Director of Forests prior to the removal or export of any tree part to be taken from listed areas for producing or developing any pharmaceutical product or medicinal compound (section 65A).

The fifth group includes actions taken at the regional level. The only existing example is Decision 391 of the Andean Pact which creates a common regime on access to genetic resources. The Pact Decision, which upon its publication in July 1996 became law in all five member states, provides a minimum set of rules for each member state to implement. More detailed national legislation can be implemented provided it does not fall below the standard set by the Decision.

The approaches taken to date with existing or draft access legislation concentrate only on excluding potential users from physically accessing genetic resources located within the jurisdiction of a country without a permit or license. This is sometimes supplemented with measures to control genetic resource exports.

The creation of informational rights (such as intellectual property rights) in wild or "unimproved" domesticated/cultivated genetic resources has not yet been manifested in national law and it is unlikely unless technical problems related to describing genetic resources and accurately identifying rights holders are overcome. At least for the time being, future access legislation will likely to continue to focus on methods of exclusion and embargo.

The final content of access legislation will depend on many State-specific considerations. Planning processes and the international legal obligations of the State will influence access legislation.

Practical considerations may be the biggest factor shaping access legislation. Careful consideration must be given to the legal status of genetic resources, the extent of bioprospecting activities currently in the country, the anticipated demand for genetic resources and what technical, administrative and financial resources are or will be available to develop and execute a regulatory regime. Other considerations might include:

- past experiences as a source of genetic resources;
- the perceived value of genetic resources ;
- whether genetic resources are shared with other States;
- the parallel existence of the State's genetic resources in *ex-situ* collections outside the country; and
- the capacity to add-value to genetic resources.

A well planned approach which is simple and cost-effective to implement, with clearly delineated rights over genetic resources, will ensure that transaction costs do not outweigh future benefits gained.

While every State is different, comprehensive future access legislation will undoubtedly share many similarities. For example, access legislation is likely to have to:

- specify principles, objectives and definitions;
- identify scope of application and clarify the legal status of genetic resources;
- establish or designate appropriate institutions to determine and enforce access; and
- outline an access determination procedure.

Legislation may also include provisions on export controls, sanctions and penalties, identification and monitoring, conservation and financial issues.

Drawing on the emerging legal frameworks, some of the legislative and institutional approaches States have been taking since the entry into force of the Convention on Biological Diversity will be highlighted. A broad set of principles and criteria from which sub-national, national or regional legislation could be fashioned can be delineated from State practice.

Box 4. Regional Approaches to Developing Access Legislation

A regional approach to creating access and benefit-sharing legislation for genetic resources may offer advantages for States which share particular genetic resources within a region by providing the basis to establish minimum principles upon which the legislation can be based. As a result, a regional approach may facilitate the creation of legislation which is more closely harmonised than if each individual State worked in isolation.

A regional approach may be attractive because it offers several opportunities for participating States to cooperate on genetic resource access and benefit-sharing issues. Perhaps most importantly, a regional approach could reduce competition between States for benefits when policies and legislation are harmonised. It may also provide the basis for reciprocal treatment between participating States, whereby the interests of each cooperating State are mutually supported by the group. Among other benefits, restrictions on the movement of genetic resources between cooperating States could be reduced and a foundation for facilitating access to the nationals of cooperating States could be provided.

continued on the next page

Box 4. Regional Approaches to Developing Access Legislation

continued from the preceding page

A regional approach may also enable participating States to develop a common regional strategy for adding value to genetic resources supplied, including identifying and sustainably using genetic resources. Regional capacity building needs could be identified. Research, training and technology transfer could be promoted. Regional mechanisms, such as a common fund, could be created to ensure that all participating States benefit when genetic resources common to one or more States are used. Finally, a common enforcement mechanism could be established.

Regional approaches have been initiated in South-east Asia and in the Andean Region of South America.

In 1992, South-east Asian countries began meeting to discuss access and benefit-sharing issues in order to identify common concerns and goals. These discussions led to the Manila Declaration (1992), which was subsequently endorsed by the Bukittinggi Declaration (1992), and the Melaka Accord (1994).

In 1996, a group of scientists and legal and governmental representatives from Indonesia, Malaysia, the Philippines, Thailand and Australia, met in Kuala Lumpur and developed guidelines to facilitate access to "biological resources" and the equitable sharing of benefits within the region (UNESCO and Malaysian Natural Products Society, 1996). In the guidelines, access to biological resources broadly includes collecting specimens from *in-situ* sources, undertaking research in libraries, museums, herbaria or other research institutes and gathering ethnobiological information.

The first three instruments establish that (1) biological resources are to be used sustainably and that (2) fair and equitable financial returns are to be used to conserve biological diversity and to promote research and sustained development in the region.

The guidelines are operationally-oriented. They are built around five themes — legislation, administration, licensing, implementation and communications. They establish principles that each country in the region is supposed to consider as they develop their approaches to access and benefit-sharing:

- the development of legislative measures to facilitate responsible access to biological resources by foreigners and nationals;
- the creation of a single, effective coordinating or administrative body to ensure that legislative measures are implemented;
- the adoption of a national system of licenses for foreigners and nationals who plan to access biological resources;
- the establishment of implementation measures such as efficient licensing and prior informed consent processes, as well as mechanisms to protect the rights of indigenous and local communities and ensure their compensation; and
- the contribution to regular regional communications relating to access issues.

An annex provides guidelines for drafting an access licence. The twenty-two principles of the annex focus on primarily procedural issues. The guidelines relate to obtaining a licence, collaboration with local scientists, the need for an environmental impact assessment, work in protected areas, over-collecting, prohibitions on collecting rare or endangered species, the content of a licence application and reporting requirements for licensees.

Interestingly only one principle addresses collecting or research with a commercial intent. It establishes the need for "equitable partnerships" in accordance with articles 15 and 16 of the Convention on Biological Diversity. The guidelines therefore treat collecting or research with a commercial intent merely as a subset of a range of collecting and research activities involving biological resources in general. Consequently, the guidelines provide the basis for creating holistic legal regimes to regulate the collection of and research on biological resources which can supplement any existing biological resource-based collection, research and export legislation in a particular country.

continued on the next page

Box 4. Regional Approaches to Developing Access Legislation

continued from the preceding page

The Andean Pact Common Regime on Access to Genetic Resources, established by Andean Pact Decision 391, is presently the only example of a regional regime to regulate access to genetic resources. The Andean Pact is a regional economic and political integration organisation formed in 1969 by treaty between Bolivia, Colombia, Ecuador, Peru and Venezuela.

Upon its entry into force for all Pact member states in July 1996, Decision 391 established a legally binding minimum framework of rules common to all member states for regulating access to genetic resources. The formal approval of the respective national legislatures was not required.

Common regimes also exist in the Andean Pact for industrial property (Decision 344, Common Regime on Industrial Property) and plant breeders' rights (Decision 345, Common Regime on Plant Breeders Rights). However, unlike the others, Decision 391 was unique for the Andean Pact because its three year development process included a participatory non-governmental phase and a governmental experts phase.

The primary political and economic justification for the Common Regime was the need to prevent unnecessary conflicting interests among member states over generally shared, easily accessible genetic resources found widely throughout their territories.

The Decision applies to (1) genetic resources of which member states are countries of origin, (2) derivatives (such as biochemicals) and (3) associated "intangible components" — any knowledge related to the genetic resources or derivatives sought. It also applies to the genetic resources of migratory species which by natural circumstances are found within and taken from the areas of jurisdiction of a member state. Human genetic resources and traditional exchange of genetic resources between indigenous and local communities are excluded from the Common Regime.

The Decision confirms that *genetic resources* are either the patrimony of the Nation or property of the State (article 6) depending on national legislation. It also confirms that *biological resources* which contain genetic resources or derivatives that are sought can be subject to the private or collective property rights of individuals or indigenous and local communities.

In addition, the Decision 391 recognises the rights of indigenous and local communities over their knowledge, innovations and practices associated with genetic resources and derivatives. The right to control access to indigenous and local knowledge, innovations and practices rests with the communities themselves, but is subject to national legislation (article 7).

The Common Regime is based upon a basic procedural principle: legal or natural persons seeking access are to negotiate an access contract with the competent authority of the member state in which genetic resources are sought (article 32). The access contract must have obligatory conditions for access such as technology transfer, national capacity building and restrictions on third party transfer of materials.

Complementary agreements must be negotiated with the providers of biological resources when they are sought as a source of genetic resources or derivatives (article 6). When intangible components are associated with the resources sought, such as the knowledge, innovations and practices of indigenous and local communities, the providers have the right to negotiate an agreement for use.

Any resulting access contract with the competent national authority is to incorporate the complementary agreements with the providers or owners of biological resources. Agreements with the holders of associated knowledge are annexed to the access contract with the competent authority (article 35).

Benefit-sharing provisions regarding commercial or industrial use of genetic resources or derivatives will be negotiated by the competent authority with the applicant. When only the State has rights over genetic resources,

continued on the next page

Box 4. Regional Approaches to Developing Access Legislation

continued from the preceding page

benefit-sharing provisions will have to take into consideration the interests of the physical providers of biological resources, especially if they are indigenous and local communities (article 34).

National or regional funds are mechanisms which member states need to consider in order to ensure that benefit-sharing is actually realised within and between member states (First Complementary Disposition).

Presently, Andean Pact member states are developing national secondary legislation to ensure the adequate implementation and enforcement of the Common Regime at the national level. National legislation will deal with such issues as the structure and establishment of a competent national authority, defming procedural aspects and sanctions.

3.1 Principles, Objectives and Definitions

Sections on principles, objectives and definitions are common features of legislation.

3.1.1 Principles

A recitation of the fundamental principles (or policies) upon which the access legislation is founded could be included. For example, a principles section might emphasise:

- the sovereign rights of the State over natural resources in areas within its jurisdiction and the authority of the government to determine access to genetic resources;
- access to genetic resources is subject to prior informed consent and mutually agreed terms of a competent authority;
- the transparency of any access determination process;
- the rights of indigenous and local communities over genetic resources located within the areas they inhabit or use, as well as their associated knowledge, innovations and practices;
- access to genetic resources must conform with conservation or sustainable use legislation and reflect a precautionary approach;
- some of the goals of benefit-sharing including technology transfer and capacity building; or
- the desire to cooperate with other States to facilitate access to genetic resources and ensure benefit-sharing.

3.1.2 Objectives

A section on objectives may specify the goals to achieved through the access legislation. These may be one output of a planning process on access to genetic resources (see section 2.4.1).

Some objectives to achieve through the access legislation could include:

- establishing a permanent participatory planning process to address access and benefit-sharing issues;
- equitably sharing the benefits derived from the use of genetic resources, and associated knowledge, with providers;
- developing the capacity to research, identify, monitor, conserve and sustainably use genetic resources;
- conserving genetic diversity and sustainably using genetic resources;
- achieving economic and social development and poverty education; or
- providing a legal and institutional framework for international cooperation in this area.

3.1.3 Definitions

Future access legislation might include a definitions or use of terms section to define and clarify terms used. Legal instruments often use definitions to give an agreed, specific meaning to certain terms which may recur throughout the text.

Most terms may be readily understood and may not need to be defined. However, at least three scenarios can be envisioned with regard to whether a particular term should be defined. First, a term may need to be defined when its meaning is unclear. Second, a term may be defined when the drafters of a legal instrument decide that the meaning of terms should differ from normal usage. Third, a term may be defined in order to define the scope of the instrument.

In many cases, drafters will not need to invent new terms and definitions for the access law. Instead, they will be able to draw on a number of existing documents, such as the Convention on Biological Diversity (see Appendix 1) and the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer, as sources.

Indeed, drafters should be encouraged to draw on these documents as the terms used and definitions provided reflect broad international consensus thereby contributing to the effectiveness of the legislation enacted. Drafters can also draw on legislative examples from other parts of the world for ideas.

"Access to genetic resources" is one term which is not defined by the Convention. Whether or not legislation actually needs to include a definition for this term is a matter of judgment. At least conceptually, however, planners and legal drafters will need to consider what "access" means. The process of doing so may ultimately assist in defining the scope of application of the legislation.

A possible definition might be "to obtain samples of biological or other material containing genetic material from areas within national jurisdiction for purposes of research on, conservation, commercial or industrial application of the genetic material." There are five aspects to this definition.

First, it focuses on genetic material, as opposed to other biomolecules. Therefore its scope is restricted. However, the definition could be easily modified to include biomolecules. A definition of genetic material may be needed and article 2 of the Convention on Biological Diversity could assist here.

Second, access means to physically obtain genetic material.

Third, the definition emphasises samples of material containing genetic material. This implies obtaining a discrete amount of material — whether biological materials or sediments, soils or liquids — or a limited number of specimens for subsequent use, recognising that the amount of material may vary depending on the materials sought or the purposes of the end-use.

Fourth, access is to occur within the national jurisdiction of the State. This could be in terrestrial, aquatic or marine areas.

Fifth, the purposes of access — research on, conservation, commercial or industrial application of the genetic material — are kept broad. The focus is on the use of the genetic material not the sample itself. This acknowledges that genetic resources can be used in variety of applications. Attention is focused on the activities most likely to result in benefit-sharing. They can be distinguished broadly along commercial and non-commercial lines although, admittedly, the lines are quite blurry (see section 3.2.7). In effect, however, the intent of the potential user as to the future use of the material collected or obtained would need to be ascertained.

The four purposes of access that are proposed manifest the intention to exclude from consideration the myriad of other uses for biological resource which would contain genetic material. For example, biological resources which are sold as a commodity for consumption or direct use would not be covered (see section 3.2.4). However, licenses granted with regard to the use or export of a commodity might reference that the authorisation does not include the use of the constituent genetic material.

Therefore if, for example, cut flowers were being exported, the export license might stipulate that the authorisation does not include the use of their genetic material for subsequent propagation (whether by seed, cell culture or any other means). Violating the terms of the permit could be grounds for withdrawal or other sanctions.

3.1.3.1 State Practice

Andean Pact Decision 391 defines "access" broadly. It includes obtaining and using genetic resources conserved *ex-situ* or *in-situ*, derived products (such as biochemicals) or, where applicable, "intangible components" for research, bioprospecting, conservation, industrial application or commercial use (article 1). Intangible components are all individual or collective knowledge, innovations and practices associated with a particular genetic resource or its derived products, whether or not protected by intellectual property regimes (article 1).

As an alternative to defining access some States have chosen to use the terms "prospecting", "bioprospecting" or "biodiversity prospecting" in their legislation. Focusing on a particular activity such as bioprospecting which results in access to genetic resources may help legislative drafters overcome the conceptual difficul-

ties involved in determining what access to genetic resources is and when it occurs. It may also help to broaden the scope of the legislation to include biochemicals, keeping in mind that the Convention only applies to genetic material.

Philippines Executive Order 247, and its accompanying implementation regulations, define prospecting and bioprospecting as "research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived there from to scientific and/or commercial purposes" (appendix A, Executive Order; section 2.1(h)), Implementation Regulations).

In the draft Sustainable Development Bill of Fiji "biodiversity prospecting" is defined as "any activity undertaken to harvest or exploit biological resources for commercial purposes ... [including] investigative research and sampling".

All three examples demonstrate that the legislation applies to more than just genetic material. Included are biochemicals as well. In addition, if the Fijian legislation was read literally, collecting biological resources for almost *any* type of commercial use might be subject to the access and benefit-sharing legislation. It is unclear whether that was the intent of the drafters because this ambiguity may create uncertainty.

For example, if the blossoms of a plant were harvested as a bulk or "biomass commodity" for direct use in an herbal tea or a cosmetic, and not for their genetic or biochemical informational value in a technological application, would harvesting and export trigger the prior informed consent and mutually agreed terms provisions under the legislation? The suppliers of the blossom more than likely have or will negotiate a supply agreement with the user. This will presumably reflect a mutually agreed price to supply a certain quantity of the blossom at a particular price per kilo. They may have to obtain State permits to export the material and the quantity harvested and exported might be subjected to a tax or other levy. Benefits therefore will accrue without creating a new regulatory regime.

However, if for example, cells from the blossoms or seeds from the plants were used as the basis for a cell culture or farm cultivation to mass produce an active ingredient, then they are being used as a genetic resource. Since the process depends on the genetic material of the cell and the metabolic processes orchestrated by it to produce the active ingredient, the use would be subject to the access and benefit-sharing provisions of the Convention.

The intent of article 15 is to fill in a gap for benefit-sharing when genetic material is used. While States can extend the spirit of the Convention to technological applications based on the informational value of useful biochemicals discovered in plants, animals and micro-organisms, extending application of article 15 to biologically-based commodities which already have a market value, are actively traded and are used in end-products with little human intervention or modification may complicate the operation of access legislation. Simply put, the number of transactions, and therefore access determinations, would be overwhelming. Therefore, the primary dilemma faced by the legislative drafter is how widely to cast the scope of application of the legislation.

3.2 Scope of Application

The effectiveness of national legislation will depend on many variables. But defining properly the scope of application of the legislation will contribute greatly to its future success. In fact, defining scope could be the single most important task facing planners and legal drafters as they consider the access issue. Furthermore, though it is important to legislate comprehensively, scope set too broadly may make impossible the effective implementation of the legislation. It could also disenfranchise some potential genetic resource providers and users by making the system too unwieldy. This would only result in lost opportunities for benefit-sharing.

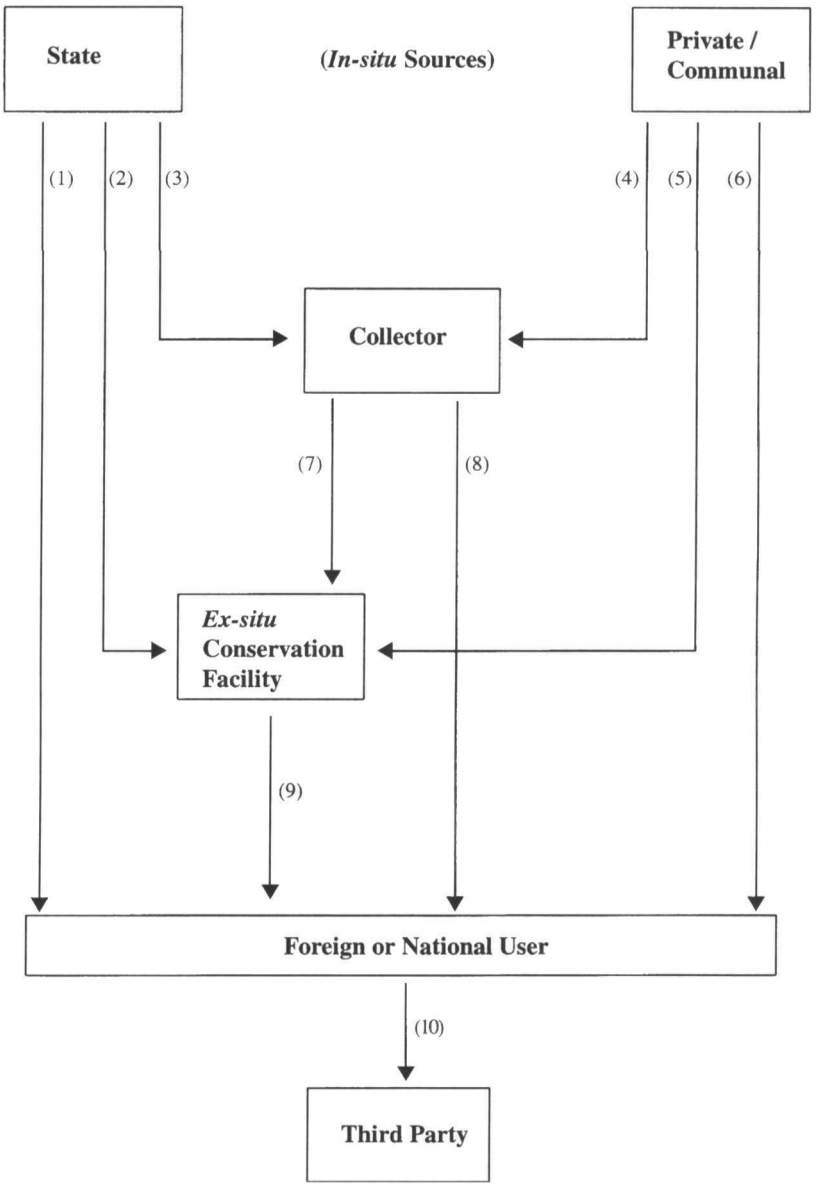
Although the actual drafted legislative text may only be one or two lines, defining the scope of application involves determining the application of the legislation to particular:

- materials and associated knowledge or information;
- geographical locales;
- activities; and
- actors.

Exclusions from the legislation should also be considered.

At the very heart of answering these seemingly simple questions is the need to have a firm understanding of what genetic resources are, their sources (see box 5), the transactions involving them (see figure 1), how they are used and by whom they are used. Furthermore, the scope of legislation will be closely related to the nature of the sovereign rights of the State, limitations placed on their exercise by international law, the property rights system of the State governing ownership of plant, animal and microbial genetic resources, tenure over land and sea areas as well as a number of legal issues related to indigenous and local communities.

Figure 1. Possible Genetic Resource Transactions Which Could be Regulated



Source: Peruvian Society for Environmental Law and IUCN Environmental Law Centre

For these reasons, ensuring that adequate information is available to legal drafters is vitally important. Wide consultations should take place among parties potentially affected by the legislation through a planning process. This will make it easier to develop consensus on policy and, therefore, any legislation. It will also facilitate development of an appropriate and effective regulatory programme if that is determined to be a goal.

3.2.1 Materials and Associated Knowledge or Information to Which the Legislation Could Apply

The application of the legislation to particular materials requires a number of fundamental questions to be answered including determining the applicable:

- types of genetic resources;
- sources of genetic resources;
- derivatives of genetic resources; and
- associated knowledge or information.

Answers to these questions may, in part, depend on the legal status of genetic resources in a country particularly with regard to property rights and accompanying rights of use.

3.2.1.1 Access Legislation Should Clarify the Legal Status of Genetic Resources

Today, in many States, the national constitution is generally the source of law specifying the legal status of biological resources within a country. It appears that genetic resources are not yet referenced specifically in national constitutions. Without this or specific supplementary legislation to clarify the legal status of genetic resources, the legal status of the material in which they are found would normally apply. In spite of this however, uncertainty concerning their legal status may continue since a trend is emerging whereby genetic resources in some States are subject to legal regimes separate from the biological resources in which they are found. Without further clarification, who will be entitled to enter into access agreements will be unclear. This will have a direct bearing on whether the access agreement can be enforced, especially in other States (see section 3.6).

Ideally, according to some observers, the legal status of genetic resources would distinguish between rights over the physical entity (an organism, its parts, including genetic material, or an environmental sample containing whole organisms or parts) and the information embodied by or in the physical entity (Correa, 1994). It is the informational component which is most valuable to bioprospectors (Vogel, 1994; Correa, 1994; Feinsilver, 1995; Swanson, 1995; Stone, 1995). But until such time as the intangible component of genetic resources can be clearly described with sufficient specificity (Correa, 1994) to allow the creation of an informational rights system, legal approaches focusing on the physical entity will probably be the primary means of controlling access to genetic resources and ensuring benefit-sharing. This is so even though subsequent access agreements can specify how the informational content of the genetic resources acquired can be subsequently used and how resulting benefits are to be shared.

Historically, ownership of biological resources has been classified in terms of physical property and associated rights of use. There are four general property regimes: (1) common property, (2) *res nullius,* (3) State or public property and (4) private property.

Common property regimes have been described as analogous to private property regimes where the co-owners are members of a group of people in a community (Lenaola *et al.,* 1996). Common property regimes exist in terrestrial, marine and coastal areas *(Fairlee et al.,* 1995).

Group members have the right to use the property, obligations to maintain it and the power to exclude non-group members from using it (Lenaola *et al.,* 1996). Land, for example, is typically regarded "as a collection of separate and distinct rights to resources which make up the land" (Lenaola *et al.,* 1996). Common property regimes over terrestrial and marine areas have generally been displaced by the *res nullius* concept or State property and private property regimes established by legislation.

Ancient Roman law considered wild animals to belong to no-one (de Klemm, 1993). In other words, they were *res nullius* and anyone could freely appropriate them.

The *res nullius* principle, adopted as it was into legal systems with Roman orgins, has given way to State ownership (de Klemm, 1993). State ownership of biological resources implies that the State alone has the exclusive right to determine how biological resources will be used. In effect, the State would need to authorise others' use of biological resources.

Private property over biological resources can be established in many countries today. The private property owners of biological resources in theory have the discretion to use them the way they see fit. In practice, however, private ownership is nearly always subject to extensive governmental restrictions. In other words, there is no guarantee of unrestricted use when biological resources are privately owned.

In *in-situ* conditions, wild fauna generally have been considered *res nullius* or subject to State ownership, when they are either generally or specifically protected by conservation or use-oriented legislation (e.g., fishing or hunting laws). Domesticated animals may be either publicly, communally or privately owned depending on a country's political system and the circumstances of the institution, community or individual possessing them. Physical property over wild and domesticated or cultivated plants has been tied to the public, communal or private ownership regime of the territory where they are collected (de Klemm, 1993; Correa, 1994).

It is likely that the legal status of micro-organisms growing in *in-situ* conditions has not been clearly established in most jurisdictions, except perhaps for commercially valuable fungi collected for food. It would appear to be tied to the territory where they are collected.

Once a biological resource has been removed from *in-situ* conditions and deposited *ex-situ,* property rights over it will depend on the agreement under which it was removed, or if there was no agreement — which is likely (ten Kate, 1997a) — the legal status of the institution (public or private) in which it

has been deposited. A 1987 FAO report succinctly summarised that plant genetic resources "held in Government gene banks or in those of public institutions belong (subject to any specific exceptions) to the State or to the individual public institution (...) in practical terms, ownership and control are vested in the State" (FAO, 1986). The situation is similar for microbial collections housed in *ex-situ* conservation facilities with the added complication of micro-organisms deposited for patenting purposes in International Depository Authorities pursuant to the 1977 Budapest Treaty on the International Recognition of teh Deposit of Micro-organisms for the Purposes of Patent Procedure (revised in 1980).

In their access legislation, some countries have tried to clarify the legal status of genetic resources. For example, Philippines Executive Order 247 recognises that section 2, article XII of the national constitution "provides that wildlife, including flora and fauna, among others, is owned by the State and the disposition, development and utilization thereof are under its full control and supervision" (preambular paragraph 1).

From ownership over wildlife, it is must then be inferred that the State also owns the constituents of wildlife such as genetic material. This is supported by the statement that ownership of all biological and genetic resources is to remain with the State when materials are removed from the country (section 8.1(16), Implementation Regulations). The State also owns wild fauna and flora found on private or communal land. Apparently domesticated plants and animals are not owned by the State, although this could have been clearly set out in the legislation to eliminate any possibility of confusion. The legal status of biochemicals is also unclear.

It is not clear, but perhaps the phrase "among others" enables the interpretation that wild micro-organisms and insects are also included. The Executive Order defines biological resources to include "organisms or parts thereof" and "micro-organisms" (Appendix A, Executive Order).

The Andean Pact Common Regime specifies that genetic resources and their derived products for which the member state is the "country of origin" are "the goods or patrimony of the Nation or State of each Member Country" (article 6). In other words they can be considered "goods of the State", "patrimony of the Nation", "goods of the Nation" or "patrimony of the State" (article 6). The cumbersome drafting reflects an effort to accommodate the phraseology of the legislation of the five member states (Ruiz, 1997). In all cases, the person seeking access to genetic resources must at minimum enter into an access contract with the competent authority of the member state.

The Common Regime is interesting because it goes on to distinguish between the legal status of biological resources and genetic resources. Biological resources which contain the genetic materials sought can be subject to private or collective property rights. But genetic resources are deemed "inalienable and imprescriptible and cannot be seized, without prejudice to property regimes applicable to the biological resources which contain them, the land on which they are found, or the associated intangible component" (article 6).

While existing private or communal property regimes over biological resources containing the genetic material or derivatives sought are not altered by Decision 391, property owners or holders are not entitled to determine access to genetic resources. However, property owners or holders can control access to genetic resources indirectly by controlling the physical access of a bioprospector to the areas or materials containing genetic resources. This ability to assert control enables these actors to negotiate a share of benefits via "accessory contracts" (see section 3.4.2.3).

3.2.2 Types of Genetic Resources to Which Access Legislation Could Apply

The scope of application of legislation can also be defined according to the types or categories of genetic resources to be regulated. Making such distinctions may provide the basis for creating different access and benefit-sharing regimes for different categories of genetic resources such as those used for food and agriculture purposes and those used in other applications.

Distinctions could be made between wild species or domesticated or cultivated species. The Convention on Biological Diversity defines "domesticated or cultivated species" as species in which the evolutionary process has been influenced by humans to meet their needs" (article 2).

Another distinction might be between plant genetic resources for food and agriculture and other types of plant genetic resources to reflect the outcome of the renegotiations of the FAO International Undertaking on Plant Genetic Resources (see box 1). In the interim period until a multilateral agreement is adopted and enters into force, however, it may be wisest for legislation not to distinguish between access to plant genetic resources for food and agriculture and other genetic resources to ensure that the possibilities for benefit-sharing are not foregone. The types of benefits which could be shared may, however, need to be distinguished.

If genetic resources are distinguished along flora/fauna

lines, access legislation should also clarify whether insect and microbial species are included, since they are potentially very valuable to bioprospectors. Insects are invertebrate animals. Micro-organisms include those groups of organisms, whether detectable with or without the aid of an electron or light microscope. They include viruses, prokaryotes such as Eubacteria (bacteria) and Archaea (archaebacteria), and eukaryotes such as protozoa, filamentous fungi, yeasts and algae (Stackebrandt, 1994).

3.2.2.1 State Practice

The Philippines Executive Order (preambular paragraph 1) and the Costa Rican wildlife legislation (article 3) only apply to wild flora and fauna. In contrast, the Andean Pact Decision has a broader scope.

It applies to all genetic resources for which a member state is a "country of origin" (article 6). The country of origin is the country which possesses genetic resources in *in-situ* conditions, including those taken from *in-situ* sources and found *ex-situ* (article 1). Emphasising the country of origin leaves open the possibility that both wild and domesticated or cultivated species fall within the scope of the Decision, whether or not they are publicly, communally or privately owned.

The draft Eritrean law also applies to wild and domesticated genetic resources (article 46(a)). Suggested legislation for Seychelles would apply to "any" species (section 53(1)).

The Andean Pact (article 4(a)) and Eritrean (article 46(a)) laws specifically state that human genetic resources are not within the scope of application of the legislation. This parallels a decision by the Conference of Parties of the Convention on Biological Diversity which stated that human genetic resources are not within the scope of the Convention (COP, 1995). Therefore, like the Convention, both States leave open the possibility that human genetic resources are still accessible without prior informed consent of or benefit-sharing with the State or the people targeted.

3.2.3 Sources of Genetic Resources to Which Access Legislation Could Apply

Related to the question of which genetic resources could be covered is the question of which sources of genetic resources could be covered by the legislation. Genetic resources can be obtained from both *in-situ* and *ex-situ* sources, whether public, communally or privately owned (see box 5). *In-situ* sources can be terrestrial, aquatic or marine.

3.2.3.1 State Practice

The Andean Pact decision applies to all genetic resources for which the member state is a country of origin, whether these are found in *in-situ* or *ex-situ* conditions within the territory of the State (article 1; article 3).

Article 5 of the Costa Rican Wildlife Conservation Law is similar. Although it does not extend to domesticated or cultivated species, the law still applies to wild fauna and flora which are located *ex-situ*. These respectively remain state owned or national patrimony, therefore access to them would require authorisation from the State.

The scope of application of the Eritrean Proclamation on Biodiversity also includes all genetic resources located *in-situ* or *ex-situ* (article 46(a)).

Protected areas are potentially very good *in-situ* sources of genetic resources. Some access legislation specifically mentions genetic resources located in protected areas. Section 27 of Nigeria's draft National Parks Decree applies to biological materials found in any Nigerian national park. No person is to prospect for genetic material, or remove any biological materials from any national park, without written prior informed consent of a designated minister (article 27(1)).

The legislation of other countries also make special reference to protected areas. Genetic resources can be removed from Costa Rican national parks with prior authorisation (article 43). In the Philippines, bioprospecting of biological and genetic resources is allowed in all categories of protected areas with prior authorisation in conformity with other national law and the rules and regulations of the protected area (sections 4.1 and 4.2, Implementation Regulations).

Though it is not a party to the Convention on Biological Diversity, biological materials removed from national parks in the United States of America remain the property of the US government and are not to be used commercially. As a result of commercial bioprospecting for hyperthermophilic micro-organisms in Yellowstone National Park modifications to the US Code of Federal Regulations (Title 36 (2.5)) and the individual research permit issued by each park superintendent have been proposed (Milstein,

1994; Robbins, 1997). They would allow, for example, the Yellowstone micro-organisms to be collected from its geothermal pools for subsequent commercial use in biotechnological applications. Materials could only be removed from the parks with the prior consent of the individual park superintendent (Lindstrom, 1996).

Box 5. Genetic Resources and Their *In-situ* and *Ex-situ* Sources

The effectiveness of access legislation will depend on identifying accurately the sources of genetic resources. Undoubtedly, every State has a different combination of *in-situ* and *ex-situ* sources. Consequently, a prominent goal of any planning process to develop policies and legislation on access to genetic resources should be the accurate identification of the numerous sources of genetic resources within the State. This might be done in parallel with the identification of bioprospecting activities currently being undertaken in the country.

As part of the planning exercise, it would also be worthwhile to identify other States or institutions which hold the country's genetic resources in *ex-situ* conditions, because these sources are a potential source of competition. In addition, it might be worthwhile to identify those States, perhaps within the region, that have similar or the same genetic resources in *in-situ* conditions, as this knowledge could provide the basis for future cooperation (see box 4).

Once the sources are identified, the individuals, communities or institutions which ultimately provide genetic resources should be included in the planning process as they are a valuable source of knowledge, and an important constituency upon which the effectiveness of the policies and legislation is directly dependent.

***In-situ* Sources**

The *in-situ* sources of genetic resources are those areas 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. The *in-situ* sources for wild species are virtually unlimited. They can be terrestrial, aquatic or marine areas.

Tropical forests and coral reefs are not the only important sources of genetic resources. For example, temperate forests and the seabed are both little explored by bioprospectors but hold enormous promise (Kaesuk Yoon, 1996; Lambshead, 1993; Broad, 1995; Pearce, 1995). Insects are drawing increased interest because of their biochemical defenses.

Micro-organisms are also important sources of Pharmaceuticals and industrial chemicals, such as enzymes. They play key roles in industrial fermentation processes. Important *in-situ* sources of micro-organisms may be extreme environments of high and low temperature, salinity, pressure, pH, desiccation or human-made contamination, the water column of marine and aquatic areas or even on or in the bodies of macro-organisms. Areas with interesting extreme environments include those with volcanic activity. Hot springs, geysers, steam holes called fumaroles and underwater hydrothermal vents are all very attractive for the bioprospecting of micro-organisms. Caves are also attractive for bioprospecting (Nadis, 1997).

The *in-situ* sources of domesticated and cultivated species are perhaps not as varied as those for wild species, but in many cases are closely tied to human cultural diversity. In the case of plant genetic resources, the fields of farmers are rich sources of land races and the margins or surrounding areas are important sources of wild relatives and weedy species. Farmers' fields and grazing areas may also be important sources of animal genetic resources including rare animal breeds.

***Ex-situ* Sources**

The *ex-situ* sources of genetic resources are those where genetic resources are held outside the natural habitat of an organism. For plants, a general distinction is discernable between genetic resources for food and agriculture and wild species.

Facilities dedicated to the *ex-situ* conservation of agriculturally important plant genetic resources can be private or public and have single or multiple species as their target. They may comprise base collections for long term

continued on the next page

Box 5. Genetic Resources and Their *In-situ* and *Ex-situ* Sources

continued from the preceding page

storage and active collections for distribution. These facilities might conserve DNA, tissue culture, seed or whole organisms such as trees. Herbarium specimens and ethno-botanical information may also be collected.

Examples include the International Agriculture Research Centres of the Consultative Group on International Agricultural Research (see box 1), which focus on internationally important commodity species and regionally used species. There is also a growing number of national facilities such as the National Agricultural Research Centres which participate in the Consultative Group system. Some national facilities provide duplicate "safe deposit" storage for national and international collections. In an increasing number of countries, especially in Latin America, national facilities are being privatised. Private companies in the areas of biotechnology and plant breeding also have collections of genetic resources.

Public and private botanic gardens and arboreta increasingly focus on wild plant species, especially those which are threatened or endangered or important for horticulture. Organisms are collected as whole live plants, pressed herbarium specimens and seeds (National Research Council, 1993; Bridson and Forman, 1992). In many cases, ethno-botanical information is collected as well.

As with plants, the *ex-situ* facilities working with animals are distinguishable along domesticated and wild species lines. For domesticated animals, especially those important as agricultural livestock, "the vast majority of livestock genetic resources will continue to be maintained in living flocks, many of which are privately owned" (National Research Council, 1993). Public or private "living farms" maintain rare animal breeds. Gametes and, in some cases embryos, are maintained in cryo-preservation facilities. The main *ex-situ* conservation facilities for wild animal species are zoological gardens and aquaria.

Ex-situ facilities for microbial genetic resources represent the known cultured microbial diversity of the world (Sly, 1994). There are three categories of culture collections: personal or research collections, institutional collections and international service collections (Sly, 1994). Cultures are supplied on demand to microbiologists for education, research and industry (Sly, 1994). Some collections act as International Depositary Authorities (IDAs) where cultures are deposited pursuant to the 1977 Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (revised in 1980) and national law to meet the description requirements for patent protection. As of November 1997, there were 30 IDAs worldwide. Finally, as with plant germplasm, some microbial collections also provide "safe deposit" services to protect against loss of primary collections (Sly, 1994).

3.2.4 Derivatives to Which Access Legislation Could Apply

The benefit-sharing provisions of the Convention on Biological Diversity only apply to genetic material. Consequently, potentially valuable materials, such as biochemicals, sometimes (and confusingly) referred to as "derivatives", are not covered by the access and benefit-sharing provisions of the Convention. Even though the scope of the Convention is limited, States are drafting access legislation to ensure benefit-sharing for useful biomolecules found in the materials for which access is sought. There are two contexts in which the term "derivative" is applicable.

In the first context, derivatives could be described as unimproved or unmodified chemical compounds, other than DNA or RNA, merely associated with targeted biological material, but formed by the metabolic processes of the organism. Like DNA or RNA, these exist in a sample of biological material when it is obtained from an *in-situ* or *ex-situ* source. For example, derivatives in this context might be biologically active chemical compounds found within plant material which is collected, but which are yet to be extracted, modified and used in a technological application.

In the second context, derivatives may refer to DNA or RNA, or a chemical compound, modified, created or synthesised from materials originally obtained from an *in-situ* or *ex-situ* source. The resulting end-product, for example, might be a breeder's hybrid seed, a traditional healer's medicine or a pharmaceutical company's synthetic version of an extracted biochemical. These, then, are end-products derived or synthesised from genetic or biochemical resources through human intervention.

Access legislation could be extended to derivatives used in the first context. This is because the ultimate source of the derivative material is likely to be biological or other materials obtained from an *in-situ* or *ex-situ* source located in an area within the jurisdiction of the State. Therefore legislative drafters only need to ensure that the scope of legislation clearly specifies this. Then it can regulate access to the materials containing the chemical compounds just as it would for genetic material. Regulating access would enable appropriate benefit-sharing arrangements to be negotiated for any subsequent use of the materials taken and used.

Access legislation would be very difficult to extend to derivatives in the second context because the government would in reality be regulating access to technologies. While in theory it is possible to regulate access to all products *subsequently* derived from the genetic material or biochemicals removed from the original source material, in practice it would not seem to be technically or politically feasible.

For example, if in the second context the prior informed consent of the government is required every time a derivative end-product is proposed to be transferred commercially, then it will be practically impossible for the State to control. The technology is likely to be proprietary and may also be subject to intellectual property rights. Furthermore, there is probably no practical way to monitor the transactions, except by putting all public and private research and development, as well as commercial activities, under governmental scrutiny. Another limitation is that there would be no way for the government to subject activities involving the derived products to its regulatory control once they are located beyond the limits of national jurisdiction.

The end-products derived from genetic material or biochemicals removed from *in-situ* or *ex-situ* sources can however be the subject of benefit-sharing arrangements established at the time of the original request for access. Products derived from genetic material or biochemicals supplied pursuant to an access agreement should certainly entitle the provider to benefit-sharing.

In both cases, therefore, it is expedient to ensure that benefit-sharing arrangements cover materials originally derived from materials provided from *in-situ* and *ex-situ* sources. Attention should be focused on regulating activities such as collecting, or acquiring materials from *ex-situ* conservation facilities, to ensure that interests in benefit-sharing are protected through access agreements when materials are removed and subsequently used.

3.2.4.1 State Practice

Even though the scope of the Convention on Biological Diversity is limited to materials containing functional units of heredity such as DNA, States are drafting access legislation to ensure benefit-sharing for useful biochemicals found in the materials for which access is sought.

In the Andean Pact access has been defined to include access to "derived products" from genetic resources (article 1). Derived products include molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms (article 1). Early drafts of the Decision extended the scope of application to end-products synthesised from genetic resources. The final Decision does not subject synthesised products to the access regime (Rosell, 1997).

Access legislation suggested in a 1993 technical report for the Seychelles covers "any species, its parts or elements of genetic or biochemical activity" (section 53(1)).

In the Philippines, the situation is a little less clear. The Philippines legislation defines "by-product" as any part taken from biological or genetic resources including compounds indirectly produced in a biochemical process or cycle (Appendix A, Executive Order; section 2(j), Implementation Regulations). "Derivatives" include extracts from biological or genetic resources such as blood, oils, resins, genes, spores and pollen taken from or modified from a source product (section 2(m), Implementation Regulations). However, neither term appears to be actually used in the legislation's substantive provisions making their application somewhat unclear.

3.2.5 Associated Knowledge or Information to Which the Access Legislation Could Apply

In many cases, knowledge or information associated with genetic resources is quite valuable. Approaches designed to tailor access legislation to apply to associated knowledge or information may need to distinguish between at least two scenarios. First, where access is sought to particular sources of knowledge or information. Second, where valuable information is derived from the genetic resources or information provided.

3.2.5.1 Access to Particular Sources of Knowledge or Information

There are a number of sources of valuable knowledge and information on genetic resources. Perhaps the most notable are (1) indigenous and local communities and (2) the specimen collections, records and databases of *ex-situ* conservation facilities and other institutions.

3.2.5.1.1 Knowledge, Innovations and Practices of Indigenous and Local Communities

The knowledge, innovations and practices of indigenous and local communities are derived from the association with and use of biological resources. Ethno-biological knowledge is valuable in its own right and has been the target of non-commercial and commercial interests in the past.

It is certainly inequitable and, perhaps not politically feasible, for States to attempt to expropriate the individual and collective rights of communities over their knowledge (Ruiz, 1997). Consequently, even though States have sovereign rights over the economic activities within their territories, it is doubtful they could or will exert sovereign rights over the knowledge itself or extend an ownership interest in it. This, of course, depends in part on the political system of a country.

In most cases, however, it would seem that the knowledge of indigenous and local communities would not fall within the scope of the access legislation. In other words, the State would not exert a sovereign right to control access to it in order for it to secure a portion of any future benefits which may accrue. However, States can exert their sovereign powers over the legal and natural persons seeking access to this information. States can also exercise their sovereignty constructively by providing the legal basis for communities to better control their knowledge (see boxes 3 and 6).

By adopting the Andean Pact Decision 391, member states "recognise and value the rights and the power of decision of indigenous, Afroamerican and local communities over their traditional knowledge, innovations and practices associated with genetic resources and derivative products thereof" (article 7). This is to be accomplished through national legislation complementing the Decision. Article 1 defines these communities as "human groups whose social, cultural and economic conditions distinguish them from other sectors of the national community, which are governed totally or partially by their own customs or traditions or by special legislation, and which, regardless of their legal status, conserve their own social, economic, cultural, and political institutions or parts thereof".

It is important to note that the Common Regime only applies to traditional knowledge where it is associated with the genetic resources sought. Application is indirect and there is no explicit provision referring to prior informed consent. Where genetic resources have an associated "intangible component" an access contract with the State must incorporate an annex which has terms for fair and equitable benefit-sharing (article 35). This to be signed by the provider, the applicant and the competent national authority. It presumably demonstrates the consent of the provider to use the knowledge. The rights of providers of associated knowledge are to be "safeguarded" by the competent national authorities of member states (article 50(d)).

Most importantly, the Decision requires the Governing Board of the Andean Pact to prepare within 1 year of the entry into force of the Decision a proposal for establishing a special regime or norm to strengthen protection of the knowledge, innovations and practices of indigenous, Afroamerican and local communities (eighth temporary provision). The work of the Governing Board is contingent upon member states first submitting national studies. The member states will also design a training programme for these communities to strengthen their capacity to negotiate accessory contracts regarding their knowledge, innovations and practices associated with genetic resources (ninth temporary provision). Therefore the application of Decision 391 to traditional knowledge could change depending on the outcome of the Governing Board's future work.

The draft Fijian Sustainable Development Bill provides that the Conservation and National Parks Authority, the competent national authority overseeing bioprospecting activities, is to ensure that a legally binding agreement is concluded with the "registered owners" of a targeted resource for the "harvesting of traditional knowledge" (section 254(6)(a)). The term registered owners is not defined in the Bill.

The second preambular paragraph of the Philippines Executive Order recognises that it is in "the interest of the State's conservation efforts to ... identify and recognise the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly or indirectly put to commercial use". Indigenous cultural communities or Indigenous Peoples are "a homogenous society identified by self-ascription and ascription by others, who have con-

tinuously lived as [a] community on communally bounded and defined territory, sharing common bonds of languages, customs, traditions and other distinctive cultural traits, and who, through resistance to the political, social and cultural inroads of colonization, became historically differentiated from the majority of Filipinos" (section 2.1(r), Implementation Regulations). Local communities are "the basic political unit wherein the biological and genetic resources are located (section 2.1(u), Implementation Regulations)." The Inter-agency Committee tasked with processing access applications is entrusted with ensuring the rights of indigenous and local communities where collecting and research are being undertaken (section 7(e)).

By reference to the non-binding preamble of the Convention on Biological Diversity, the Implementation Regulations of the Executive Order recognise "the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices" (section 1.3). Prospecting within the areas of local communities, including those of Indigenous Peoples, is to be with their consent. However, the definition of prospecting does not include knowledge associated with biological or genetic resources (section 5). These deficiencies could be ameliorated if the collector or principal fully disclose the scope of the research activity in the access application process.

The scope of the provisions on access to genetic resources in the Eritrean Draft Proclamation apply to associated traditional knowledge (article 46). However, no explicit provisions on consent from the holders of traditional knowledge are provided. Consent is only explicitly required in the context of genetic resources sought (article 49).

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

The ability of indigenous and local communities to actually capture benefits from genetic resources and/or associated knowledge will require going beyond the mere expression of a moral right to fair and equitable benefit-sharing. An assortment of approaches and techniques may need to be considered depending on the circumstances. For purposes of illustration it is useful to look at tools for capturing benefits from genetic resources and associated knowledge separately and then look at tools which may be common to both, such as contracts and capacity-building.

For genetic resources, a threshold issue is whether indigenous and local communities will have a right entitling them to be providers of genetic resources found in the areas they inhabit or use. Where an entitlement is possible, a related sub-issue is whether distinctions in entitlement should be made between wild and domesticated genetic resources. Where an entitlement to genetic resources is not possible, an entitlement over the biological resources or other materials (e.g., soil or other environmental samples) which may contain genetic resources could act as a surrogate. In other words, even though no entitlement exists to actually provide genetic resources, a right to be a provider of biological resources or environmental samples could also enable the negotiation of a benefit-sharing arrangement.

Another important issue is whether the communities have the right to control physical access to the land or sea areas they inhabit or use where genetic resources may be found. How this issue is addressed will be especially important in situations where indigenous and local communities have no entitlements over genetic resources, biological resources and environmental samples, because the ability to control access to land and sea areas could operate as a surrogate whereby benefit-sharing agreements could still be negotiated albeit for physical access to the areas where bioprospecting activities would take place. In other words, such an entitlement would enable indigenous and local communities to act as "gatekeepers" to the land and sea areas which they inhabit or use.

Once the entitlements are clarified the tool to secure benefit-sharing can be chosen. Undoubtedly, contracts will be used (see below). Capacity-building measures for contract negotiation may be needed (see below).

Whether indigenous and local communities have rights over genetic resources or not, issues concerning any knowledge associated with genetic resources must still be addressed. For example, where the State has declared ownership over genetic resources, and consequently prevents indigenous and local communities from acting as legitimate providers, arrangements will still be needed for access to and benefit-sharing from the use of any associated knowledge. Special approaches to provide indigenous and local communities with control over the

continued on the next page

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

continued from the preceding page

knowledge associated with genetic resources are particularly needed because, except in limited instances, current forms of intellectual property protection, such as patents and plant breeders' rights, cannot be applied for either technical reasons or because they are contrary to the practices and beliefs of some communities.

A number of commentators now argue that *sui generis* systems should be designed to protect the knowledge associated with genetic resources *separate* from existing intellectual property rights systems. Since the entry into force of the Convention on Biological Diversity, the conceptual underpinnings for such *sui generis* systems, for example traditional resource rights (see below) and community intellectual rights (see below), are now being proposed in the literature. The actual implementation of such systems will face a tough litmus test in terms of their gaining acceptance globally, especially if there is a proliferation of different approaches at the national level.

In the interim period before *sui generis* systems are established and recognised, other recently conceived tools, such as community registers, protecting associated knowledge through trade secrets and know-how licenses (see all below), may be especially useful in protecting the knowledge of indigenous and local communities. Contracts will likely be the primary means to reflect an agreement for access and subsequent benefit-sharing (see below).

Traditional Resource Rights

Traditional resource rights (TRRs) are described as "an integrated rights concept that recognises the inextricable link between cultural and biological diversity" (Posey and Dutfield, 1996). The concept delineates a collection of "overlapping and mutually supporting bundles of rights" which "can be used for protection, compensation and conservation". Traditional resource rights are viewed as more holistic than intellectual property rights. They set out the range of considerations which may need to be taken into account in developing benefit-sharing systems for genetic resources and associated knowledge. Posey and Dutfield argue that TRRs "seek not only to protect knowledge relating to biological resources but also to assert the right of [indigenous] peoples to self-determination and the right to safeguard 'culture' in the broadest sense".

Applicable at the local, national or international levels, TRRs can provide a source of principles to guide the development of legislation and guide dialogues between indigenous and local communities, governmental agencies and non-governmental organisations (Posey and Dutfield, 1996). From a wide variety of international legal instruments sixteen categories that collectively make up TRRs have been delineated: human rights, the right to self-determination, collective rights, land and territorial rights, the right to religious freedom, the right to development, the right to privacy, prior informed consent, environmental integrity, intellectual property rights, neighbouring rights, the right to enter into legal contracts, cultural property rights, the right to protect folklore, the right to protect cultural heritage, the recognition of cultural landscapes, the recognition of customary law and practice and Farmers' Rights (Posey and Dutfield, 1996).

The concepts underpinning traditional resource rights compliment work undertaken within the Working Group on Indigenous Populations of the UN Sub-Commission on Prevention of Discrimination of Minorities (see box 3).

Community Intellectual Rights

The Third World Network has proposed elements for a *sui generis* system "to protect the innovations and intellectual knowledge of local communities" (Singh Nijar, 1996). The central premise of the system is primarily defensive since it is based on the "underlying assumption that...indigenous peoples and local communities need to be protected *from* commoditisation of their knowledge and their resources" (Singh Nijar, 1996).

The system is conceptually designed around the rejection of "the concept of privatised, individualised or corporatised knowledge or concepts of creativity" since indigenous and local knowledge is created collectively

continued on the next page

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

continued from the preceding page

(Singh Nijar, 1996). It therefore follows that the community as a whole would own its knowledge. Furthermore, because indigenous and local knowledge has accrued incrementally over time, and will continue to evolve into the future, the right created endures for perpetuity and cannot be extinguished. Communities would be designated the custodians of their innovations for the benefit of future generations; the right could not be divested, though the community could commercialise the protected innovation. Finally, it is proposed that no exclusive monopoly rights could be extended over the knowledge so protected.

Other elements of the system address free exchange of the innovations between communities when commercial use is not contemplated, seeking consent to commercially use a protected innovation along with general parameters for benefit-sharing, local community registration, a registry of invention, proof of invention, designation of a technical institution to identify and characterise a community's innovations, co-ownership of an innovation between two or more communities, and rights to enforce, monitor or further the innovation.

Community Registers

In India, traditional knowledge systems tend not to be recorded (Kothari, 1997). They are orally transmitted. A project is now underway to create "people's biodiversity registers". The registers are data banks of local knowledge on wild and domesticated plants, animals and local conservation practices (Dutfield, 1997). They are the centrepiece of a larger proposal to establish a decentralised regime on access to biological resources and associated knowledge within India. The regime would be supported by legislation and overseen by local institutions (panchayati raj) on behalf of local people. Local people would develop and maintain the registers. As of early 1998, approximately sixty people's biodiversity registers have been completed or are nearing completion in nine Indian states (Dutfield, 1998). In its five year plan the State of Kerala has undertaken to document biodiversity through biodiversity registers. Financial and administrative resources have been allocated (Anuradha, 1997).

The registers are premised on the need to heighten the awareness of local people and the Indian government of the value of and trade in Indian biological and genetic resources and associated knowledge, while empowering local communities to control access attractive for commercial uses. Knowledge in the registers would not be released by the panchayati raj without the knowledge and consent of the villages from which it came (Kothari, 1997). Access to the registers, and access to biological resources within community areas, will depend on payment of a fee. Fees deposited into a fund will be distributed according to decisions made at village level meetings (Dutfield, 1997).

Three major informational components of the people's biodiversity registers have been identified: (1) knowledge about species, their uses and related techniques of use; (2) knowledge and facts about nature; and (3) traditional ecological knowledge. The first category primarily interests entrepreneurs, whereas all three categories are interesting to local people (Ghate, 1997). Therefore, the registers could be used as a tool to enrich the knowledge of local people. The system would not actually require secret knowledge about species, uses or techniques to be recorded but only "enough detail to establish legitimate prior claims of the original holders" to ensure control over subsequent use and benefit-sharing (Ghate, 1997). A legal and policy framework would be established to sanction misuse of secret knowledge.

Translating Traditional Knowledge into Trade Secrets

The traditional knowledge of indigenous and local communities is like many other information goods: once the information is released to others, and enters the "public domain", virtually all control over its consumption by third parties is lost (Vogel, in press). Intellectual property rights, such as trade secrets, can help maintain control over how a community's intellectual property is used and what benefits may accrue. According to Vogel, "trade secrets are confidential information for which the possessors have taken demonstrable efforts to maintain as confidential" (Vogel, in press).

continued on the next page

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

continued from the preceding page

Vogel has argued that just as a cartel is needed to prevent countries from competing in a price war for the provision of biological resources in random screening bioprospecting (Vogel, 1994), a cartel is also needed to prevent indigenous and local communities from competing in a price war for the provision of useful knowledge in ethnobioprospecting (Vogel, 1997). By transforming traditional knowledge into trade secrets communities can achieve a cartel over their knowledge.

A project sponsored by the Inter-American Development Bank, CARE-Ecuador and EcoCiencia sets out to achieve a cartel over traditional knowledge within Ecuador, and later, within neighbouring countries. The objective of the project's pilot phase is to catalogue traditional knowledge in a customised database housed in regional centres such as universities or NGOs.

Confidentiality will be maintained through a hierarchy of access restrictions and contractual obligations over the database and its data sets. Participating communities manage their own file of traditional knowledge and cannot access the files of other communities.

A central database manager will filter deposited knowledge across communities to determine which communities hold the same knowledge. The database manager will then filter the knowledge against that which already exists in the public domain through NAPRALERT, the on-line botanical database offered by the University of Illinois-Chicago.

Knowledge not yet in the public domain, and therefore classifiable as a trade secret, can be marketed to a potential user directly by a participating community or through an intermediary. Any transfer will be subject to a material transfer agreement to ensure benefit-sharing and maintain the knowledge as confidential. Public domain knowledge listed in NAPRALERT regarding a local species, but forgotten or unknown to the community, can be repatriated.

All benefits are to be paid in money and split between the government and all communities that deposited the same knowledge in the database. The community share of the economic rents will be used to finance public projects.

Know-how Licenses

A know-how license is a contractual legal instrument applied to the intellectual property embodied in, for example, biotechnology or computer software. Know-how licenses allow knowledge to be used without actually passing title to it (Tobin, 1997b).

A know-how license, derived in-part from model biotechnology licenses provided by the World Intellectual Property Organisation, has recently been used to protect the interests of the Aguaruna people of the Nor Marañon region of the Peruvian Amazon over their medicinal knowledge (Tobin, 1997b). The Aguaruna are participating in a bioprospecting project sponsored by the government of the United States' International Cooperative Biodiversity Group Program (ICBG) with researchers from Washington University, two Peruvian Universities and Searle & Co., the pharmaceutical division of Monsanto.

The project targets for screening only biological resources used by the Aguaruna for medicinal purposes. This key point was used by the legal team of the Aguaruna to argue that "it was not the resource itself but the use which had value...therefore indigenous peoples should control the use of resources" in the screening activities proposed (Tobin, 1997a). The strong nexus between the use and the targeted biological resource led to the negotiation of a know-how license that covered the use of medicinal knowledge. Importantly, if the know-how license was ever terminated, all rights over the respective biological resources collected would also terminate.

The strong nexus between medicinal use and the targeted biological resources led the Aguaruna and Searle to agree to apply the know-how license to medicinal knowledge regardless of whether the knowledge was in the

continued on the next page

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

continued from the preceding page

public domain. This was an important achievement for the Aguaruna because it meant that a major transnational corporation acknowledged that "indigenous peoples have an absolute right to control use of their knowledge in spite of it being in the so-called 'public domain'" (Tobin, 1997a).

Other highlights of the deal include (Tobin, 1997a):

- direct and continuing economic benefits to the Aguaruna, including a collection fee and an annual know-how license fee, as well as milestone payments as research and development progresses;
- full knowledge over sample use;
- grant backs of royalty free licenses over products developed;
- non-exclusivity;
- no patents over life forms;
- unrestricted worldwide use, sharing, selling or transfer of medicinal plants, products or knowledge covered by the agreement for the Aguaruna, Huambisa and other indigenous peoples, provided there is no infringement of patents held by Searle;
- a trust fund administered by the Aguaruna and Huambisa peoples;
- full university scholarships for selected Aguaruna students;
- parataxonomy training;
- software for local and national registers of indigenous knowledge;
- preferential treatment to Peruvian companies to distribute resulting products; and
- closely monitored entry into indigenous lands with collecting limited to those communities which signed the agreement.

At the time of the negotiation Peru had no legislation, for example, covering who could legitimately represent the interests of indigenous peoples in negotiations over rights to use biological resources associated with medicinal knowledge. Additionally, the customary laws of the indigenous peoples involved did not help to resolve the issue either. The deal between the Aguaruna and Searle was essentially negotiated in a legal and institutional void, guided only by the framework provided by international legal principles such as ILO Convention 169 and the Convention on Biological Diversity. Reliance on international instruments strengthened the bargaining position of the Aguaruna (Tobin, 1997a). Because the negotiation process did not involve direct intervention by the Peruvian government, the Aguaruna were responsible for ensuring that the agreement not only benefitted them and other indigenous communities, but also the national interest as well (Tobin, 1997a).

Contracts

Contractual methods to capture benefits are probably the most practical tool for ensuring benefit-sharing. They have been used in situations even where the legal framework for genetic resources has not yet been created. However, contracts should work best in situations where a legal and institutional framework for genetic resources is already in place.

Contracts involving indigenous and local communities will be most useful if they are undertaken within a larger framework of environmental and human rights law, contract law (the ability to contract and enforce), intellectual property law, tort law (conversion, duties to disclose information) and property law (trespass) (Shelton, 1995; Laird, 1995). Where parties to the contract are foreign, then private international law, notably that dealing with international business transactions, is also relevant (Laird, 1995; Shelton, 1995). The relationship between customary or traditional law and the statutory legal framework needs to be reviewed to minimise conflicts. Whenever possible, the contract should consider customary legal traditions and this could be specified in legislation.

The possible limitations of contractual approaches for indigenous and local communities should not be overlooked, but many can be addressed in the negotiation phase of the agreement. Factors such as contracts not being binding on third parties, high transaction costs for the parties to enter into and enforce the agreement, unfamiliarity with formal legal systems and a disparity in bargaining power, may significantly limit the extent to which

continued on the next page

Box 6. Tools for Indigenous and Local Communities to Capture the Benefits from Genetic Resources and Associated Knowledge: Theory and Practice

continued from the preceding page

this approach can be used effectively. Contractual methods also may not adequately protect intellectual property rights in relation to genetic resource innovations such landraces or associated knowledge unless they are used in combination with tools such as community registers, trade secrets or know-how licenses.

The limitations of contractual approaches could be minimised if legislation was drafted keeping in mind the special needs of indigenous and local communities. Downes *et al.* (1993), Laird (1993), Shelton (1995), Grifo and Downes (1996) and Putterman (1997) have all discussed possible elements for contracts derived in part from contracts currently being used in various parts of the world. A contractual arrangement proposed by the Global Coalition for Biological and Cultural Diversity, particularly with indigenous peoples in mind, tries to move beyond the conventional contract approach.

This group developed a model "Covenant on Intellectual, Cultural and Scientific Property" (Posey and Dutfield, 1996). The Covenant is designed to be more than simply a contract. Instead it endeavours to provide the basis for a long-term commitment between indigenous communities and potential users. It is intended to guide the parties into ethical and equitable long term associations of mutual benefit with regard to genetic resources and associated knowledge. Some of the features of the Covenant include establishing:

- a legal fund for a community as part of an "up front payment", which is meant to help offset the financial handicap of indigenous peoples in access to legal assistance and litigation;
- an independent monitor to evaluate the state of the agreement;
- informed consent and joint planning; and
- concern for the environment (Posey and Dutfield, 1996).

It also emphasises planning within the community on the implications of cultural, social and economic change, mechanisms for income sharing and distribution, the improvement of communal life and income allocation to strengthen the larger ethnic group.

Capacity-Building Considerations

In some instances intervention by governmental or non-governmental organisations on behalf of indigenous or local communities may be needed to develop their capacity to control access and secure benefits. Of course, intervention through governmental channels may be viewed with scepticism, particularly by indigenous peoples, if it will merely lead to centralisation and government control over the genetic resources found in the areas that indigenous and local communities inhabit or use. Scepticism will likely be greatest where governments have not acted in the best interests of indigenous and local communities in the past. Any governmental intervention should support the capture of benefits by community institutions and avoid centralised control.

In States where indigenous and local communities are comfortable working with the government, mechanisms might be explored which guarantee respect for the wishes of communities in whose areas activities targeted at genetic resources and/or associated knowledge are proposed. These might include (1) identifying the communities living in areas where the activities will occur; (2) consultation by the government or by a designated NGO with the communities to ascertain their interest in allowing the activities in their areas and in negotiating an agreement with potential users; (3) assisting communities to negotiate terms of access and benefit-sharing; (4) reviewing the agreement between a community and a potential user to ensure conformity with relevant access criteria (IUCN, 1994); and (5) monitoring the relationships developed.

To supplement these mechanisms, in addition to providing the fundamental rights described earlier, legislation might specify that prior to a potential user's access to the areas inhabited or used by indigenous and local communities their informed consent, based on full knowledge from the information supplied to them, must be obtained first. It might also specify that access and benefit-sharing must be consistent with the communities' beliefs, traditions, practices or laws. This could be taken one step further by requiring positive proof of informed consent before the State can make an affirmative access determination (see section 2.1.4).

3.2.5.1.2 Collections, Records and Databases

The specimen collections, records and databases of *ex-situ* conservation facilities and other institutions, such as museums, are also potentially valuable sources of information. In some cases, ethno-biological knowledge is associated with these sources. Any planning process on access to genetic resources should identify these sources of information to facilitate a decision as to whether proposed legislation should cover them. Access legislation could potentially reach these sources depending on the legal status of the materials, as well as that of the corresponding institutions within which the materials are located.

Ownership issues predominate. Distinctions may need to be made between materials and institutions which are publicly or privately owned. One criterion which might be considered is whether the institution or the data collected is or was supported by government funding. Charging fees for access to collections and databases (Cohn, 1995) and entering into access agreements could be contemplated.

As with physical access to genetic resources, a line may need to be drawn between access for non-commercial and commercial uses, so as not to impede non-commercial scientific research.

3.2.5.2 Access to Information and Knowledge Derived From Genetic Resources

As in the situation with derivatives of genetic resources, it will be difficult to actually regulate access to information derived from genetic resources. Therefore, this type of derived product probably cannot be readily defined within the scope of application of the access legislation.

Nevertheless, access agreements can provide for who is to own or control the information subsequently derived from genetic resources after access in order to clarify control and help ensure benefit-sharing. Legislatively mandated minimum terms and conditions for access agreements could clarify ownership of this information and ownership over biological samples, set limits on dissemination and ensure that derived benefits are shared fairly and equitably.

3.2.6 Geographical Locales to Which Access Legislation Could Apply

Access legislation should clarify to which geographical areas within the jurisdiction of the State it applies. Areas within the limits of the national jurisdiction of the State are (1) the land territory within its internationally recognised borders and, for any coastal State, its (2) territorial waters, as well as the (3) various maritime zones adjacent to them (for example, the fishery zone, exclusive economic zone and the continental shelf).

The jurisdiction of a State over its land territory is only limited by the rights of other States to exercise the same jurisdiction over their own territory, or by obligations under international law. In contrast, the rights of States over the maritime zones varies. The geographical limits, as well as the rights and obligations of the coastal States with regard to each of them, are defined by the law of the sea (see boxes 7 and 8).

The geographical locale issue is particularly important in regionalised or federal States. Depending on the circumstances within the State, access legislation should also indicate whether it applies to communal land and sea territories and private property. It could refer to whether or not consent of the owner, holder or usufructuary is required prior to access.

Box 7. The Legal Status of Marine Genetic Resources

The provisions of the Convention on Biological Diversity (CBD) apply to the marine environment though this is not explicit. For example, the term "biological diversity" is defined in article 2 to include marine systems.

Article 4 defines the jurisdictional scope of the Convention on Biological Diversity. For components of biological diversity, article 4(a) defines the jurisdictional scope as the areas "within the limits of national jurisdiction". This includes the maritime zones under national jurisdiction. Pursuant to article 4(b), the Convention applies to processes and activities carried out within the areas of national jurisdiction or beyond the limits of national jurisdiction, such as the high seas.

continued on the next page

Box 7. The Legal Status of Marine Genetic Resources

continued from the preceding page

Article 22 requires Contracting Parties to "implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea". In effect, this requirement means that measures to implement the Convention may not contradict or undermine national rights and obligations deriving from the law of the sea as defined by customary international law and treaty. It also implicitly means that the law of the sea can be used to support the implementation of the Convention.

The law of the sea is important because the rights and obligations of coastal States and of other States conducting activities in the ocean vary depending on the location of the activity. In other words, in defined offshore zones coastal States have specified rights and obligations vis-a-vis other States.

Since its entry into force, the 1982 United Nations Convention on the Law of the Sea (UNCLOS) is the primary source of "newer" law of the sea as it sharpens and makes more precise ambiguities found in earlier treaties, while introducing new rights and obligations as between its parties. UNCLOS entered into force on 16 November 1994 and presently has over 110 parties. It has been widely signed and ratified by developing States, but only by a handful of developed States.

Among its parties, UNCLOS prevails over the four earlier Conventions on the Law of the Sea' (UNCLOS article 311(1)). Furthermore, many of its provisions have been accepted as customary international law. The preamble to UNCLOS notes, however, that "matters not regulated by this Convention continue to be governed by the rules and principles of general international law" (UNCLOS preambular paragraph 8).

Unlike the Convention on Biological Diversity, UNCLOS makes no reference to genetic resources. Instead, UNCLOS refers to "natural resources", "living marine resources" and "living organisms". These references clearly relate to all living species, but considering the period and circumstances during which they were negotiated, negotiators probably had not anticipated these terms to be used in the context of genetic resources (Glowka, 1996). For the purposes of access and benefit-sharing, however, these terms are broad enough to include animals, plants and micro-organisms such as bacteria and fungi and their genetic material.

The Law of the Sea Convention creates various maritime areas within which coastal States can expect to exercise various rights and fulfil certain obligations. For example, in some cases, coastal State rights must be exercised consistently with the rights and obligations of other States with respect to marine living resources. In summary:

- Within the internal waters and territorial sea, the coastal State has sovereignty over its living resources *(see generally,* UNCLOS Part II).
- On the continental shelf, the coastal State has sovereign rights over the exploration and exploitation of natural resources, including non-living resources and sedentary species *(see generally,* UNCLOS Part VI).
- In the exclusive economic zone (EEZ), the coastal State has sovereign rights for purposes of exploring and exploiting living resources, qualified by conservation and management obligations and, in principle, sharing of surplus living resources not harvested by coastal State *(see generally,* UNCLOS Part V).
- Subject to the rights of other States, the living resources of the high seas — the water column and seabed beyond the limits of any national jurisdiction — are freely accessible by every State *(see generally,* UNCLOS Parts VII and Part XI).

Article 15(1) of the Convention on Biological Diversity reaffirms that States have sovereign rights over their natural resources, and by extension sovereign rights over the genetic resources found in areas within their jurisdiction. The authority for governments to determine access to genetic resources derives from a State's sovereign rights over them. The legal status of genetic resources under the Convention on Biological Diversity neither conflicts with nor undermines that for the exploration and exploitation of marine living resources within the maritime zones designated by UNCLOS.

[1] These are the Convention on the Territorial Sea and the Contiguous Zone (Geneva 1958), the Convention on the High Seas (Geneva 1958), the Convention on Fishing and Conservation of the Living Resources of the High Seas (Geneva 1958) and the Convention on the Continental Shelf (Geneva 1958).

continued on the next page

Box 7. The Legal Status of Marine Genetic Resources

continued from the preceding page

A coastal State exercises sovereign rights over the genetic resources found within its EEZ and on its continental shelf for purposes of their exploration and exploitation. Neither "exploration" nor "exploitation" are defined by UNCLOS however.

In the minerals and fisheries contexts in which they are typically applied, the terms "exploration" and "exploitation" are generally associated with commercial activities intended to generate information and discover useful natural resources. The information, data or samples collected may be economically important and consequently may not be freely available even to the particular coastal State in whose waters the activities are occurring except if required by law. This is in contrast with information, data and samples collected for purposes of marine scientific research (see box 8).

Under UNCLOS, a Coastal State has sovereign rights over the exploration and exploitation of living resources which enable it to control access for these purposes. It follows from this that a government has the authority to determine access to marine genetic resources when their exploration or exploitation neither conflicts with nor undermines the law of the sea.

3.2.6.1 State Practice

The draft Fijian legislation is a succinct example to refer to. It provides that biodiversity prospecting in any marine or terrestrial area is prohibited without prior approval via a special permit (section 254(2)). In addition, the application procedure includes submitting "any agreement concluded with native land owners ... concerning access to land or resources on such land" (section 254(4)(vii)(A)).

The Philippines Executive Order is limited to prospecting of all biological and genetic resources in the "public domain, including natural growths in private lands" (section 3, Implementation Regulations). The public domain comprises the "waters and lands owned by the State that have not been declared alienable and disposable" (article 2.1(z), Implementation Regulations). What constitutes "natural growths" is not clarified.

Prospecting is "allowed within the ancestral lands and domains of indigenous cultural communities only with [their] prior informed consent" (section 2(a), Executive Order). The prior informed consent of "concerned local communities" is also required but the requirement is not explicitly linked to geographical locale (section 2(b), Executive Order).

The Andean Pact Decision speaks more generally in terms of genetic resources found in the territories of member states (article 3). For purposes of the Common Regime, the legal status of genetic resources is distinct from that of biological resources. The property regime over a particular area in which are found biological resources containing the genetic material or derivatives sought only entitles the owner, occupier or administrator to enter into accessory contracts (article 41 (a)). They cannot grant access to genetic resources and derivatives. This is reserved for the competent national authority. However, the rights of communal or private holders of land from which biological resources are sought as genetic resources are to be safeguarded by the competent national authority of each member state (article 50(d)).

The Second Draft Proclamation on the Conservation of Biological Diversity of Eritrea applies to the areas under national jurisdiction. This includes land subject to a private right of use and "land used by pastoralists or other communities or groups with traditional interests in that land" (article 49(a) and (b)). Consent of the usufructuary or the communities/ groups involved is required for access to resources located on these lands.

3.2.7 Activities to Which the Access Legislation Could Apply

The activities regulated by the access legislation are very much related to the ultimate purposes or objectives of physical access to genetic resources, in others words, why the genetic resources are sought. Genetic resources will be sought for commercial and non-commercial reasons. It may be advantageous for planners and legal drafters to consider whether access legislation should distinguish between the two.

The primary rationale for making a distinction is that it is presumed that non-commercial scientific research advances human understanding of the natural

world primarily through publication and dissemination of the research results generated. But, because of resource limitations, researchers undertaking non-commercial scientific research may not be able to afford expensive or time consuming regulatory processes, unless the time and money have been factored into the overhead of their project. Burdensome regulatory procedures could become a disincentive for undertaking important research within a country because researchers may simply stay home or go elsewhere.

Access procedures could be tailored to take these issues into consideration, while at the same time maintaining the country's interests in future benefit-sharing through access agreements. It is important to realise however that resource limitations have also pushed greater numbers of academic institutions to enter into strategic alliances with industry. As a result, the distinction between non-commercial "scientific" use and commercial use of genetic resources is becoming less clear. A possible solution would be to shift the point of negotiating direct financial benefits for end uses of genetic resources to the time of commercialisation instead of at the point of access (Vogel, 1997), keeping in mind that an access agreement would still be necessary prior to access.

In determining whether to distinguish between commercial and non-commercial activities involving genetic resources the State will also need to review its international obligations. For example, coastal States party to the 1982 United Nations Convention on the Law of the Sea, should keep in mind that the Part XIII marine scientific research provisions emphasise the distinction between commercial investigative activities and non-commercial scientific activities on the continental shelf and within exclusive economic zones (see box 8). Discretion to withhold consent can be executed when the research is of direct significance to the commercial exploration and exploitation of living or non-living resources (article 246(5)(a)).

It may also be desirable to negotiate agreements with appropriate States to ensure that bioprospecting does not occur on embassy or other grounds not subject to the laws of the host country.

3.2.7.1 State Practice

Even with the blurred lines between non-commercial and commercial activities, the Costa Rican (article 50) and Philippine (section 3, Executive Order; sections 7 and 8 Implementation Regulations) laws do make the distinction between commercial and non-commercial activities. They set out different requirements for each.

In general, non-commercial uses of genetic resources are subject to less rigorous rules than uses with commercial intent. Typically non-commercial research is to be undertaken by an institution accredited with the national government as is the case in the Philippines (section 3, Executive Order). This implies the creation of an accreditation procedure, and the existence of a list of approved institutes. These do not seem to be provided for in the legislation examined to date.

Aside from applying to activities related to physical access to genetic resources, another activity to which some legislation applies is the export of genetic resources (see section 3.5).

Box 8. Marine Scientific Research Activities and Access to Genetic Resources

A coastal State has sovereign rights over the commercial exploration and exploitation of the genetic resources found within its maritime zones (see box 7). Therefore, the government has the authority to determine access to marine genetic resources. Under the 1982 United Nations Convention on the Law of the Sea (UNCLOS) sovereign rights over genetic resources are qualified when marine scientific research is proposed for the genetic resources of the continental shelf and exclusive economic zone.

"Marine scientific research" has not been defined in either the 1958 or 1982 Law of the Sea Conventions. Physical, chemical and biological oceanography, marine biology and marine geology are the basis of marine scientific research. Marine scientific research involves information, data or sample collecting without the intent of commercial gain. Although the information gathered may be commercially valuable it is freely available and exchanged. Marine scientific research therefore adds to the sum of human scientific knowledge on a particular subject. In contrast, information, data and samples collected as a result of the commercial investigative activities which characterise "exploration" are typically not freely available.

continued on the next page

Box 8. Marine Scientific Research Activities and Access to Genetic Resources

continued from the preceding page

Marine scientific research is characterised by publication and dissemination of research results. Publication and dissemination are key distinguishing features and are fundamentally important to ensure that all States, at least in principle, benefit from the work undertaken (Soons, 1982; UN Office for Ocean Affairs and the Law of the Sea, 1991); UNCLOS article 246(3)). Article 244 of the 1982 UNCLOS requires States and competent international organisations to publish and disseminate information and knowledge on proposed research programmes and their results including scientific data.

The nature of the activity appears to distinguish the terms applied — whether marine scientific research or exploration — and therefore the consequent rights available and the obligations incurred under UNCLOS. One problem realised by the drafters of UNCLOS is that it is increasingly difficult to distinguish between marine scientific research and commercial investigative activities related to exploration or exploitation of a coastal State's natural resources.

Balancing the tension between the equally valid needs of facilitating marine scientific research worldwide, and permitting coastal States to control it in areas where they exercise jurisdiction over natural resources to better ensure benefit sharing, is the ultimate goal of the treaty-based legal regime governing marine scientific research under UNCLOS (Soons, 1982).

The 1982 UNCLOS was intended to be "comprehensive of all ocean uses and their inter-relationships" (UN Office for Ocean Affairs and the Law of the Sea, 1991). Its preamble recognises the study of the marine environment as desirable.

Part XIII of UNCLOS governs marine scientific research in all areas of the sea. Coastal States have jurisdiction to regulate, authorise and conduct marine scientific research in their EEZ and on their continental shelf (UNCLOS article 246(1)).

Coastal States are to grant consent in "normal circumstances" if marine scientific research projects are to be a carried out (1) in accordance with the Convention; (2) exclusively for peaceful purposes; and (3) to increase scientific knowledge of the marine environment for the "benefit of (hu)mankind as a whole" (UNCLOS article 246(3)). To minimise delays and create a uniform process, coastal States are to establish appropriate rules and procedures (UNCLOS article 246(3)) for communication through "appropriate channels" (UNCLOS article 250)) including diplomatic channels (UN Office for Ocean Affairs and the Law of the Sea, 1991). Normal circumstances may exist despite the absence of diplomatic relations (UNCLOS article 246(4)).

Coastal States have the discretion to withhold consent if the research project "is of direct significance to the [commercial] exploration and exploitation of natural resources, whether living or non-living" (UNCLOS article 246(5)(a)). They can also withhold consent when information transmitted concerning the nature and objectives of the project is inaccurate or if the researching State or competent international organisation has outstanding obligations to the coastal State from a prior research project (UNCLOS article 246(5)(d)).

As an incentive for compliance, the outstanding obligations of an institution with regard to the conditions of consent are justification for the coastal State to withhold its consent to other research projects from different institutions within the same researching State (UN Office for Ocean Affairs and the Law of the Sea, 1991).

A coastal State cannot exercise discretion to withhold consent for marine scientific research projects on the continental shelf in areas beyond 200 nautical miles from the baseline of the territorial sea if activities are proposed outside specific areas publicly designated by the coastal State. The designated areas must have, or within a reasonable period of time will have, exploitation activities or detailed exploratory operations occurring within them.

To initiate the consent process the researching State or competent international organisation is to provide the coastal State with, among other things, a full description of the nature and objectives of the project (UNCLOS article 248). This is to occur not less than six months in advance of the starting date of the project.

continued on the next page

Box 8. Marine Scientific Research Activities and Access to Genetic Resources

continued from the preceding page

Coastal State consent for marine scientific research projects in the EEZ or on the continental shelf can be either express or implied. Implied consent occurs (1) when the coastal State fails to respond within four months of the date information is supplied to obtain consent (UNCLOS article 252) or (2) when research is to be undertaken by a competent international organisation of which the coastal State is a member and which the coastal State approved when the organisation decided to undertake the project (UNCLOS article 247; Soons, 1991).

A short exhaustive (UN Office for Ocean Affairs and the Law of the Sea, 1991) list of conditions are imposed on the researching State or competent international organisation by UNCLOS after the coastal State grants consent (UNCLOS article 249). The researching State or competent international organisation is to:

- ensure the participation or representation of the coastal State in the marine scientific research if it so desires, without the coastal State being obliged to contribute to the costs of the project (UNCLOS article 249);
- provide preliminary reports and final results at the request of the coastal State (UNCLOS article 249(1)(b));
- undertake to provide access to the samples and data collected, at the request of the coastal State, and furnish copiable data and samples capable of being divided without diminishing their scientific value (UNCLOS article 249(1)(c));
- provide, at the request of the coastal State, sample and data assessment and research results or assist in their assessment or interpretation (UNCLOS article 249(1)(d)); and
- ensure international availability of the research results (UNCLOS article 249(1)(e)), subject to the prior agreement of the coastal State (UNCLOS article 249(2)).

In instances where there is no duty to grant consent, but consent is granted, a coastal State may impose any conditions (UNCLOS article 249(2); UN Office for Ocean Affairs and the Law of the Sea, 1991)).

Coastal States have the right to suspend marine scientific research particularly where it is not being conducted pursuant to the information upon which consent is based (UNCLOS article 253(1)(a)).

Part XIII makes special reference to neighbouring land-locked and geographically disadvantaged States. Researching States or competent international organisations are to (1) notify them of the proposed project (UNCLOS article 254(1)), (2) supply relevant project information after coastal State consent is granted (UNCLOS article 254(2)), (3) give them, where feasible, the opportunity to participate at their request and (4) provide upon request an assessment of data and samples collected or assist in their assessment (UNCLOS article 254).

States and competent international organisations are responsible for ensuring that marine scientific research undertaken by them or on their behalf is conducted in accordance with UNCLOS (UNCLOS article 263(1)). In instances of dispute, States party to the 1982 UNCLOS can avail themselves to compulsory dispute settlement procedures of UNCLOS (UNCLOS article 264). Disputes involving issues of a coastal State's right or discretion regarding marine scientific research (UNCLOS article 246) are exempt from binding results (UNCLOS article 297(2)).

The consistent implementation of article 15 with the law of the sea, will require coastal State Parties to the Convention on Biological Diversity to carefully consider UNCLOS Part XIII if they are also a party to UNCLOS. For marine scientific research involving the EEZ and the continental shelf, UNCLOS attempts to carefully balance the needs of coastal States, researching States and land locked and geographically disadvantaged States. At the same time it tries to further marine scientific research. In these areas, UNCLOS sets the standard and stricter measures taken pursuant to the Convention on Biological Diversity which disrupt this balance could be interpreted as inconsistent.

There are a number of potential problem areas. One example relates to the exhaustive list of conditions a coastal State is allowed to impose on marine scientific research. On face, it would be inconsistent for a coastal State to add an additional condition, for example protecting its interests in the event that some time in the future organisms collected pursuant to marine scientific research are used in commercial biotechnological applications. In the

continued on the next page

Box 8. Marine Scientific Research Activities and Access to Genetic Resources

continued from the preceding page

end, to ensure their commercial interests in the materials collected from the continental shelf or EEZ coastal, States might simply regard any marine scientific research involving biological resources as of direct significance to their commercial exploration and exploitation, thereby defeating the purpose of Part XIII.

In 1989 the United Nations Office for Ocean Affairs and the Law of the Sea conducted a survey of national legislation and regulations regarding marine scientific research. The document produced compiles legislation from 103 of 140 coastal States, self-governing associated States and Territories (UN Office for Ocean Affairs and the Law of the Sea, 1989). None of the legislation referred to genetic resources directly. Instead, many laws reflected the text of the 1982 UNCLOS marine scientific research provisions, in particular, subjecting such research to their consent. Some were particularly oriented to minerals and fisheries.

Even though the survey was conducted before the entry into force of the Convention on Biological Diversity, it is instructive in three respects. First, it indicates the synergistic effect the 1982 UNCLOS could have on the implementation of article 15 of the Convention on Biological Diversity. Second, it indicates that many coastal States may already have in place legislation that is adaptable for ensuring the sharing of benefits derived from the scientific or commercial use of genetic resources taken from their internal waters, territorial sea, continental shelf, fishing zone or exclusive economic zone. Third, and perhaps most importantly, with proper internal harmonisation, marine scientific research legislation, and similar legislation for terrestrial scientific research, could serve as the basis for a comprehensive treatment of genetic resources and the benefits derived from their use.

3.2.8 Actors to Which Access Legislation Could Apply

One of the early scope-related decisions to be made is whether the legislation should apply to nationals, non-nationals or both. Ideally, access legislation should apply to both nationals and non-nationals.

The rationale is simple. Genetic resources can generate benefits when used within the country and outside, even if endogenous technological capabilities are not far advanced. Furthermore, in practice, it may be difficult to distinguish between nationals and non-nationals, especially where local collectors are acting as intermediaries for non-national actors, or where transnational enterprises have affiliate offices in the country.

In some cases the local research community can be the knowing or unknowing gateway for genetic resources to leave a country, especially where the lure of collaborative research, access to financial resources and technology transfer create incentives to work with foreign researchers and institutions. This could, however, be overcome by subjecting the agreement between a commercial collector and its principal to scrutiny as part of the access determination procedure (see section 3.4). In addition, a registry of authorised, accredited or licensed collectors might be established.

Access legislation should also clarify whether it applies to natural or legal persons or both. Access legislation should clearly apply to governmental institutions within the providing country which may wish to access genetic resources.

For diplomatic personnel it will be necessary to negotiate agreements with the appropriate States to ensure that genetic resources do not leave via diplomatic channels.

3.2.8.1 State Practice

The legislation of the Republic of Korea only applies to foreigners hoping to access genetic resources (article 25-4). Other than the draft Kenyan law (section 38(1)) which apparently applies only to non-citizens of Kenya, it is unclear whether the other African enabling laws described in section 3.0 apply only to foreigners, although in all cases developing guidelines on germplasm export seems to be the primary focus.

The draft Fijian legislation (section 254(3)), draft Nigerian National Parks Decree (section 27(a)), and the Philippines Executive Order (section 3) apply to both nationals and non-nationals. This is also suggested

in the legal technical report for the Seychelles (section 53(1)).

The Philippines legislation subjects the agreement between a commercial collector and its principal to scrutiny as part of the access determination procedure (section 3, Executive Order). In addition, the legislation clearly applies to natural and legal persons as well as governmental institutions (section 3. l(a), Implementation Regulations). The Implementation Regulations are quite comprehensive and apply to "foreign and local individuals, entities, organisations, whether government or private" (section 3.1(a)).

In some cases, for instance in Costa Rica, nationals may be entitled to special treatment. This includes being subject to lower licensing fees or being authorised for access longer than for non-nationals (article 39).

In the Philippines only "duly recognised" national institutions can enter into non-commercial research agreements with the government (section 3, Executive Order). Foreign entities, whether legal or natural persons, must enter into a commercial research agreement (section 3, Executive Order).

3.2.9 Exclusions From the Legislation's Scope of Application

Another aspect of the scope of legislation issue which could be considered is whether to include explicit exclusions to the application of the law. In other words, what will not be regulated by the legislation. Three possibilities might be considered. These are (1) customary use of genetic resources (2) specific uses of biological resources and (3) genetic resources obtained prior to the enactment of the legislation (retroactivity).

3.2.9.1 Customary Use of Genetic Resources Excluded

The use and free exchange of genetic resources is integral to the economic, religious and cultural well-being of indigenous and local communities throughout the world. Preambular paragraph 12 of the Convention on Biological Diversity recognises this. In addition article 10(c) requires each Party to protect and encourage customary use of biological resources compatible with conservation and sustainable use of biological diversity. Use must be in accordance with traditional cultural practices.

While customary uses of genetic resources could be excluded implicitly from the scope of access legislation it may be desirable to make explicit their exclusion. In so doing the validity and significance of customary use to indigenous and local communities will be more widely recognised outside of these communities, and there will be no confusion when the law is applied.

Article 4(b) of the Andean Pact Decision 391 is perhaps most comprehensive. It excludes from the scope of the Decision the biological and genetic resources exchanged among indigenous and local communities when these are used for their own consumption and in their daily practices. Included as well are "derived products", such as molecules, mixtures and raw extracts (article 1)).

The draft Eritrean biodiversity proclamation excludes genetic resource exchanges among local communities for traditional, non-commercial purposes (article 46(b)). A customary use exclusion is provided for in the Philippines Implementation Regulations (section 3.l(b)).

3.2.9.2 Specific Uses of Biological Resources Excluded

The existing examples of access legislation typically specify what intended genetic resources uses will trigger the prior informed consent requirement. Typically the trigger is "access" or "bioprospecting". These are then defined to include certain activities such as research, collection or use for particular commercial or non-commercial purposes. Specifying which uses or activities trigger the prior informed consent procedure of the legislation, implicitly highlights those that do not (IUCN, 1994).

The Andean Pact Decision clarifies State authority over genetic resources and derived products. The procedures triggered do not prejudice the property regimes already in place over biological resources in the member states (article 6). At the same time it provides that concessions or approvals to use biological resources for purposes other than those involving genetic resources do not permit subsequent use of these materials for purposes of access (article 23). There are at least two implications of this example for access legislation.

First, access legislation could clearly exclude other uses of biological resources (see section 3.2.9.2). Second, access legislation could also provide an enabling clause which would require the modification of existing biological resource-related legislation to ensure that other authorisations specifically exclude the use of the biological resources for their genetic or biochemical properties when there is no prior informed consent.

3.2.9.3 Retroactivity

Legal rules as a general rule do not to apply to past actions. This is the principle of non-retroactivity. Incorporating a non-retroactivity clause into access legislation would establish a cut-off date, usually the entry into force of the legislation, before which transactions involving the acquisition of genetic resources would not be subject to benefit-sharing. State practice seems to be going in the opposite direction however. There are two situations.

The first situation is not truly retroactive. The Philippines (section 11, Implementation Regulations) and the Andean Pact (article 50(j)) have illustrative legislation. Both require existing agreements to be renegotiated to conform to the principles specified in their respective laws within some period after the entry into force of the legislation. In the Philippines existing research can continue pending the negotiation of a new agreement.

Whether the second situation, which only exists in the Andean Pact, is retroactive depends on how one interprets the legal status of genetic resources prior to the entry into force of Decision 391 (Rosell, 1997). Pursuant to the first temporary provision at the end of Decision 391, where genetic resources within the Pact have been collected prior to the entry into force of the Decision, a negotiation for an access contract for those genetic resources must take place. This provision has implications for legal and natural persons, for example *ex-situ* conservation facilities, both within and outside the Andean Pact.

3.3 Institutions to Oversee Access to Genetic Resources

Governmental institutions overseeing the components of biological diversity exist in almost every State. Their competencies vary with the circumstances. They are divided along sectoral lines in many cases. Competencies can be distributed vertically at national and sub-national levels and horizontally within these levels.

Dividing competencies along sectoral lines has constrained efforts to conserve biological diversity and sustainably use its components because a fragmented approach to biological resource management is encouraged. This problem has been accentuated by limited budgetary and staff resources, poor coordination, as well as conflicting mandates and jurisdictions between agencies and levels of government.

Sectoralism extended to the access and benefit-sharing realm may result in the loss of important genetic resources, as well as lost benefit-sharing opportunities. For example, when governmental competencies are solely divided along sectoral lines there may be instances where some organisms especially useful in biotechnological applications — such as microorganisms or insects — literally "fall through the cracks" and are not within the clear competence of any institution. Sectoralism also increases the likelihood that decision-making will be accomplished in a vacuum, without consultation, and may result in one arm of the government not knowing what the other is doing.

Because access and benefit-sharing involve issues which cut across sectoral lines, planners need to consider how to approach institutionally the issue in a cross-sectoral or integrated manner. Integrating the access determination process could provide a means for better, more integrated decision-making.

Integrated decision-making will in turn limit arbitrary decisions and missed opportunities. Access to genetic resources will be facilitated, increasing the likelihood that benefits can be captured to meet national goals.

3.3.1 Designating a Competent Authority to Oversee Access Determinations

If a regulatory process is envisaged, an institution with authority to process access determination applications will need to be designated or established. A threshold question is the governmental level at which the access determination will be made.

The question is especially important for federated and regionalised States. For example, decision-making with regard to biological resources may take place at the sub-national level. Therefore it will be important to clarify which level of government is competent to determine access to genetic resources.

A national approach could be advantageous where genetic resources are shared between two or more sub-national jurisdictions. This might involve the promulgation of national standards or criteria to harmonise sub-national approaches. Alternatively, it could involve oversight or decision-making authority at the national level.

Another planning consideration might be whether the authority should be a governmental agency at all. It could be a government or university-related research institution, a private contractor or an independent, private, non-profit organisation. Whether an existing sectoral line agency or a newly created public or private institution is designated will depend on the circumstances within the State.

Care should be taken to ensure that the competencies of the authority do not conflict with those of other agencies. It should promote coordination, both within and especially outside the government.

Depending on the level of expertise and involvement envisioned for the competent authority, an advisory panel of experts might be created to provide multidisciplinary advice. The competencies of the advisory panel might include providing the competent authority with scientific, economic and legal advice on applications submitted. Both might be supported by a secretariat.

The simplest approach may be to create a centralised inter-ministerial or inter-agency governmental body with clear competency over access to genetic resources. In this case, the competent authority could be composed of individuals representing different sectoral governmental ministries or agencies with portfolios over biological resources. Non-governmental, communal and private sector representatives might also be invited to participate and add their perspectives.

This arrangement may be advantageous because it could provide the possibility for maximum coordination. All relevant arms of the government and, ideally, representatives from the non-governmental, private and communal sectors could be involved in the decision-making process.

This option is most feasible if the competent authority is established within the government. It might be an independent body or set-up within a ministry or agency.

Access legislation should clearly outline the jurisdictional competencies, powers and functions of the competent authority, especially since those seeking access will need to be confident they are dealing with the correct institution. A key question will be whether the competent authority will have decision-making authority or merely oversight authority. In other words, will the competent authority make access determinations or simply pass judgement on determinations made by another entity?

An example of the former would be the power of the competent authority to actually decide who can gain access to genetic resources. An example of the latter might be approval of an access determination made by other agencies or ministries regarding genetic resources located in areas within their competence. This could also be the case where genetic resources are located in private or communal areas.

In either capacity, important functions of the competent authority would be to gather information from and coordinate with potentially affected parties and others, both inside and outside the government. The information gathered would then need to be considered. This could be either prior to making an access determination or prior to approving one. Information gathering and coordination could be undertaken as part of a public notification process (see section 3.4.2.1).

Other functions of the competent authority might be to:

- collect and disburse fees, royalties, other financial returns and benefits;
- reach or evaluate mutually agreed terms for access;
- carry out or coordinate identification and characterisation of genetic resources to ascertain their potential use or value;
- seek further legislation in the area; or
- identify and inform potential users of the national or sub-national access rules.

3.3.1.1 State Practice

A number of examples exist which can be drawn on to tailor an institutional approach. The Philippines illustrates a comprehensive approach.

Executive Order 247 recognises "an inter-agency approach [as] the most appropriate way of regulating the research, collection, exploitation and use of biological and genetic resources" in the Philippines (preambular paragraph 1). Section 6 creates the Inter-agency Committee on Biological and Genetic Resources. The Committee is located within the Philippines Department of Environment and Natural Resources (DENR). It oversees the implementation of the Executive Order.

The membership of the Committee includes representatives from the Departments of Environment and Natural Resources, Science and Technology, Agriculture, Health and Foreign Affairs. Membership also includes two permanent representatives from the Philippine science community, one from the National Museum, one from a non-governmental organisation and one from a "peoples"' organisation representing indigenous cultural communities and/or their organisations. Each member serves for a three year period.

A technical secretariat, headed by the Philippine Protected Areas and Wildlife Bureau of the DENR, supports the Inter-agency Committee. Its functions include initially screening proposals submitted for academic and commercial research agreements.

The Inter-agency Committee neither makes access determinations nor enters into research agreements. Individual access determinations are made and research agreements entered into at the line agency level upon the recommendation of the Inter-agency Committee. Competency over genetic resources, which are owned by the State, remains with the relevant sectoral line agencies (Executive Order, section 7(a); section 6.2.6, Implementation Regulations).

For example, upon the recommendation of the Committee, the Secretary of the Department of Agriculture, who sits on the Committee, signs and approves agreements related to agricultural and fishery biological resources (section 10.3.1 (c), Implementation Regulations). The Secretary of the Department of Health signs and approves agreements related to activities on pharmaceutical or medicinal research especially involving extracts and compounds produced by metabolic processes (by-products and derivatives) (section 10.3.4 (b), Implementation Regulations). The Secretary of the Department of Environment and Natural Resources signs and approves agreements related to terrestrial wildlife (section 10.3.5 (c), Implementation Regulations).

The signed agreements are then furnished to the local communities involved and the collector. The Protected Areas and Wildlife Bureau, which monitors the implementation of the agreements, also receives a copy (sections 8, Implementing Regulations).

Other functions of the Philippine Inter-agency Committee are clearly specified in the Implementation Regulations of the Executive Order. They include ensuring that the conditions of the research agreement are strictly observed (section 10.2.b), deputising and training appropriate agencies to control exports of genetic resources without an agreement (section 10.2.d), ensuring the rights of indigenous and local communities in whose territories bioprospecting activities will occur (section 10.2.e) and developing a conceptual framework for using research agreements to increase knowledge on Philippines biodiversity (section 10.2.h).

In the Andean Pact, Decision 391 sets out some of the minimum functions of the national competent authority of each member state. Each member state decides the ultimate composition and function of their own national authority (article 50).

Some functions are self evident. For example, the competent authorities are to negotiate access contracts, make access determinations, modify or suspend the contracts and monitor their implementation (article 50(c), (b), (g) and (i)).

Others are less obvious. For example national competent authorities can "gap fill" in areas that the Decision does not cover (article 50(a)). They are to "safeguard the rights" of the providers of biological resources which contain the genetic resources sought (article 50(d)). The rights of the providers of associated knowledge are to be safeguarded as well. National authorities can also review accessory contracts between the applicant and third parties (article 50(j)).

In addition, they are to supervise the conservation status of targeted biological resources and maintain a national inventory of genetic resources (article 50(1) and (n)). National authorities are also to establish permanent contact with the intellectual property authorities in the member state and establish appropriate information systems (article 50(o)).

The draft Fijian legislation would designate the Conservation and National Parks Authority to establish a system to regulate biodiversity prospecting (section 254(1)). Unlike the Philippines where an inter-agency committee is established, the Authority will not be an inter-agency body.

The Authority will have a number of primary functions. For example, when an application is received it will collect the views of other agencies and the public. It will consult with other agencies including the Native Land Trust Board, the Departments of Health and Customs and the ministry responsible for fisheries (section 254(5)(a)(i)). If necessary, the Authority would be able to extend the consultative process to other government ministries, departments or statutory bodies (section 254(5)(a)(i)). The views of the public would be solicited upon the release of a public notice (section 254(5)(a)(ii)).

Another primary function will include ensuring that a legally binding agreement exists between the potential bioprospector and the registered owners of the resource (section 254(6)(a)). It will also ensure that the applicant completes an operational plan for the intended research (section 254(6)(b)). A monitoring plan and a process for undertaking an inven-

tory are also required. An auditing system to verify the activities of the applicant must also be ensured (section 254(6)(c)). All requirements must be satisfied before a biodiversity prospecting permit, which represents consent, is issued.

In addition, the Authority also oversees the export of materials collected. Prior to granting an export permit it will verify compliance with "the conditions of any authority granted" (section 254(14)(a)) prior to granting an export permit. Prior to granting an export permit, it will also inspect the specimens collected to confirm compliance with any CITES requirements (section 254(14)(b)). The Authority will have the power to issue directives when the permit is not being complied with (section 254(16)).

3.4 Prior Informed Consent: The Access Determination Process

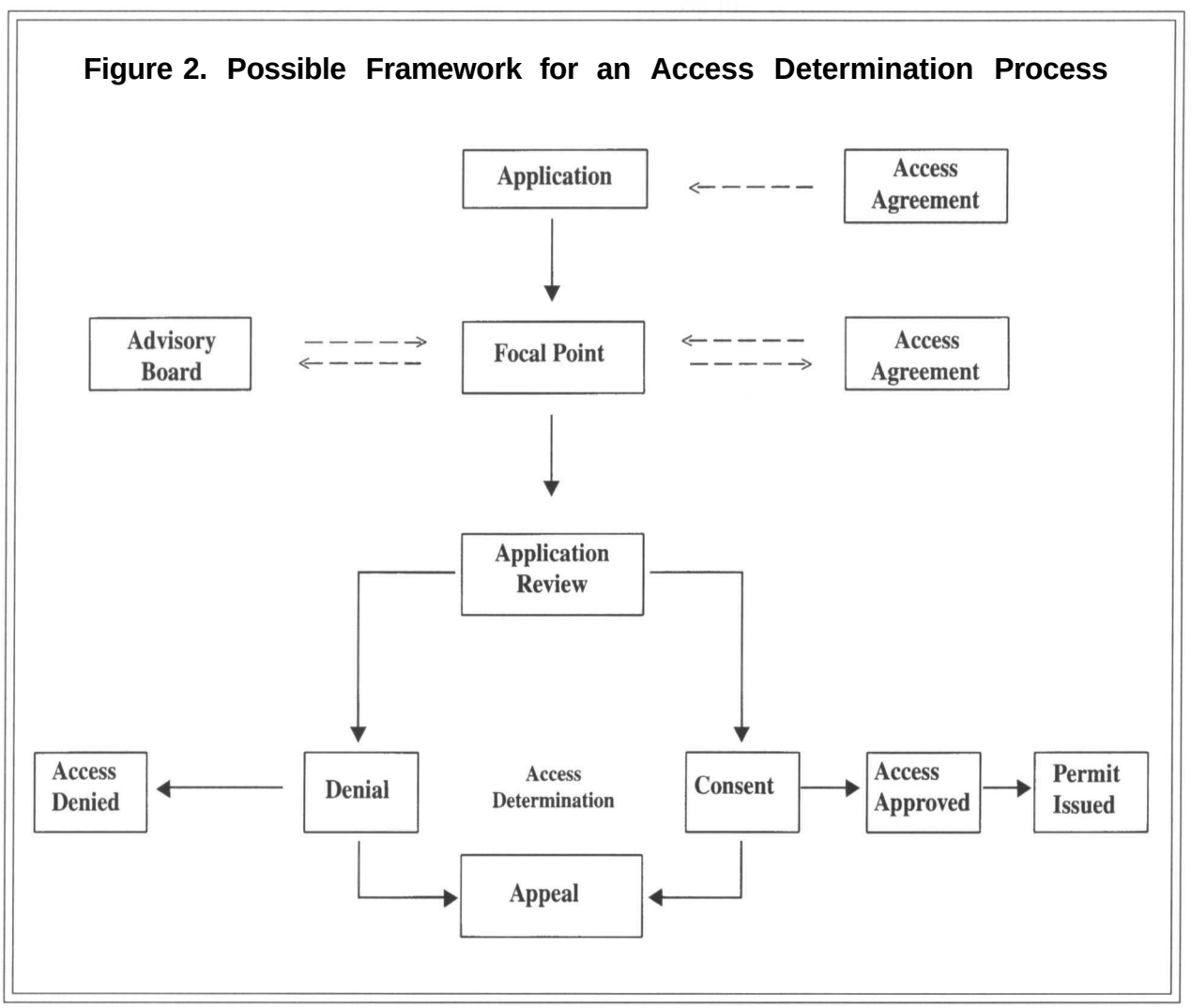
Prior informed consent of a competent authority implies that an administrative "access determination process" is created to handle requests for access to genetic resources. The process is a manifestation of the State's sovereign rights over genetic resources within its jurisdiction.

The primary goals of the process should be (1) to ensure sufficient information exists for the competent authority to make an informed access determination (that is, whether to grant or deny consent to the applicant) and, where appropriate, (2) to facilitate reaching mutually agreed terms.

The access determination process could have four primary components (see figure 2):

- application submitted to a designated institutional competent authority;
- review of the application;
- access determination (denial of or consent to access); and
- appeal.

Figure 2. Possible Framework for an Access Determination Process



3.4.1 Application to a Competent Authority

The information required for an access determination can be supplied to the competent authority via an application form. The receipt of the application would trigger the access determination process.

Access legislation could outline the broad informational requirements, while more detailed regulations could be promulgated if need be. An access determination application form could be created to standardise the presentation of relevant information. This will facilitate the access determination process.

It may also be desirable to create an "application package" for prospective applicants to make it as easy as possible for them to apply for access to genetic resources. Ideally, it would clearly and succinctly explain the information required for the application and the process for determining access. A diagram or schematic of the process might be especially helpful for the applicant. The package could be made available in printed form and electronically on the World Wide Web.

In addition, even before an application is formally submitted, prospective applicants might be encouraged to seek a "pre-application meeting" with the competent authority. This could help resolve any outstanding matters related to a draft application. It could also provide the basis to discuss and ensure that all requirements are fully understood. This might ultimately facilitate the access determination process.

3.4.1.1 State Practice

Andean Pact Decision 391 sets out the minimum information that each member state should require as part of an access application (articles 17 and 26). This information contributes to the criteria against which the application is evaluated. It will also provide the basis for ultimately conditioning any access contract granted.

For example, the application should address participation of nationals from the Pact region in the proposed activity and how the proposal will support research in the particular member state or the region. Mechanisms to strengthen technology transfer and regional, national or local capacity are to be described. Information on the deposit of samples and third-party transfer is also required (article 17).

In addition to the more self-evident requirements such as the name of the applicant and the identity of the genetic resource provider, Decision 391 also requires the applicant to demonstrate its legal capacity to enter into an access contract (article 26(a)). The identity of a national collaborating person or institution must be provided (article 26(c)). A proposal is to be submitted describing the activity and the areas for which access is sought (article 26(e) and 8(f)).

The Pact will establish a common project proposal format (article 26). The Andean Committee on Genetic Resources will prepare an explanatory guide to the Decision (article 51(j)). In addition, the Pact will develop models for access applications (final disposition 10).

Complete applications result in the file being registered. Incomplete applications are returned with a rationale (article 27).

The draft Eritrean biodiversity proclamation states that an application for access to *in-situ* or *ex-situ* genetic resources should provide a description of the specimens to be taken and their intended use (article 48(b) and (c)). For access to *in-situ* sources, work sites are to be identified. A description of the proposed activities, including collection methods and sample amounts, as well as the results of an environmental impact assessment, are to be provided along with the conservation status of the species or organisms sought (article 48(d)). Access to *ex-situ* sources requires the identification of the institution holding the materials which are sought (article 48(e)). A copy of the material transfer agreement is to be submitted with the application (article 48(e)).

Under the draft Fijian legislation, the information to be submitted reflects many of the same elements as legislation from other States. One unique requirement, however, is that the applicant is to provide information on "the nature of any intellectual property rights that may be affected concerning the traditional use of any biological resource" (section 254(4)(b)(iv)).

The Philippines have created a standard application form for an academic or commercial research agreement. When completed, signed and notarised, the applicant certifies statements made are correct and truthful and that the applicant will abide by the decision of the Inter-agency Committee (annex B, Implementation Regulations).

In addition to a letter of intent and a research proposal (section 6.1.1, Implementation Regulations), some other information requested includes a list of foreign and local researchers collaborating in the

undertaking (annex A, Implementation Regulations). Letters of acceptance from counterparts in Filipino institutions and letters of endorsement from the head of the applicant's institution, or that from another reputable institution, are also required (sections 6.1.2 (a) and (b), Implementation Regulations). The Implementation Regulations provide a standard format for research proposals (annex A, Implementation Regulations).

Submitting the application triggers an initial screening by the technical secretariat to determine whether the proposed activity is within the scope of the Executive Order (section 6.2.1, Implementation Regulations). If it is, then additional information is requested pursuant to a checklist. For example, an environmental impact assessment may be required by the technical secretariat (section 6.1.4, Implementation Regulations). In addition, when a commercial research agreement is requested, a "prior informed consent certificate", obtained from the relevant holder or ultimate provider of genetic resources must also be submitted to the technical secretariat to complete the application (section 6.2.3 and annex E, Implementation Regulations).

The entire application process is facilitated by a short publication which disseminates and describes the relevant legislation and provides background information for applicants. The access determination process is schematically represented to enable the applicant to visually understand the process (La Vina *et al.,* 1997).

In the United States of America, the information requirements for an application to obtain a research permit in Yellowstone National Park are compiled in an application package. The package includes a standard application form, the criteria for reviewing a research proposal, a copy of the relevant applicable laws, a research proposal outline and a standard form for peer review comments on the research proposed along with a criteria for the peer reviewer. Among other things, the application form requires the name of the curator and the address of the repository for storage of collected specimens or data.

3.4.2 Reviewing the Access Application

The access determination process could provide the opportunity for the competent authority to gather information relevant to making an access determination. Depending on the circumstances, the access determination process may also be the point where mutually agreed terms are negotiated and concluded between the government and someone seeking access.

Submitting an access application would trigger the access determination process thereby initiating the review of the application. After the application is made, the actual review of the application might be broken down into two primary elements:

- public notification and availability of the access application; and
- reaching mutually agreed terms.

Timing milestones might be added to the review procedure to ensure timeliness of the procedure.

3.4.2.1 Public Notification and Availability of the Access Application

There are a number of information sources which the competent authority can rely upon as it undertakes its review. The obvious primary source is the applicant applying for an access determination. The applicant will be required to submit an application to the competent authority.

There may be other sources of important information. For example, depending on its technical expertise the competent authority may need the advice of a specially created advisory board (see section 3.3.1). Membership and terms of reference of the advisory board should be established by the access legislation.

In addition, parties potentially affected by the access determination or with special expertise, such as indigenous or local communities, business or the scientific community, may have useful information to share with the competent authority regarding the particular application. For example, competing rights over the genetic resources to be provided or the collection areas targeted could be identified. Valuable information about the potential environmental impact of the proposed undertaking could come to light. In regional contexts, notification of adjoining States may also provide the competent authority with valuable information. Therefore, an important element of access legislation could be to require the competent authority to publicise the receipt of the access application, and its contents to potentially affected parties. The legislation could specify the content of the public notice.

Whenever possible the public notice should be in local languages. A comment period of sufficient length to allow for responses to be made should be

provided. The access legislation could then specify that the comments are to be considered by the competent authority in combination with the other aspects of the application. Standards of review could be considered.

Public notification not only provides the competent authority with information. The exercise should also increase the transparency of the access determination process. For example, the public could be granted access to the application file itself.

Generally, the access determination process should be as transparent as possible. The presumption should be that all applications for access are freely available for the public to review. In some cases, however, it may be necessary for some information in the application to be kept confidential. For example, the confidential nature of some traditional knowledge, and the ability to establish intellectual property protection, could be jeopardised, if the knowledge is made public. In addition, some commercial information could lend a competitive advantage to the competitors of the applicant, if made public. Access legislation could specify which aspects of the application file are open to public scrutiny and which are to remain confidential.

Any confidentiality provisions in the access legislation should provide the competent authority with well-defined criteria to enable it to make a confidentiality decision. This will help avoid arbitrary decision-making and any appearance of a conflict of interest. The burden should be placed on the applicant to demonstrate why any part of an application should be kept confidential. The competent authority could be required to justify in writing why certain aspects of the application are to be kept confidential. Criteria might also be specified for removing any confidentiality restrictions when certain contingencies have been met. This would help eliminate situations where information is permanently removed from the public record.

Public notification after receipt of an access application might also initiate a more localised or grass roots access determination process. This process might lead to mutually agreed terms and prior informed consent between the applicant and the ultimate providers of genetic resources located in *in-situ* or *ex-situ* conditions.

3.4.2.2 Reaching Mutually Agreed Terms

An important goal of access legislation should be to provide a framework for reaching mutually agreed terms for access to genetic resources, and ultimately, prior informed consent. Access legislation should make clear:

- with whom the applicant must negotiate mutually agreed terms;
- when mutually agreed terms should be negotiated; and
- minimum criteria that an access agreement must fulfil.

Expedited procedures may be appropriate in cases where multiple access determinations are required (see box 9).

3.4.2.2.1 With Whom Must the Applicant Negotiate Mutually Agreed Terms?

While the Convention on Biological Diversity only speaks in terms of mutually agreed terms and prior informed consent as between its Contracting Parties, State practice reflected in national legislation will likely provide the basis for mutually agreed terms and prior informed consent to be sought between (1) the applicant and the State, (2) the applicant and an ultimate provider of genetic resources from *in-situ* or *ex-situ* sources or (3) both. The legal status of genetic resources (see section 3.2.1.1) will be a key determining factor.

3.4.2.2.2 When Should Mutually Agreed Terms Be Negotiated?

Timing the negotiation of mutually agreed terms within the access determination process will differ with the State. It will depend on who mutually agreed terms are to be negotiated with and what role the competent authority plays in the negotiation.

For example, access legislation may not allow an applicant to negotiate mutually agreed terms until an access application is submitted to and reviewed by the competent authority. In other situations, the applicant might simply enter into a draft agreement with the ultimate provider of genetic resources and submit this to the competent authority with the access application for review (see figure 2).

Box 9. Variations on the Basic Access Determination Process

The basic access determination process could be modified in any number of ways to accommodate the particular circumstances existing in the country. Expedited access determination procedures are a particularly important option to be considered.

Reaching mutually agreed terms and obtaining prior informed consent implies a case-by-case review of access applications. Case-by-case review will work well in most instances, especially where discrete one time only access is sought. Expedited procedures may be desirable in at least two cases where multiple requests for access are expected.

In the first case, there may be situations where an institution needs to undertake field work involving genetic resources on a regular basis. To minimise the burden of multiple access determinations for it and the competent authority, it may be desirable for a single access determination and access agreement to be made. This could lead to granting access to the institution and its researchers for a particular period of time.

In the second case, *ex-situ* conservation facilities may process hundreds of requests a year for genetic resources. Case-by-case access determinations for every request would quickly strain the administrative capabilities of the competent authority and the facility. Therefore, it may be possible and desirable for the competent authority to make a single access determination and agreement with the *ex-situ* conservation facility which requires the facility to ensure that in its material transfer agreements the interests of the State, or other genetic resource providers such as indigenous and local communities, are maintained. The extent to which this can be accomplished may be limited by national law. It may only be a solution for publicly owned facilities.

Andean Pact Decision 391 recognises that there may be instances where it would be desirable for the competent national authority of a member state to enter into "framework" access contracts with universities, centres of investigation and recognised investigators (article 36). In addition, *ex-situ* conservation facilities can enter into access contracts with the competent national authority to facilitate exchange of genetic resources which originate from the Andean Pact (article 37).

The Philippines legislation also provides some flexibility for researchers affiliated with institutions which have received an academic research agreement. Affiliated researchers are allowed to undertake research under the academic agreement after obtaining a prior informed consent certificate at the local level (section 8.3(2), Implementation Regulations). Affiliated researchers are bound to comply with the conditions of the agreement and the institute is to inform the Inter-agency Committee about the research to be undertaken.

3.4.2.2.3 What Minimum Criteria Must the Access Agreement Fulfil?

Mutually agreed terms should include terms and conditions for benefit-sharing. But they might also include other terms and conditions. For example, how the materials sought can be used and by whom. Limitations might be included to ensure that the proposed activities do not threaten the conservation status of target or non-target organisms. Terms on environmental compliance might also be required.

To ensure consistency of approach and to notify potential applicants of the requirements which need to be fulfilled to gain access, it may be advantageous for access legislation to provide minimum criteria for access agreements. A general policy on access and benefit-sharing, derived from a planning process, could form the basis for deriving minimum criteria. Depending on the circumstances, the criteria could be used by the competent authority to judge the merits of an access agreement to be reviewed or might guide it in negotiating an agreement itself.

Minimum criteria might address (1) whether consent of the ultimate providers of genetic resources has been attained; (2) collection and export restrictions including those based on the conservation status of the target organisms; (3) research participation and publication; (4) provision of duplicate samples; (5) technology transfer; (6) royalties or fees; (7) ownership of samples, derivatives and associated knowledge or information; (8) intellectual property rights; (9) limits on third party transfer; (10) reporting and tracking requirements; (11) the term or duration of the agreement; (12) the terms for nullifying or rescinding the agreement; or (13) choice of law provisions and any contingencies when the agreement is breached.

3.4.2.3 State Practice

Existing and proposed national and regional legislation covering the elements of the application review procedure provide good examples of different levels of regulatory complexity.

In Eritrea, the draft biodiversity proclamation does not include provisions for public notification. The application for an access permit would ultimately lead to the conclusion of mutually agreed terms between the applicant and the State. An access permit would reflect mutually agreed terms (article 50).

In Eritrea all land is owned by the State. However, where access is sought to land where a private right of use has been granted, consent of the usufructuary would be required (article 49(a)). Similarly, access to land used by pastoralists or other communities or groups with traditional land interests would also require their consent (article 49(b)). In both cases, any future access permit issued by the State would need to include terms to ensure benefit-sharing with these individuals or groups. No criteria are provided.

In addition, the legislation does not clarify whether access agreements providing a share of benefits can be negotiated with individuals or communities in addition to the access permit issued by the State. If a permit is issued for access to Eritrean genetic resources it would "contain" the consent of any group or community. It would also include terms on the duration of consent, restrictions on future use, third party transfer, benefit-sharing requirements, research participation, reporting requirements or conservation measures (article 50(6,4,7-10,12 and 13)).

Under the proposed draft Fijian legislation, an application for a special permit for biodiversity prospecting would trigger (1) a consultative process among governmental agencies and (2) a public notice, both of which are to be undertaken by the Conservation and National Parks Authority (section 254(5)(a)(i) and (ii)). The draft bill does not give any details on the nature of the inter-agency consultation.

The public notice would be published in daily newspapers in the three principal languages of Fiji (section 254(5)(b)). It would include a description of the activity and its nature, the methodology of the activity and the date to be undertaken, a statement on impacts to human, marine or environmental health and plans for environmental monitoring and management (section 254(5)(b)(i-v)). A provision in the public notice would state that any person may make a written submission on the application. It would also provide the closing date for submissions (at least 30 days from the notice's publication) and the address where submissions could be sent (section 254(5)(viviii). A copy of the public notice would be submitted to the National Council for Sustainable Development (section 254(5)(c)).

In both cases the draft bill does not provide criteria relating to the extent to which the Authority would have to consider comments derived from the governmental consultative or the public notification processes. Rather, the submissions would only have to be considered before a decision on the permit is made.

The draft Fijian legislation has very broad confidentiality provisions. Upon the written request of the applicant, any information contained in the application must be kept confidential by the Authority (section 254(4)(c)) until the Authority is notified by the applicant in writing that the "confidentiality is no longer required" (section 254(4)(d)). Therefore the Authority has no discretion to decide the validity of the request. In effect all the information in the application could be removed from public scrutiny, except of course that required for the public notice.

The Fijian bill is interesting because land in Fiji is owned communally by registered groups defined roughly according to customary law principles (Smith, 1996). These are now embodied in statute (Smith, 1996).

"Native ownership" is a trust relationship with the government (Smith, 1996). Prior to making any decision on the application, the Authority is required to ensure that the applicant and the registered owners of the targeted resource conclude a legally binding agreement (section 254(6)). The terms of the agreement would include (1) rights of access, (2) limitations on sample exploitation and removal, (3) harvesting or specimens or traditional knowledge and (4) fees for any concessions granted (section 254(6)(a)(i-iv)). It does not appear that the Authority can negotiate a benefit-sharing agreement on behalf of the government itself.

The Authority would also ensure that operational and monitoring plans, including a system proposed for recording and inventorying information collected, is completed by the applicant (section 254(6)(b)). The Authority is to ensure an auditing system is established to verify the activities of the applicant (section 254(6)(c)).

Finally, the approval of the application by the Authority would be conditioned upon the applicant submitting a legally binding agreement to "negotiate and conclude suitable royalty agreements with the resource owner upon the registry of any patent or copyright by the applicant" (section 254(7)). If a permit is issued, the conditions stipulated would include (1)

the species sought and quantities that could be harvested, (2) the methods of scientific evaluation, sampling or harvesting, (3) methods for storage and transport and (4) any environmental monitoring or management plans needed (section 254(9)(c)). A full description of the bioprospecting activity and its location is also required (section 254(9)(a) and (b)).

In the Andean Pact, submitting an access application to a member state will trigger a review procedure in the state *prior* to the negotiation of an access contract. Within six days of receiving a complete access application, an extract of the application will be published nationally, and locally in the targeted region. This will publicly announce the receipt of the application and solicit comments (article 28).

The competent national authority of the member state will issue a technical and legal opinion on the appropriateness of the application within a time frame specified by national law (article 29). The competent authority will consider the comments submitted pursuant to the public notice. During this time a field visit to the targeted area to confer with potentially affected communities may also take place.

The national authority accepts or denies the application (article 30). Applications denied are done so without prejudice. This means that the applicant could revise the application and re-submit it at a later date. A rationale for denial is to be provided by the competent national authority. One reason for denying the application might be that an environmental impact assessment needs to be undertaken (article 31).

If the application is accepted, the applicant is notified within 5 working days. Negotiations for an access contract then begin (article 30).

Decision 391 acknowledges that in some cases it may be desirable to make exceptions to the general rule that all access procedure documents are to be placed in the public record and made accessible to anyone (article 18). The Decision allows member states to keep some information or aspects of an access contract confidential. The primary criterion is whether the information could provide the basis for unfair commercial use by third parties, unless the information is already public knowledge or is necessary to protect social or environmental interests (article 19).

The applicant must justify why certain information must be kept confidential, while providing a non-confidential summary of the application which would be placed in the publicly available file (article 19). Some information, such as the identity of the applicant, cannot be made confidential (articles 18 and 19). The competent authority will keep a reserved file for confidential information (article 19).

In addition to notifying the general public, the member state is also obliged to notify the other member states of all access applications (article 48). It is unclear, however, what information is to be supplied as part of the notification and whether confidential information can be withheld.

The Pact Decision supports the possibility of at least two types of contract through which mutually agreed terms can be immortalised: (1) "access contracts" between the applicant and the national competent authority (Title V, Chapter III), and (2) "accessory contracts" (Title VI) between the applicant and either a (1) landholder or owner, (2) an *ex-situ* conservation facility, (3) the holder or owner of biological resources containing genetic resources or (4) a national support institute.

The access contract governs the terms and conditions of access to genetic resources and derivatives. The minimum terms of the access contract between the applicant and the competent national authority are to be in accordance with the Decision and national implementing legislation (article 33).

The access contract is to take into "account the rights and interests of the suppliers of the genetic resources and their derivative products, of the biological resources which contain them and of the intangible component in accordance with the corresponding contracts" (article 34).

In addition, every access contract is to have an annex which refers to benefit-sharing when there is knowledge or information associated with the genetic resources provided (article 35). The annex is actually a third type of contract possible under the Decision (ten Kate, 1997b). It becomes an integral part of the access contract upon the approval of the contract (article 35). The annex is to be signed by the provider of the associated knowledge and the applicant. National legislation will decide whether the competent authority will also sign the annex (article 35). A possible tripartite agreement seems designed to protect indigenous and local communities which may not have the resources to enforce the annex.

Accessory contracts apply to activities associated with access to genetic resources (or derivatives) (ten Kate, 1997b). For example, the applicant may need to negotiate an accessory contract to enter land on which genetic resources are found.

The minimum terms and conditions for accessory contracts are suggested (article 17) but it is unclear whether they are mandatory. It appears the parties to the accessory contract have flexibility to freely contract perhaps while drawing on article 17 for guidance. The minimum terms refer to such issues as research participation, capacity building for indigenous

and local communities, deposit of duplicate samples, reporting on research results and terms on third party transfer of materials.

The execution and enforcement of the accessory contract is the complete responsibility of the parties to it (article 42). The accessory contract must have a "suspense clause" (article 42). The suspense clause prevents the entry into force of the accessory contract until certain conditions are fulfilled. The accessory contract becomes effective when the access contract is approved. Nullifying the access contract between the competent authority and the applicant nullifies the accessory contract (article 44).

In the Philippines, PIC is two-tiered. It is sought at the national level and at the local level. Therefore reviewing the access application and reaching mutually agreed terms must necessarily occur at both levels. The access determination process is usefully depicted diagrammatically in annexes to the Implementation Regulations of the Executive Order.

After the initial screen of the application by the technical secretariat of the Inter-agency Committee, the applicant is to seek a "prior informed consent certificate" from a local provider to complete the application. The location of the proposed activity will determine whose prior informed consent must be sought. Prior informed consent will be required either from the recognised head of an indigenous community, head of local government in a community, the local or district office of the Philippine Protected Area Management Board or a private land owner.

The procedure to secure prior informed consent at the local level varies depending on whether a commercial or academic research agreement is sought (section 7, Executive Order; annex D, Implementation Regulations). The primary distinction turns on when the PIC certificate is obtained in relation to the commencement of the activity.

For commercial agreements, PIC must be secured as a condition for the Inter-agency Committee to process the application further and a subsequent recommendation in favour of a commercial research agreement (section 7.1, Implementation Regulations). In contrast, for academic agreements, PIC only needs to be secured prior to the commencement of the bioprospecting activity (section 7.2, Implementation Regulations).

The PIC procedure has two basic components. One is public notification. The other is sector consultation. In both cases the applicant has the burden of initiating the process.

As part of the public notification for a commercial agreement, the principal or collector must inform the recognised head of an indigenous community, head of government in a local community, the Protected Area Management Board or private land owner through various media (section 7.1.1, Implementation Regulations). Notification could include newspaper, radio or television advertisements. These are to be designed to (1) notify on the intent of the applicant to collect within specified areas and fully disclose the activity, (2) state that a summary of the research proposal has been filed locally with the relevant provider of genetic resources and (3) highlight that a research agreement application has been filed with the Inter-agency Committee for a commercial research agreement (section 6.2.2, Implementation Regulations).

Public notification for academic agreements is similar, but the option is given for "direct communication" in lieu of media advertisements. Additionally, notification can include either information that an application has been made for an academic research agreement or that an academic research agreement already exists between the applicant and "the agency concerned" (section 7.2.1, Implementation Regulations). The last qualification is not clarified in the regulations.

The sector consultation is essentially a community level public hearing in the area where bioprospecting will occur (sections 7.1.2 and 7.2.2, Implementation Regulations). Notice of the consultation is to be conspicuous and made at least one week before the assembly. A brief summary of the proposal, in the local language or dialect, is to be submitted to the appropriate person or institution mentioned earlier.

The summary is to include the purpose and methodology of the activity, duration, species or specimens and quantity taken or used. It must also describe the benefits to be shared during and after the activity. In addition, a categorical statement is to be included that the proposed activity will not in any way affect the traditional use of resources. Where Indigenous Peoples are involved, the sector consultation for a commercial research agreement is to be vetted according to their customary laws and traditional practices.

Sector consultations are not required for the academic research of undergraduate, masters or doctoral students, where their research is not funded by a commercial entity (section 7.2.5, Implementation Regulations)

The recognised head of the indigenous community, head of government in a local community, the Protected Area Management Board or private land owner signs and issues the PIC certificate when public notification and sector consultation have been complied with (sections 7.1.3 and 7.2.3, Implementation Regulations). A standardised form for the certificate is

provided. Signature certifies the implications of the project have been understood. It also demonstrates that the respective constituencies have been contacted and do not oppose the project (annex E, Implementation Regulations).

The Implementation Regulations present at least two discrepancies. First, even though private landowners are required to issue a PIC certificate, the certificate form does not appear to be tailored to their circumstances.

Second, the regulations do not specify how opposition to the proposal is to be considered in the decision for a prior informed consent certificate (section 7.2.3, Implementation Regulations), although it appears from the PIC certificate form that the certificate can only be issued where there is no objection. In fact, the only reference the regulations make to opposition is raised in the provisions for the academic research agreement.

The Implementation Regulations outline the minimum terms and conditions for a research agreement (section 8). General terms for all research agreements are listed. Specific terms for commercial and academic research agreements are then provided.

For example, all Filipino citizens and any Philippine governmental entities are to have complete access to specimens deposited at an internationally recognised *ex-situ* depository (section 8.1(4)). All commercial discoveries are to be available to the Philippine government and local communities (section 8.1(9)). Most interestingly, technologies developed from Philippine endemic species are to be made available to the Philippine Government for commercial and local use without requiring a royalty (section 8.1(13)). The details can be negotiated however.

All bioprospecting research by foreign legal and natural persons is to be undertaken in collaboration or cooperation with Philippine scientists. The expenses are to be borne by the collector (section 8.1(12)). Another condition requires a separate benefit-sharing agreement to be negotiated in addition to the research agreement (section 8.1(14)). When this is to occur however is not clear.

When the commercial or academic collector is an agent for another legal or natural person, the agency agreement between them must be reviewed by the Inter-agency Committee to ensure its consistency with the Executive Order (section 8.1(17)).

Commercial agreements are limited to a duration of 3 years. In addition, the applicant must submit "a performance, compensation, ecological rehabilitation bond" deposited in favour of the government (section 8.2(4)). If the terms of the research agreement are broken the bond is forfeited (section 14.3).

Academic research agreements are valid for 5 years and can be used by affiliates of the institution awarded the agreement provided they secure a PIC certificate (section 8.3(7) and (2)) and that institution ensures that affiliates abide by a code of conduct which is appended to the academic research agreement (section 2 (b), Academic Research Agreement). Data or materials collected cannot be transferred to a commercial entity without the reclassification of the academic agreement as a commercial agreement (section 8.2(6)).

3.4.3 The Access Determination

The actual access determination will be simply a decision to deny or grant consent to access genetic resources. It is essentially a yes or no answer. But, for purposes of transparency and possible appeal (see section 3.4.4), a rationale for the decision should be provided and made publicly available.

The criteria against which the application is judged should provide the minimum basis upon which the access determination is made. Legislation might specify the general criteria against which the application is to be judged, as well as to what extent the competent authority must consider comments received in a public notification process (see section 3.4.2.1). Criteria might include an assessment of the environmental or social impact of the proposal; whether the terms for benefit-sharing are in keeping with development goals developed in the planning process; whether all relevant permits have been obtained or applied for; and, importantly, whether the informed consent of, for example, indigenous and local communities, has been obtained.

If access is denied, it should be in writing. The written justification of the competent authority could be required. The legislation should clarify whether the denial of access is without prejudice. In other words, can the applicant seek access again in the future, even though the immediate application has been denied.

Consent should be manifested in writing. This could be in the form of a permit. Appended to this could be conditions of access, in particular conservation and sustainable use provisions, and an access agreement representing mutually agreed terms. Wherever possible, these documents should be made publicly available to ensure transparency and their enforcement.

The permit document demonstrates that the potential user has obtained the prior informed consent of the competent authority. Therefore, it could be used as a certificate of origin or proof in other countries that prior informed consent has been obtained and as a possible means to ensure benefit-sharing.

3.4.3.1 State Practice

Decision 391 of the Andean Pact provides a number of criteria which may be used in the access determination process. Many will be considered early on when the application is first submitted and before the applicant is allowed to enter into negotiations for an access contract.

A good example is the Decision's short list of situations where, pursuant to national legislation, the member state can impose limitations on access (article 45). Limitations can be imposed where (1) endemic, rare, threatened or endangered species are targeted, (2) the activity involves a fragile ecosystem, (3) adverse impacts to human health or the essential elements of cultural identity are at stake, (4) undesirable environmental impacts may occur, (5) there is a danger of genetic erosion, (6) biosecurity issues present themselves or (7) the proposed activity targets strategic genetic resources or geographical areas (article 45(a)-(g)).

Another interesting example is the prohibition placed on using genetic resources from the Andean Pact in biological warfare applications (article 24). This is a good example of how the qualification on facilitating access for environmentally sound uses, found in article 15(2) of the Convention on Biological Diversity, could be applied in practice (see section 2.1.2).

Early screening of these details makes the access determination process more efficient because efforts to ensure the acceptability of the application are expended up-front. This should lower the risk that the application will be rejected late in the process, when the applicant might otherwise have expended considerable resources to follow the process only to have access then denied. This, therefore, may actually facilitate access in the long-run.

The actual access determination in the Pact is called "perfecting the access contract". When the access contract is completed and signed, the competent national authority issues a resolution along with the contract (article 38). The combination manifests consent to access genetic resources. The access determination process is then complete.

A registration number is assigned. The resolution and an abstract of the agreement is published in the official gazette of the member state. It is unclear whether abstracts of the accessory contracts are also published. The entry into force of the agreement is the publication date. On this date any suspense clause on accessory contracts is lifted and these enter into force immediately (article 42). The Pact member states are to be notified of the decision immediately (article 48).

In the Philippines, after evaluating the application, the Inter-agency Committee recommends to the secretary of the governmental agency with competence over the particular genetic resources at issue that the agency should approve the research agreement applied for (section 6.2.5, Implementation Regulations).

The agency then is to approve the agreement (section 6.2.6, Implementation Regulations). Upon the recommendation of the Committee, the particular agency makes the actual access determination. A signed copy of the agreement is transmitted to the applicant, land owner, head of local government or indigenous community (section 6.2.7, Implementation Regulations).

While the agency seems to be obliged to issue the research agreement upon a positive recommendation from the Inter-agency Committee, it is unclear what happens to the application if the Inter-agency Committee does not recommend approval. Neither the Executive Order nor the Implementation Regulations have provisions on the public availability of the agreement or its final terms though the Protected Areas Wildlife Bureau acts as depository of all original and official documents, such as research agreements (section 12, Executive Order). Presumably, therefore, the availability of these documents is subject to Philippines administrative law.

In Fiji, the Conservation and National Parks Authority would first have to consider submissions made pursuant to the public notification process and verify minimum criteria have been met before it making an access determination. There are three possibilities for a decision: (1) refuse the permit, (2) require an environmental impact assessment or (3) issue the permit with specific conditions (section 254(8)). Within seven days of issuing a permit, the Authority would submit a copy of the public notice and a copy of the permit to a public registry (section 254(11)).

3.4.4 Appeal

An administrative appeals process could be instituted as part of the access determination procedure. Appeals could be handled through existing administrative procedures.

Whether based on procedural or substantive grounds, the appeals process could be accessible to applicants denied consent, as well as potentially affected parties whose views may not have been adequately considered by the competent authority in the access determination process. If a substantive right of action is provided, an appropriate margin of discretion should be maintained for the competent authority.

3.4.4.1 State Practice

The Philippines Executive Order provides for appeal. Individual agency decisions to approve, disapprove or rescind a research agreement can be appealed to the office of the Philippines president within 30 days of the receipt of the decision (section 9, Executive Order; section 13.1, Implementation Regulations). Recourse to the courts can be sought after all administrative remedies have been exhausted.

The Andean Pact Decision does not create a right of appeal. Denial of the access application is done so without prejudice, but any right of appeal is pursuant to a member state's national legislation (article 30).

3.5 Export Controls

Export controls could be used by the State providing genetic resources to ensure that prior informed consent requirements have been fulfilled, both with the State and with others. Export controls might be used to confirm that the applicant has complied with the conditions of the agreement or a permit issued.

Targeted species may also be endangered or threatened and could be subject to specific legislation which limits their taking and subsequent export. In addition, endangered or threatened species may be listed in the appendices of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Export controls might also be designed to complement CITES implementation, especially since CITES controls apply to the whole organism, its parts and derived products.

In many cases, existing mechanisms such as export permits, biosecurity controls for quarantine or postal regulation could be modified to ensure prior informed consent. New mechanisms may need to be developed particularly for micro-organisms.

There are a number of measures States could take. Most importantly, access legislation could explicitly state that the export of genetic resources is prohibited without prior informed consent. Transparent rules will be important for minimising the likelihood of trade disputes between States.

Special attention is needed to tie any export embargo very closely to the purposes and scope of the access legislation. This will minimise adverse impacts on the wider use of biological resources. Permits or licenses to export biological resources for purposes beyond the scope of the access legislation could stipulate that the approval does not represent consent to use their associated genetic resources.

General restrictions or limits could be imposed on the kinds and amount of biological material exported from the country. Ports of exit could be designated. Access legislation must also clearly establish the authority of border officials to ensure prior informed consent and provide them with the power of seizure where needed. Penalties for exporting genetic resources without prior informed consent could be established.

In addition, access legislation could facilitate the institutionalisation of a formal coordination mechanism between the competent authority and customs authorities to ensure that customs officials are aware of access determinations. Customs authorities should be made thoroughly familiar with the documentation issued by the competent authority which establishes its consent.

3.5.1 State Practice

Export controls are a typical feature of the existing and proposed access legislation examined. For example, the enabling legislation either proposed or finalised in The Gambia (section 35(2)(a)), Kenya (section 38(2)(b)), Malawi (section 36(2)(a)) and Uganda (section 45(2)(b)) directs a competent authority to make regulations or guidelines on measures for regulating the export of "germplasm".

The proposed Eritrean legislation would require a certificate of origin to be issued prior to export (article 51 (b)). The certificate of origin would be issued by the competent national authority when compliance monitoring, undertaken in cooperation with local authorities, indicates that some of the conditions of the access permit have been fulfilled (article 51 (a)). The details of this process would probably be elaborated in subse-

quent regulations designed to implement the law's section on access to genetic resources.

The 1992 Wildlife Conservation Law of Costa Rica requires written permission to export wildlife from the Wildlife Office of the Ministry of Natural Resources, Energy and Mines, pending verification of compliance with the established procedure or conditions of the agreement (article 44).

The export control provisions of the draft Fijian legislation seem to be more elaborate than the provisions to gain access for bioprospecting purposes. Before the bioprospector could export any specimen harvested pursuant to a bioprospecting permit, an application would need to be made for removal and export (section 254(12)(a)).

The application would specify (1) the number and size of the specimen exported and the harvesting location (2) the manner of export and (3) the impact removal and export would have on other species (section 254(12)(b)(i-iii)). As it considers the application, the Conservation and National Parks Authority would inspect the specimens collected to verify compliance with any authority granted (section 254(14)(a)) and CITES (section 254(14)(b)).

The Authority then decides whether to refuse permission to export or to issue an export permit (section 254(13)). The approval of the application would be contingent upon the applicant submitting a legally binding agreement to (1) report regularly on any subsequent scientific research flowing from the bioprospecting activity, (2) notify the Authority when any patents or copyrights are sought or registered and (3) negotiate royalty arrangements with the resource owner upon registry of any patent (section 254(15)(a)(b) and (c)). Financial security to warrant performance could be required by the Authority.

The Andean Pact Decision does not have any explicit provisions on export. The movement of biological resources between the member states of the Andean Pact is allowed provided no use of genetic resources is contemplated (article 14). Transfer of genetic resources between member states therefore appears to be prohibited. Sanitary certification for biological resources pursuant to Pact Decision 378 must include the new wording "use as genetic resources is not authorized" (complementary provision 4).

The Philippines Executive Order recognises the importance of export controls, but does not explicitly ban the export of genetic resources. Instead, without referring to the customs agency, the Inter-agency Committee is required to deputise and train "appropriate agencies" to ensure that genetic resources are only exported pursuant to valid research agreements (section 7(d)).

The Implementing Regulations also refer to export in the context of the minimum terms and conditions of research agreements. For example, wild animals collected and/or exported are to be free from disease (section 8.1(1)). Exports will be subject to strict quarantine and existing CITES rules (section 8.1(5). Plant germplasm exports need to comply with the Philippine Seed Industry Development Act (1992) (section 8.1(6)). Transport of genetic resources is subject to a transport or postal clearance permit (section 8.1(7)).

3.6 Breaches of the Access Legislation and the Access Agreement

The prior informed consent requirement will be difficult to enforce primarily because of the nature of genetic resources particularly their wide availability and ease of dissemination or replication. It will be impossible to ensure enforcement of prior informed consent for all genetic resource transactions because of the sheer number which can and will take place (see figure 1). The threat of sanctions and penalties for breaches of the access legislation, and recision, modification or suspension of the agreement when its terms are breached, can help bring credibility to the access determination process and increase the likelihood that the access agreement will be honoured.

Civil remedies and criminal penalties could be provided in the access legislation. The power of the competent authority to impose sanctions and penalties should be specified. In addition, the access legislation may indicate whether consent, or the access agreement, can be rescinded, modified or suspended. If so, the grounds, criteria or conditions for these actions could be specified. More detailed procedures may need to be enacted. These could be elaborated in subsequent implementation regulations.

3.6.1 State Practice

In the Andean Pact, persons undertaking "access activities" without the required authorisation are subject to unspecified sanctions (article 46). Unpermitted transactions involving derivatives, synthesised products or associated knowledge are also grounds for sanctions. Administrative sanctions such as fines, confiscation and barring the violator from applying for access in the future are all possible according to the national legislation of each member state (article 47). The competent national authority can apply sanc-

tions in addition to suspending, cancelling or nullifying an access contract, require payment for damage to biological diversity and impose any civil or criminal sanctions which may apply (article 47).

The proposed Fijian legislation would give the Conservation and National Parks Authority the power to issue directives to cease bioprospecting activities, recover samples taken and institute financial proceedings to recover any financial security which may have been deposited if the permit issued is not strictly complied with (section 254(16)(a)-(b)). Criminal and financial penalties for a person's failure to comply with the directives, requirements or conditions of the Conservation and National Park Authority can be imposed (section 254(17)).

Financial penalties will range from US $10,000 to US $20,000 (section 279). Liability assessment or the settlement of other disputes would be assigned to a proposed sustainable development tribunal (section 254(18)).

The Philippines Executive Order provides for criminal penalties when activities are undertaken in violation of it (section 10). Prosecution would be under existing criminal laws including the provisions of the National Integrated Protected Areas System Act (1992) and the Revised Forestry Code (section 14.1, Implementation Regulations). For legal persons, such as corporations, liability extends to the corporate head, president or general manager (section 14.2, Implementation Regulations).

The Executive Order allows the government to unilaterally terminate the research agreement when any of the terms of the agreement have been violated (section 5(f)). The research agreement can also be revoked for reasons of public interest or welfare. Non-compliance will cause the government to confiscate the collected biological and genetic specimens (section 14.3, Implementation Regulations).

In the event of non-compliance, the performance, compensation and ecological rehabilitation bond, provided by the holder of a commercial research agreement as a condition of the agreement, would be forfeited. In addition to any other administrative sanctions, a perpetual ban on future bioprospecting within the Philippines would be imposed. The violation would also be published in the national and international media and the Inter-agency Committee would notify intergovernmental organisations.

The Implementation Regulations also have specific provisions on the rescission of the research agreement (section 9). For example, after a prior informed consent certificate has been obtained and the research agreement enters into force, subsequent rescission of the certificate will not be grounds for rescinding the agreement (section 9.1). Exceptions are made, however, when the agreement was obtained fraudulently, the right of indigenous peoples to traditionally use biological resources is impaired or the public interest or welfare would be violated (section 9.1(1-3).

The violation of the terms of the agreement by either party are grounds for rescission (section 9.2). The principal associated with the agreement can apply for rescission in cases of bankruptcy, force majeure or security problems (section 9.3).

The Republic of Korea National Environmental Preservation Act of 1991, as amended in 1994, also has particularly strong provisions on sanctions and penalties for commercial, medical and scientific use of biological resources without prior approval. Persons may be imprisoned for up to one year or fined up to 3 million Won (article 39(3)).

3.7 Identification and Monitoring

Access legislation can address identification and monitoring in a number of different ways. The planning process should highlight which areas need to be addressed in the State's approach. The State's national research policy could be drawn on for guidance. The identification and monitoring provisions of the access legislation can be targeted to at least three actors: the government, the competent authority overseeing the access determination process and the legal or natural persons seeking an access agreement.

The access legislation could require the government to undertake new identification and monitoring activities specific to genetic resources or maintain or redirect existing activities. The ability to do this will be dependent on a sustainable flow of financial resources to support these efforts as well as training for in-country scientists and para-taxonomists.

Increased financial resources may be politically justifiable if identification and monitoring activities are directly connected to wealth-building or other "spin-off" activities within the country. For example, identification and monitoring activities could expand the potential uses for genetic resources already known in the country, while uncovering genetic resources with new uses.

In addition, identification and monitoring activities could strengthen a State's position in negotiating mutually agreed terms for access to genetic resources. Finally, since collecting and other pressures can threaten genetic resources, and therefore bio-

prospecting activities, identification and monitoring, along with related research efforts, will contribute to conservation and sustainable use measures. All three situations could provide important support to a State's biotechnology sector, while contributing important biodiversity-related information to the country.

The competent authority, which may or may not be a governmental entity, could be charged by access legislation with coordinating identification, monitoring and other associated research efforts. It could also be charged with ensuring that access-related activities help the State accomplish its identification, monitoring and other research goals. This would be reflected in an access agreement.

Pursuant to an access agreement, the legal or natural person who sought access could be required to contribute to the identification and monitoring efforts. Such "process benefits" (Laird and Wynberg, 1997) could be very valuable up-front "payments" for access to genetic resources. They should not be overlooked.

At a minimum, the agreement should require duplicate samples to be deposited with an identified in-country institution. An access agreement could also provide for training of personnel in such areas as taxonomy and database management. The researchers of a country could participate in taxonomic research proposed whether in the field or in the laboratory. Data assessments, research results and relevant publications resulting from access which could contribute to identification and monitoring activities should also be provided.

Access legislation should require the permittee to monitor the impacts of proposed collecting activities, especially if they will involve potentially intensive or destructive methods. This will ensure that activities do not threaten populations of the target organism, its habitat and other organisms as well. This could be manifested through an access agreement condition.

Monitoring, however, pre-supposes some level of baseline information is available. Baseline information could be required as a pre-condition to an access determination, perhaps via an environmental impact assessment. Additional research may be needed.

Because monitoring is the measurement of a situation in a time series, periodic reports should be submitted. The access agreement should contain provisions to enable the parties to reconsider the amount of materials taken if monitoring indicates that present activities are threatening the target organism or biological diversity.

Monitoring should also be devised for existing or on-going collecting activities to ensure their sustainability. This can be accomplished if the access legislation requires it, especially if agreements pre-dating the legislation need to be renegotiated. This would be in keeping with the article 7(c) (identify processes and activities which have or are likely to have significant adverse impacts on biodiversity), and articles 8(1) (regulate or manage threats identified) and 8(i) (compatibility between present uses and conservation and sustainable use), of the Convention on Biological Diversity.

3.7.1 State Practice

The Philippines legislation provides a comprehensive example. A Philippine national policy is "to promote the development of local capability in science and technology" in selected areas (section 1, Executive Order).

The access legislation is designed to achieve the policy in several ways. First, non-commercial research agreements can only be obtained by in-country institutions (section 3, Executive Order). An outside institution seeking to undertake non-commercial work needs to enter into a collaborative arrangement with a Philippine institution, otherwise it would need to apply for a commercial agreement through a more elaborate process.

Second, minimum terms for research agreements include the deposit of specimens with the national museum (Executive Order, section 5(b); section 8.1(2) Implementation Regulations). Living specimens are to be deposited in designated depositories (section 8.1(3), Implementation Regulations). Filipino citizens and Philippine governmental entities are to have access to specimens and data collected (section 5(c), Executive Order). Access is qualified and is to be consistent with future international obligations such as the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture (section 8.1(4), Implementation Regulations).

Third, whenever the commercial collector or its principal is foreign, the participation of scientists with Philippines citizenship is required. Participation will be at the cost of the commercial collector (section 5(h), Executive Order; section 8.1(12), Implementation Regulations). Additionally, commercial collectors or their principals are encouraged to "avail ... the services of Philippine universities and academic institutions" (section 5(i), Executive Order).

Fourth, the Inter-agency Committee is directed to involve local scientists in the decision-making proc-

ess to facilitate local involvement in research, collection and use of biological and genetic resources (section 7(g), Executive Order). Research agreements are to be monitored by the respective governmental agency which gave consent using a standard scheme (section 12.1, Implementation Regulations).

Fifth, a specially designated inter-agency monitoring team is also designated. Its members include the participating agencies within the Inter-agency Committee (section 12.2, Implementation Regulations). This team will create a mechanism to integrate and disseminate information generated from research, collection and utilisation activities.

Finally, the Inter-agency Committee is to develop a conceptual framework for using research agreements to significantly increase knowledge on Philippine biodiversity (section 7(h), Executive Order).

Under Andean Pact Decision 391, the competent national authority of each member state is to maintain a national inventory of genetic resources and derivative products (article 50(n)). Research participation, supporting research and capacity building are all provided for by the Decision (article 17). Explicit provisions on monitoring genetic resources for conservation purposes are not provided, but the competent national authorities are to supervise and monitor the conditions of the access contract (article 50(g)) and "to supervise the conservation status of biological resources which contain genetic resources" (article 50(1)).

The Fijian Draft Sustainable Development Bill does not mention inventories or research. A permit application is to state whether an environmental monitoring or management plan is needed (section 254(4)(b)(ix)). A permit issued would stipulate conditions on monitoring (section 254(9)(c)(iv)).

3.8 *In-situ* Conservation, Sustainable Use and Environmental Impact Assessment

Collecting activities may threaten biological diversity at the genetic, taxonomic and ecosystem levels. For example, collecting from a small population of organisms could cause genetic erosion or even extinction. Species dependent on the targeted species could be threatened. If the targeted species is critical to the structure or function of an ecosystem intensive collecting could have ecosystem-level impacts. Therefore access legislation will need to ensure that collecting activities represent a sustainable use. Steps taken should be guided by a precautionary approach.

Access legislation can rely on already existing conservation and use legislation. In general, the access legislation could simply state that access activities must be in keeping with existing environmental conservation laws. There are two aspects to this. First, decisions taken by the competent authority must be consistent with existing laws. Second, where consent is given, the activities of the permittee must comply with existing laws. Where existing legislation is deemed inadequate, access legislation could provide supplemental provisions tailored to the particular threats which collecting and resupply pose.

A threshold question will be how to determine when a proposed or existing activity represents a threat. The question presupposes that the competent authority has the mandate and the expertise to consider threats in the first place. While access legislation should require the competent authority to consider environmental and conservation issues in its decision-making process, where the competent authority does not have the expertise it should be required to seek advice. This could be from an advisory board, a ministry or agency or another recognised source.

For proposed activities there are at least two information sources for determining the level of threat posed. An access application is the first source of information (see section 3.4.1). At minimum, the applicant should be required to supply information about the species targeted. This might include information on conservation status, relationship with other organisms, the methods of collection, the amounts needed, storage methods and the need for a continuing supply of materials collected.

Comments received from a public notification process are another source of information. They can help to identify situations which might be problematic. The knowledge of indigenous and local communities may be invaluable in this regard.

Depending on the circumstances, information gathered could either supplement or trigger an environmental impact assessment (EIA) for the activity proposed. Whether an EIA is required should be clarified in the legislation. Existing legislation could be drawn on. Alternatively, access legislation could also provide stand alone EIA provisions tailored to the circumstances of collecting and resupply. The content of the EIA could be specified in the legislation or in more detailed regulations.

For existing activities, the primary source of information could be obtained from an environmental audit. A public notice could be issued announcing the audit to solicit comments from parties potentially affected by the on-going activities. Analysing existing activities via an environmental audit would be in keeping with article 7(c) and articles 8(i) and (1).

Finally, though it is not required by the Convention on Biological Diversity, the scope of environmental impact assessment could be broadly defined to include social impacts.

3.8.1 State Practice

Existing legislation reflects varying degrees of conservation awareness. The Andean Pact Decision is perhaps most comprehensive.

In the Andean Pact, member states are to adopt precautionary measures to slow genetic erosion, environmental degradation and natural resource degradation (article 13). Lack of scientific certainty is not to be used as a reason for postponing effective measures. The threshold is "the danger of grave and irreversible damage" (article 13).

The applicant can be compelled to comply with existing environmental provisions in a member state (article 31) which could include EIA for example. The competent national authorities are directed to consider environmental issues in the process leading up to a determination as to whether the access application will be accepted for further review (article 31).

The Common Regime amplifies the precautionary principle by allowing member states to establish partial or total limitations on access (article 45). Measures taken must be provided "by means of an explicit legal norm" (article 45). They include instances where (1) the species, sub-species variety or race is endemic, rare or threatened with extinction; (2) the access activity could threaten a vulnerable or fragile ecosystem; (3) impacts on ecosystems are undesirable or difficult to control; or (4) access threatens genetic erosion. In addition, competent national authorities are entrusted with supervising the conservation status of biological resources targeted for their genetic resources (article 50(d)). As a group, the member states are to design and implement joint genetic resource conservation programmes (complementary provision 1).

In Fiji, the biodiversity prospecting system developed by the Authority is to ensure that research and exploitation do not cause ecological harm and that taking biological samples "does not cause any undesirable impact upon Fiji's biodiversity" (section 254(1)). The permit application requires an accurate description of the biodiversity prospecting activity, a description of the area where it will occur, species sought, quantities harvested, sample and harvest methods, storage methods and a statement on ecological impact (section 254(4)).

Comments from the public and other agencies will be solicited (section 254(5)), a monitoring programme will be identified and an auditing system will be established prior to issuance of a permit (section 254(6)). Based on the information it has, the Authority's determination will be either to issue or deny the permit or refer the matter for an EIA pursuant to another section in the Draft Sustainable Development Bill. Permits issued can have conservation-related conditions (section 254(9)(c)).

An application for an export permit also requires conservation related information including "the impact of the removal and export on other species of flora and fauna and the biodiversity of the local, national and regional habitat" (section 254(12)). If the materials have already been collected, the usefulness of this information is unclear, unless the export permit application is made concurrently at the time the prospecting permit application is made or prior to undertaking biodiversity prospecting activity itself. Such a requirement might be useful for on-going activities. Prior to an export permit decision verification with the conditions of any authority granted and CITES compliance is undertaken (section 254(14)).

In the Philippines, the interest of the State in conservation provides one of the bases for regulating bioprospecting activities (preambular paragraph 2, Executive Order). The policy of the State is to regulate bioprospecting of biological and genetic resources to ensure that they are protected and conserved (section 1, Executive Order)

Research agreements are to specify a limit on samples (section 5(a), Executive Order). An approved list and quantity of samples is to be drawn-up by the Inter-agency Committee (section 10.2.c) and strictly adhered to by the permittee. A requisite for research agreements provides that prospecting will not directly or indirectly harm biological diversity and the biological balance of the inhabitants of the targeted site (appendix B, requisite b, Executive Order).

Prospecting in protected areas must comply with the Philippines National Integrated Protected Areas System Act and a protected area's management plan (appendix B, requisite c, Executive Order). Finally, activities must comply with all Philippine environmental laws, including those on EIA where necessary (appendix B, requisite d, Executive Order). Exports are also to comply with CITES rules (section 8.1(5), Implementation Regulations).

3.9 Financial Issues

There are at least two financial issues which will need to be addressed as an approach to regulate access to genetic resources is developed: (1) financial resources to set-up and run the regulatory programme

and (2) creating mechanisms into which can flow money generated from the use of genetic resources for subsequent dispersment.

An effective access determination process, and follow-up monitoring, will require adequate funding. Therefore, financial resources may be the most critical consideration in an attempt to develop a regulatory scheme to determine access to genetic resources and ensure benefit-sharing. The financial burden of establishing a regulatory programme will have to be weighed against the probability that there will be a possible pay-off in the future.

Cost-effective options could be explored as part of the planning process. Funding sources could also be identified. Limited financial resources will be a major incentive for keeping a future regulatory programme simple.

Administrative fees could be a possible source of user derived funds. However, if the volume of requests is low it is doubtful a regulatory programme could be fully funded from these. Furthermore, it may not be feasible to make up the difference with higher fees since to do so could simply encourage collectors to go elsewhere. Therefore to remain viable most regulatory programmes will probably require supplemental funding.

If prior informed consent will be a two-tiered process involving, for example, indigenous and local communities, funding for local access determination processes will also need to be considered.

For benefit-sharing, the planning process should identify the options for capturing, managing and distributing any financial benefits generated, once it is established who will derive financial benefits. It may be desirable to establish a fund within which financial benefits derived from genetic resources may be deposited.

The planning process could also identify how the money could be best allocated. A threshold question may be to determine whether funds will be directed only into conservation activities or others, such as development activities. At the local level the distinction between funding conservation or development activities may be artificial. How to appropriately direct benefits down to the local level is an important issue to address as well.

Furthermore, it may be desirable to avoid the temptation of financing the regulatory programme from financial benefits generated. There are at least two reasons for this. First, there is no certainty that access will result in financial benefits in the first place. Therefore a sustainable source of funding will be needed to maintain the regulatory programme until a profitable end-product is developed. Second, separating operating costs from financial benefits derived will ensure financial benefits are not eaten up by administrative costs.

If a fund is created rules should be created to govern its management. These would include the management and distribution of capital.

3.9.1 State Practice

Under the complementary provisions of Decision 391, the member states are to create or strengthen funds or other financial mechanisms for benefits derived from genetic resources (complementary provision 1). This is to be pursuant to national legislation. Additionally, the member states as a group will analyse the "feasibility and convenience" of creating an Andean Fund to conserve genetic resources. Early in the consultative process leading up to Decision 391 it was proposed that a portion of the financial flow generated from species common to two or more member states could be diverted into a regional fund to support regional activities regardless of where they were collected from (IUCN, 1994).

In the Philippines, financial resources for the Interagency Committee can come from a number of sources. The most important appears to be an annual appropriation from each of the participating governmental agencies (section 16.1, Implementation Regulations). The Inter-agency Committee can also be supported by nominal application processing fees (section 6.1.5, Implementation Regulations). Fees depend on the nationality of the applicant.

In addition, "bioprospecting fees" from research agreements can also support the Committee (section 16.1, Implementation Regulations). The bioprospecting fee is determined by the Inter-agency Committee. It is to be paid by the principal when a research agreement is approved (section 8.15, Implementation Regulations). The Implementation Regulations do not provide criteria for determining the amount of the bioprospecting fee assessed.

Appendix 1 - Convention on Biological Diversity and Resolution 3 of the Nairobi Final Act

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 authorized, 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. Contri-

butions 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 shal 1 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

Parti

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.

Resolution 3

THE INTERRELATIONSHIP BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PROMOTION OF SUSTAINABLE AGRICULTURE

The Conference,

Having agreed upon and adopted the text of the Convention on Biological Diversity at Nairobi on 22 May 1992,

Recognizing the basic and continuing needs for sufficient food, shelter, clothing, fuel, ornamental plants and medicinal products for peoples of the world,

Emphasizing that the Convention on Biological Diversity stresses the conservation and sustainable use of biological resources,

Recognizing the benefits from the care and improvement by the peoples of the world of animal, plant and microbial genetic resources to supply those basic needs and from the institutional research on and development of those genetic resources,

Recalling that broadly-based consultations in international organizations and forums have studied, debated and achieved consensus on urgent action for the security and sustainable use of plant genetic resources for food and agriculture,

Noting that the Preparatory Committee of the United Nations Conference on Environment and Development has recommended that policies and programmes of priority for *in-situ,* on-farm and *ex-situ* conservation and sustainable use of plant genetic resources for food and sustainable agriculture, integrated into strategies and programmes for sustainable agriculture, should be adopted not later than the year 2000 and that such national action should include *inter alia:*

(a) Preparation of plans or programmes of priority action on conservation and sustainable use of plant genetic resources for food and sustainable agriculture based, as appropriate, on country studies on plant genetic resources for food and sustainable agriculture;

(b) Promotion of crop diversification in agricultural systems where appropriate, including new plants with potential value as food crops;

(c) Promotion of utilization of, as well as research on, poorly known but potentially useful plants and crops, where appropriate;

(d) Strengthening of national capabilities for utilization of plant genetic resources for food and sustainable agriculture, plant breeding and seed production capabilities, both by specialized institutions and farmers' communities;

(e) The completion of the first regeneration and safe duplication of existing *ex-situ* collections on a worldwide basis as soon as possible; and

(f) The establishment of *ex-situ* base collection networks,

Noting further that the Preparatory Committee for the United Nations Conference on Environment and Development has recommended:

(a) The strengthening of the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture operated by the Food and Agriculture Organization of the United Nations in close cooperation with the International Board for Plant Genetic Resources, the Consultative Group on International Agricultural Research and other relevant organizations;

(b) The promotion of the Fourth International Technical Conference on the Conservation and Sustainable use of Plant Genetic Resources for Food and Sustainable Agriculture in 1994 to adopt the first State-of-the-World Report and the first Global Plan of Action on the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture; and

(c) The adjustment of the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture in line with the outcome of the negotiations on a Convention on Biological Diversity,

Recalling the agreement in the Preparatory Committee for the United Nations Conference on Environment and Development on provisions regarding conservation and utilization of animal genetic resources for sustainable agriculture,

1. *Confirms* the great importance of the provisions of the Convention on Biological Diversity for the conservation and utilization of genetic resources for food and agriculture;

2. *Urges* that ways and means should be explored to develop complementarity and cooperation between the Convention on Biological Diversity and the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture;

3. *Recognizes* the need for the provision of support to the implementation of all activities agreed upon in the programme area on conservation and sustainable utilization of plant genetic resources for food and sustainable agriculture and in the programme area on conservation and utilization of animal genetic resources for sustainable agriculture in the Agenda 21 proposed to be adopted at the United Nations Conference on Environment and Development in Rio de Janeiro;

4. *Further recognizes* 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 this Convention; and

(b) The question of farmers' rights.

Adopted on 22 May 1992

References

Anderson I. 1995. *Oceans Plundered in the Name of Medicine.* NEW SCIENTIST (25 November 1995).

Anuradha R.V. 1997. *In Search of Knowledge and Resources: Who Sows? Who Reaps?* 6 REVIEW OF EUROPEAN COMMUNITY & INTERNATIONAL ENVIRONMENTAL LAW 263.

Barton J. and Siebeck W.E. 1994. *Material Transfer Agreements in Genetic Resources Exchange: The Case of the International Agricultural Research Centres.* ISSUES IN GENETIC RESOURCES, no. 1 (May 1994). International Plant Genetic Resources Institute, Rome, Italy.

Broad W.J. 1995. *The World's Deep Cold Sea Floors Harbor a Riotous Diversity of Life.* NEW YORK TIMES (17 October 1995).

Bridson D. and Forman L. (eds.). 1992. THE HERBARIUM HANDBOOK. Royal Botanic Gardens, Kew, United Kingdom.

BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit). 1996. PROCEEDINGS OF THE INTERNATIONAL WORKSHOP ON GENETIC RESOURCES: COOPERATION MODELS BETWEEN THE PHARMACEUTICAL INDUSTRY AND COUNTRIES OF ORIGIN, Oberursel, 25-26 August 1996.

Castenholz R. 1996. Personal Communication with Richard Castenholz, Department of Biology, University of Oregon (3 May 1996).

Chandler M. 1993. *The Biodiversity Convention: Selected Issues of Interest to the International Lawyer.* 4 COLORADO JOURNAL OF INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 141.

Cohn J.P. 1995. *Connecting by Computer to Collections.* 45 BIOSCIENCE 518.

Conference of the Parties to the Convention on Biological Diversity (COP). 1995. DECISION II/11 ACCESS TO GENETIC RESOURCES, REPORT OF THE SECOND MEETING OF THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY (U.N. Doc. UNEP/CBD/COP/2/19).

Cooper D. 1993. *The International Undertaking on Plant Genetic Resources.* 2 REVIEW OF EUROPEAN COMMUNITY & INTERNATIONAL ENVIRONMENTAL LAW 263.

Correa C. 1994. *Sovereignty and Property Rights Over Plant Genetic Resources.* Background study prepared for the FAO Commission on Plant Genetic Resources.

Downes D.R., Laird S.A., Klein C. and Kramer Carney B. 1993. *Biodiversity Prospecting Contract,* in, Reid W. *et al.* 1993. BIODIVERSITY PROSPECTING. WRI, Washington, DC, USA.

Dutfield G. 1997. *Implementing Article 8(j) of the Convention on Biological Diversity Through Peoples Biodiversity Registers.* BULLETIN OF THE WORKING GROUP ON TRADITIONAL RESOURCE RIGHTS (Winter 1997).

Dutfield G. 1998. Personal Communication with Graham Dutfield, Working Group on Traditional Resource Rights (30 January 1998).

Environmental Resources Management. 1995. *Identification of Community Measures for the Implementation of Articles 15 and 16 of the Convention on Biological Diversity.* Technical report (no. 3223) prepared for Directorate General XI of the European Commission.

European Commission (Directorate General XI) and Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit. 1998. *Elements for Best Practices in Access to Genetic Resources.* MAIN FINDINGS OF THE WORKSHOP ON BEST PRACTICES TO GENETIC RESOURCES, Cordoba, 15-16 January 1998.

Fairlie S., Hagler M. and O'Riordan B. 1995. *The Polities of Overfishing.* 25 THE ECOLOGIST 46.

FAO Commission on Plant Genetic Resources. 1986. *Legal Status of Base and Active Collections of Plant Genetic Resources* (U.N. Doc. CPGR/87/5).

Feinsilver J. 1995. *Biodiversity Prospecting: Prospects and Realities,* in, Zakri A.H. (ed.) 1995. PROSPECTS IN BIODIVERSITY PROSPECTING. GENETICS SOCIETY OF MALAYSIA, Selangor, Malaysia.

Garson M. 1995. *Bioprospecting the Sea: Winners and Losers.* Paper presented to the Horizons of Science Forum, University of Technology, Sydney, 14 November 1995.

Ghate U. 1997. *In Defence of Documenting Peoples' Knowledge.* BULLETIN OF THE WORKING GROUP ON TRADITIONAL RESOURCE RIGHTS (Winter 1997).

Glowka L. 1995. *Determining Access to Genetic Resources and Ensuring Benefit-sharing: Legal and Institutional Considerations for States Providing Genetic Resources.* Paper presented to the International Workshop on Access to Genetic Resources, Global Biodiversity Forum, Jakarta, 4 November 1995.

Glowka L. 1996a. *The Convention on Biological Diversity: Issues of Interest to the Microbial Scientist and Microbial Culture Collections,* in, Samson R.A., Stalpers J.A. van der Mei D. and Stouthamer A.H. (eds.). 1996. CULTURE COLLECTIONS TO IMPROVE THE QUALITY OF LIFE. Proceedings of the Eighth International Congress for Culture Collections. Veldhoven, The Netherlands, 25-29 August 1996.

Glowka L. 1996b. *The Deepest of Ironies: Marine Scientific Research, Genetic Resources and the Area.* 12 OCEAN YEARBOOK 154.

Glowka L. 1997. *Legal and Institutional Considerations for States Providing Genetic Resources,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

Glowka L. 1998. A GUIDE TO UNDERTAKING NATIONAL BIODIVERSITY LEGAL AND INSTITUTIONAL PROFILES. IUCN, Gland, Switzerland and Cambridge, United Kingdom.

Glowka L., Burhenne-Guilmin F. and Synge H. 1994. A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY. IUCN, Gland, Switzerland and Cambridge, United Kingdom.

Grifo F.T. and Downes D.R. 1996. *Agreements to Collect Biodiversity for Pharmaceutical Research: Major Issues and Proposed Principles,* in, Brush S.B. and Stabinsky D. (eds.). 1996. VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS. Island Press, Washington, DC, USA.

Hendrickx F., Koester V. and Prip C. 1993. *The Convention on Biological Diversity-Access to Genetic Resources: A Legal Analysis.* 23 ENVIRONMENTAL POLICY AND LAW 250.

Holmes B. 1996. *Life Unlimited.* NEW SCIENTIST (10 February 1996).

IUCN-The World Conservation Union. 1994. *Toward a Legal Framework to Regulate Access to Genetic Resources in the Andean Pact.* Technical legal report prepared by the IUCN Environmental Law Centre for the Board of the Cartagena Accord in collaboration with the Peruvian Society for Environmental Law. IUCN, Bonn, Germany.

Kaesuk Yoon C. 1996. *Forget the Tropics, Pharmaceuticals May Lie in Nearby Woods.* NEW YORK TIMES (5 November 1996).

King S.R., Carlson T.J. and Moran K. 1996. Biological Diversity, Indigenous Knowledge, Drug Discovery and Intellectual Property Rights, in, Brush S.B. and Stabinsky D. (eds.). 1996. VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PROPERTY RIGHTS. Island Press, Washington, DC, USA.

de Klemm C. 1993. BIOLOGICAL DIVERSITY CONSERVATION AND THE LAW: LEGAL MECHANISMS FOR CONSERVING SPECIES AND ECOSYSTEMS. IUCN, Gland, Switzerland and Cambridge, United Kingdom.

de Klemm C, Tolentino A., Burhenne-Guilmin F., Tarasofsky R.G., Glowka L. and Craig D. 1995. *Conserving Biological Diversity: Legal and Institutional Issues,* in, McNeely J. (ed.). 1995. BIODIVERSITY CONSERVATION IN THE ASIA AND PACIFIC REGION. Asian Development Bank, Manilla, Philippines and IUCN, Gland, Switzerland.

Kothari A. 1997. *Access and Benefit-sharing: Options for Action in India,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

Laird S.A. 1993. *Contracts for Biodiversity Prospecting,* in, Reid W. *et al.* 1993. BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT. WRI, Washington, DC, USA.

Laird S.A. 1995. ACCESS CONTROLS FOR GENETIC RESOURCES. WWF International, Gland, Switzerland.

Laird S.A. and Wynberg R. 1997. *Biodiversity Prospecting in South Africa: Developing Equitable Partnerships,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

Lambshead J. 1993. *Recent Developments in Marine Benthic Biodiversity Research.* 19 OCEANIS 5.

La Viña A., Caleda M.J.A. and Baylon M.L.L. 1997. REGULATING ACCESS TO BIOLOGICAL AND GENETIC RESOURCES IN THE PHILIPPINES: A MANUAL ON THE IMPLEMENTATION OF EXECUTIVE ORDER NO. 247. Foundation for Philippine Environment and WRI, Manila, Philippines.

Leaman D., Schippmann U. and Glowka L. 1997. *Environmental Protection Concerns of Prospecting for and Producing Plant-based Drugs.* Paper presented at the International Symposium on Herbal Medicine, Honolulu, 1-4 June 1997.

Lenaola I., Jenner H.H. and Wichert T. 1996. *Land Tenure in Pastoral Lands,* in, Juma C. and Ojwang J.B. (eds.). 1996. IN LAND WE TRUST. Zed Books, London, United Kingdom.

Lindstrom B. 1996. Personal communication with Bob Lindstrom, Yellowstone National Park (6 May 1996).

Miller K.R. and Lanou S.M. 1995. NATIONAL BIODIVERSITY PLANNING: GUIDELINES BASED ON EARLY EXPERIENCES AROUND THE WORLD. WRI. Washington, DC, USA.

Milstein M. 1994. *Yellowstone Managers Eye Profits From Hot Microbes.* 264 SCIENCE 655.

Mugabe J. and Clark N. 1996. *Technology Transfer and the Convention on Biological Diversity.* BIOPOLICY INTERNATIONAL no. 18. ACTS Press, Nairobi, Kenya.

Nadis S. 1997. *Looking Inside Earth for Life on Mars.* TECHNOLOGY REVIEW (November/December 1997).

National Research Council. 1993. MANAGING GLOBAL GENETIC RESOURCES: LIVESTOCK. National Academy Press, Washington, DC, USA.

National Research Council. 1993. MANAGING GLOBAL GENETIC RESOURCES: THE U.S. NATIONAL PLANT GERMPLASM SYSTEM. National Academy Press, Washington, DC, USA.

Noble Wilford J. 1996. *Exploring the Glacial Depths: Scientists Chart Lakes That Lie Beneath Ice.* THE INTERNATIONAL HERALD TRIBUNE (23 May 1996).

Paine S. 1996. *Hostages of the Deep.* NEW SCIENTIST (14 September 1996).

Pearce F. 1995. *Rockall Mud Richer than Rainforest.* NEW SCIENTIST (16 September 1995).

Posey D.A. 1996a. TRADITIONAL RESOURCE RIGHTS. IUCN, Gland, Switzerland.

Posey D.A. 1996b. *Identifying and Respecting Boundaries Between Indigenous Peoples, Traditional Farmers and Local Communities.* Paper presented to Conference of the Science Centre of North-Rhine Westphalia, Wuppertal, 21 - 22 November 1996.

Posey D.A. and Dutfield G. 1996. BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES. International Development Research Centre, Ottawa, Canada.

Putterman D.M. 1997. *Model Material Transfer Agreements For Equitable Biodiversity Prospecting,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

Reid W., Barber C.V. and La Vina A. 1995. *Translating Genetic Resource Rights into Sustainable Development: Gene Cooperatives, the Biotrade and Lessons Learned from the Philippines.* PLANT GENETIC RESOURCES NEWSLETTER, no. 102 (1995). International Plant Genetic Resources Institute, Rome, Italy.

Robbins J. 1997. *Yellowstone's Microbial Riches Lure Eager Bioprospectors.* NEW YORK TIMES (14 October 1997).

Rosell M. 1997. *Access to Genetic Resources: A Critical Approach to Decision 391 'Common Regime on Access to Genetic Resources' of the Commission of the Cartagena Accord.* 6 REVIEW OF EUROPEAN COMMUNITY & INTERNATIONAL ENVIRONMENTAL LAW 274.

RuizM.M. 1997. ACCESS REGIME FOR ANDEAN PACT COUNTRIES: ISSUES AND EXPERIENCES, in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

Shelton D. 1995. *Fair Play, Fair Pay: Preserving Traditional Knowledge and Biological Resources.* 6 INTERNATIONAL YEARBOOK OF INTERNATIONAL ENVIRONMENTAL LAW 77.

Singh Nijar G. 1996. IN DEFENCE OF LOCAL COMMUNITY KNOWLEDGE AND BIODIVERSITY: A CONCEPTUAL FRAMEWORK AND THE ESSENTIAL ELEMENTS OF A RIGHTS REGIME. Third World Network, Penang, Malaysia.

Sly L.I. 1994. *Culture Collections World-wide,* in, Kirsop B. and Hawksworth D.L. (eds.). 1994. THE BIODIVERSITY OF MICROORGANISMS AND THE ROLE OF MICROBIAL RESOURCE CENTRES. World Federation of Culture Collections.

Smith R. 1996. Personal communication with Reed Smith, Rainforest Alliance (21 August 1996).

Soons A.H.A. 1982. MARINE SCIENTIFIC RESEARCH AND THE LAW OF THE SEA. Kluwer, Deventer, the Netherlands.

Stackebrandt E. 1994. *The Uncertainties of Microbial Diversity,* in, Kirsop B. and Hawksworth D.L. (eds.). 1994. THE BIODIVERSITY OF MICROORGANISMS AND THE ROLE OF MICROBIAL RESOURCE CENTRES. World Federation of Culture Collections.

Stone C.D. 1995. *What to do About Biodiversity: Property Rights, Public Goods and the Earth's Biological Riches.* 68 SOUTHERN CALIFORNIA LAW REVIEW 577.

Swanson T. 1995. *Diversity and Sustainability: Evolution, Information and Institutions,* in, Swanson T. (ed.). 1995. INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY CONSERVATION: AN INTERDISCIPLINARY ANALYSIS OF THE VALUES OF MEDICINAL PLANTS. Cambridge University Press, Cambridge, United Kingdom.

ten Kate K. 1997a. *Access to Ex-situ Collections: Resolving the Dilemma,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

ten Kate K. 1997b. *The Common Regime on Access to Genetic Resources in the Andean Pact,* in, 2 BIOPOLICY, paper 6 (PY97006) Online Journal - URL: http://www.bdt.org.br/bioline/py. Bioline Publications, Lincolnshire, United Kingdom.

Tobin B. 1997a. *Putting the Commercial Cart Before the Cultural Horse (Part II): The Search for Equity in the International Cooperative Biodiversity Group Project in Peru* (unpublished draft manuscript, September 1997).

Tobin B. 1997b. *Know-how Licenses: Recognising Indigenous Rights Over Collective Knowledge.* BULLETIN OF THE WORKING GROUP ON TRADITIONAL RESOURCE RIGHTS (Winter 1997).

Tobin B. 1997c. *Certificates of Origin: A Role for Intellectual Property Regimes in Securing Prior Informed Consent,* in, Mugabe J. *et al.* (eds.). 1997. ACCESS TO GENETIC RESOURCES: STRATEGIES FOR SHARING BENEFITS. ACTS Press, Nairobi, Kenya.

UNESCO and Malaysian Natural Products Society. 1996. *Guidelines to Facilitate Access to Biological Resources and the Equitable Sharing of Benefits in the South East Asian Region.*

United Nations Office for Ocean Affairs and the Law of the Sea. 1989. THE LAW OF THE SEA: NATIONAL LEGISLATION, REGULATIONS AND SUPPLEMENTARY DOCUMENTS ON MARINE SCIENTIFIC RESEARCH IN AREAS UNDER NATIONAL JURISDICTION. United Nations, New York, USA (UN Sales Publication No. E.89.V.9).

United Nations Office for Ocean Affairs and the Law of the Sea. 1991. MARINE SCIENTIFIC RESEARCH: A GUIDE TO THE IMPLEMENTATION OF THE RELEVANT PROVISIONS OF THE UNITED NATIONS CONVENTION ON THE LAW OF THE SEA. United Nations, New York, USA (UN Sales Publication No. E.91.V.3).

United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities. 1995. Statement of Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples (UN Doc. E/CN.4/sub.2/1995/26).

Vogel J.H. 1994. GENES FOR SALE. Oxford University Press, New York, USA.

Vogel J.H. 1997. *Bioprospecting and the Justification for a Cartel.* BULLETIN OF THE WORKING GROUP ON TRADITIONAL RESOURCE RIGHTS (Winter 1997).

Vogel J.H. (ed.). (in press). FROM TRADITIONAL KNOWLEDGE TO TRADE SECRETS. EcoCiencia, Quito, Ecuador.

von Websky. 1998. Personal communication with Michael von Websky, Bundesministerium fur Umwelt, Naturschutz und Reaktorsicherheit, Government of Germany (15 January 1998).

Wolfrum R. and Stoll P.T. 1996. ACCESS TO GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE LAW OF THE FEDERAL REPUBLIC OF GERMANY. Erich Schmidt Verlag, Berlin, Germany.

WRI, IUCN and UNEP. 1992. GLOBAL BIODIVERSITY STRATEGY. WRI, Washington, DC, USA, IUCN, Gland, Switzerland and UNEP, Nairobi, Kenya.

IUCN Communications Division
Rue Mauverney 28
CH-1196 Gland, Switzerland
Tel.: ++ 41 22-999 00 01
Fax: ++ 41 22-999 00 10
E-mail: mail@hq.iucn.org

IUCN Publications Services Unit
219c Huntingdon Road
Cambridge, CB3 0DL, UK
Tel.: ++ 44 (1) 223-277894
Fax: ++ 44 (1) 223-277175
E-mail: iucn-psu@wcmc.org.uk

IUCN
The World Conservation Union