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BENEFIT-SHARING
Third meeting
Bangkok, 14-18 February 2005

REVIEW OF EXISTING NORMS, STANDARDS AND PRACTICES RELEVANT TO ACCESS AND BENEFIT-SHARING—ABS MANAGEMENT TOOL PROJECT

Background research report submitted by Switzerland

Note by the Executive Secretary

1. At the request of the Government of Switzerland, the Executive Secretary is pleased to circulate herewith, for the information of participants in the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, a background research report on review of existing norms, standards and practices relevant to access and benefit-sharing—ABS Management Tool Project. This report was prepared for the Project on a Management Tool for Implementation of Access and Benefit-Sharing Activities, funded by the Swiss Federal Government and implemented jointly by the International Institute for Sustainable Development (IISD) and Stratos Inc. – *strategies to sustainability.*

2. The report is being circulated in the form and the language in which it was received by the Convention Secretariat.

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BACKGROUND RESEARCH REPORT

Review of Existing Norms, Standards and Practices Relevant To Access and Benefit Sharing

ABS Management Tool Project

June 2004

Staatssekretariat für Wirtschaft
Secrétariat d'Etat à l'économie
Segretariato di Stato dell'economia
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iisd International Institute for Sustainable Development / Institut international du développement durable

Stratos strategies to sustainability

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TABLE OF CONTENTS

Executive Summary

Lessons from Existing Biological Resource and ABS Management Initiatives and Practices

This report provides a review of a range of existing standards, codes of practice and guidelines which have been developed to address access and benefit sharing arrangements, and the ecological and social management of biological resources. The report also reviews and briefly summarizes several comprehensive reviews and publications on management approaches and guidance on accessing genetic resources and biological resources.

The main purpose of this report is to consider a selection of different approaches that may provide useful lessons and specific best practices to be applied in the design of an ABS management tool to be used by individual organizations. It is hoped that the report will also prove useful to broader audiences.

There are a number of important lessons on the development of an ABS management tool that can be drawn from this report. These lessons can be broadly grouped into five categories:

1) examples of good practice standards for ABS;
2) types of substantive requirements needed to address the full range of ABS issues;
3) degree of flexibility needed to ensure that outcomes and processes are appropriate to the local and/or sectoral context;
4) locus of responsibility; and
5) differentiation of responsibilities by role and use

Good practice standards

The initiatives reviewed have different starting points. Some take an ethical focus (at the professional level or at the corporate level related to reputation and business opportunity); some take a sustainable development approach ensuring ecological sustainability, economic contribution and social justice are provided for; others focus on transparent and open relations. The following provides a synthesis of good practice standards for key elements of access and benefit sharing arrangements.

Prior informed consent: A number of guidelines and code requirements make specific reference to clear documentation of country of origin of samples. Some go further to require maintaining a record of country of origin through various transfers to third parties, to allow tracing of the original provider through the supply chain for the purposes of evidence of PIC and to provide for benefits to accrue to the appropriate local source. While the need to obtain written PIC from governments is a standard requirement, only some voluntary schemes or contractual arrangements put an emphasis on ensuring prior informed consent from a range of affected stakeholders, and in particular local communities which are the source of the material to be collected. Customary frameworks have PIC requirements

from the bottom-up – i.e. from the perspective of what a community expects from those seeking access.

One interesting aspect found in some schemes is specification of sponsor responsibility for ensuring PIC is properly sought and received, in effect establishing accountability between the funder and collector of genetic resources. Another aspect relates to purchasers of genetic resources requiring intermediaries to provide documented evidence of PIC.

Mutually agreed terms. A number of schemes provide specific guidance on negotiation of access and/or benefits on mutually agreed terms, and in some instances provided model agreements (e.g. model Material Transfer Agreements). In some cases, MTAs must be negotiated with local communities, resource providers (e.g. farmer, forest owner) and host countries. Model MTAs include specific provisions for non-commercialization of the genetic resources collected or a requirement for a new PIC to be obtained if commercialization becomes a possibility. Another important element is supply of the genetic resources originally provided to 3rd parties, which may include a guarantee that the conditions negotiated with the original provider of the genetic resource of use are, at minimum, maintained.

Benefit sharing. This is a fundamental element of all schemes reviewed. Requirements typically provide for benefit-sharing with both the country of origin (government) and communities/other stakeholders involved in provision of materials. Benefits are to accrue from the direct use by collectors of genetic resources provided, from use by subsequent users, and from derivatives obtained from the genetic resources. Substantial guidance is available in the guidelines and supporting documentation to most sets of principles/standards on the types of monetary and non-monetary benefits which may be appropriate to include in MAT agreements for the provision of genetic resources. A few schemes provide specific reference to resources flowing back to conservation of biological diversity and specific to the sustainable production or harvest of the material of interest. One scheme explicitly provides for benefit sharing, regardless of the date of acquisition of the material, for the purposes of *ex situ* sources of genetic resources.

Some schemes require differentiation at the outset of commercial intent or potential, with guidance on addressing this in benefit sharing. For example, this can include provision for mutually agreed guarantees for protection of intellectual property, and for setting out from the start, ownership understandings for intellectual property rights related to genetic resources and derivatives/derived technology. Some schemes provide a list of types of in-kind, capacity-related, technology transfer and financial benefits. Others provide specific guidance and even formulas on financial benefits, such as on royalty levels.

Traditional knowledge associated with genetic resources. A fundamental aspect of most codes and guidelines is respect for local and indigenous customs and traditions. Some schemes go beyond this with an emphasis on control of collection/harvesting activities on their land, and protecting resource and land rights. Another aspect is explicit recognition that traditional knowledge is a part of

genetic resource collection, and that traditional knowledge itself should be subject to ABS agreements – although the provisions reviewed are not specific about requiring PIC nor ensuring benefit sharing related to traditional knowledge. In some cases, such as the botanical gardens' Principles on Access to Genetic Resources and Benefit-Sharing and Common Policy Guidelines, researchers and collectors are required to undertake cultural orientation with the indigenous community.

Conservation and sustainable use. A common requirement is for collection/harvesting (wild or cultivated resources) to not exceed sustainable yield or use levels, but in most cases little guidance is provided. A small number of schemes provide more detailed requirements specifying ecological considerations for sustainable collection, or for information to be collected that will enable conservation status to be assessed. On the conservation side, some standards or guidelines include prohibition of collecting or other safeguards for rare/threatened/endangered species, including requirement to adhere to CITES provisions for listed species. In one case there is specific reference to the need to assess resources that are culturally significant to indigenous peoples.

Community participation. Only a few schemes emphasize this essential aspect, although several include local communities in the request for and granting of PIC. Both customary frameworks and international certification schemes place an emphasis on community involvement in both decision-making and in participating directly in benefits derived from the collection and use of the biological resources. Another important element, seldom included, is a mechanism for resolving grievances at the community level, although some model contracts/agreements have some form of dispute resolution clause.

Transparency and information sharing. Transparency in the sharing of information both on collections to be carried out and the intended use of genetic resources collected is an important aspect of a number of initiatives. Most include specific information requirements, for example information to record and trace the PIC obtained, and a description of the resources (e.g. species) collected. This may include information for the objective of fostering scientific availability of results; or, for acknowledgement of the source/provider of the genetic resources. Documentation for monitoring of materials from country of origin through various users is another important aspect to ensure that past agreements are honoured.

One aspect of information sharing that is not often acknowledged in existing standards and guidelines is ensuring that traditional and local knowledge is protected in the process of access, and not made widely available without the consent of local communities.

Types of substantive requirements needed to address ABS issues

It is clear from a review of the literature that the implementation of the ABS provisions of the CBD by users and providers of genetic resources must be based on two general types of requirements. The

UNU-IAS Report *User Measures*[1] distinguishes between '*standards'* and '*best-practices'*, whereby '*standards*' refer to a desired end-state, and '*best-practices*' refers to the means by which the desired end-state is achieved. In a similar respect, the introduction to Laird's book *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*[2], identifies the need for both '*fair*' decision-making processes and '*equitable*' outcomes. A number of the codes or guidelines reviewed in Section 4 also include both performance and procedural requirements.

Although a number of universal principles do seem to emerge, it is clear from this review that a management tool intending to guide implementation of ABS cannot address all of the possible range of issues or situations that might reasonably be expected to arise. As a result, there is a need for clear guidelines on the process by which decisions are made – presumably differentiating between processes that lead to decisions that have (in)direct impacts on other stakeholders, community groups and indigenous peoples, and those that do not. On the other hand, an ABS management tool that does not include certain underlying principles and performance requirements would also fall far short of the mark: there are some universal principles and performance outcomes that can be considered a baseline for good-practice.

Thus, any management tool on ABS will need to include a mix of both equitable outcomes (what might be called policies/principles and performance requirements) and fair processes (process requirements).

Degree of flexibility needed to apply in local or sectoral context

As the lessons above on good practice standards and types of substantive requirements demonstrate, there is a need for some form of overarching or global/universal principles and requirements for access and benefit sharing relationships and arrangements, regardless of the specific context and the actors involved. Most of the schemes reviewed have some broad requirements which apply in all cases. However, as can be seen from such diverse schemes as the botanical gardens ABS Principles and Common Policy Guidelines, and the Forest Stewardship Council (FSC), a certain degree of flexibility is not only needed but is desirable to ensure that the requirements in an internationally-used management tool are appropriate to the context in which they are being applied. It seems likely, then, that the design and implementation of a management tool on ABS will require a tiered set of requirements and guidance, to provide flexibility to translate or elaborate requirements at various levels of organization (e.g. national, sub-national, local), and for different sectors (e.g.

[1] Barber, Charles, Sam Johnston and Brendan Tobin. 2003. *User Measures: Options for Developing User Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity* – 2nd Edition. Report by the United Nations University – Institute of Advanced Studies. Tokyo, Japan.

[2] Laird, Sarah (ed), 2002; "Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice", Earthscan, London, UK. Information on this publication can be found at: http://www.rbgkew.org.uk/peopleplants/manuals/biological/index.html

pharmaceuticals or botanicals); different types of organizations (e.g. research or industrial); or, for specific ecosystem or community conditions. Examples of such tiered "standards" are:

- Core standards – best practice guidelines – site specific collection plan
- Principles – institutional policy – written agreements
- Principles + criteria - local/ecosystem standards/indicators

One way to characterize such flexibility for the purposes of an ABS management tool is as follows:

- Actions to achieve a fixed outcome (e.g. no use of species listed in CITES Appendix 1)
- Actions to achieve a variable outcome (e.g. ensure fair and equitable sharing of benefits)
- Actions to establish a fixed process (e.g. seek prior informed consent from local communities); and
- Actions to establish a variable process (e.g. involve local communities in sustainable-use planning)

The distinction between these levels of action requires further analysis and elaboration, but the example is intended to demonstrate the need for a balance between commonly-held and adhered to requirements (to ensure that a basis of good-practice is understood and followed in all cases); and, flexibility (to ensure that processes and outcomes are appropriate to their national or local, sectoral, and ecosystem/cultural context).

While a management tool on ABS will necessarily include guidance on both outcomes and processes, there is a need for a certain degree of flexibility in interpreting and implementing both types of requirements.

Locus/onus of responsibility

The implementation of ABS arrangements, like the management of biological or renewable natural resources in general, is based on the stakeholders involved, i.e. it requires the creation of a relationship among the interested and affected parties (actors). In the case of access to genetic resources and benefit sharing, 'interested parties' is widely understood to include at a minimum the provider/owner of genetic resources (e.g. governments, indigenous peoples, community groups, or research institutions), and the intended user of the resource (e.g. research institution, curating organization, company). The relationship between these actors is at the centre of ABS arrangements and good practices. In any fair relationship, all actors have associated rights and obligations: the user of the resource is not the only party with obligations; and, the provider or other stakeholders are not the only parties with rights.

This underlines the need to consider carefully where the onus for ensuring good practice should lie – and the need to ensure that all actors have a common understanding of their rights and responsibilities. The onus of responsibility can fall on the local communities themselves (who adopt responsibilities when granting access or negotiating mutually agreed terms); on collecting institutions (the subject of procedural requirements in most guidelines); on individual researchers (who may

commit to documenting the origin of a sample or restricting access to third parties); on sponsoring organizations (who may commit to ensuring that those acting on their behalf follow appropriate practices); or to commercial entities (who may commit to sharing revenue and transferring technologies).

Thus it is evident that an ABS management tool must clearly establish rights and responsibilities between all actors involved in the decision-making process, and foster conditions in which confidence and trust can be built between the interests involved.

Differentiation of responsibilities by role and use

Both the review of specific schemes and initiatives, and the review of key literature sources demonstrate the need for differentiation of responsibilities according to the role that the institution/organization is playing. For example, the botanic gardens guidelines specify different responsibilities and guidance for cases where institutions are primary users/collectors of genetic resources; and, for cases where they are providers/suppliers of genetic resources to third parties.

Another important differentiating factor recognized in requirements of a number of initiatives is whether collection is being undertaken for research purposes only, for direct commercial purposes, or for research with an intent or possibility of future commercialization.

What emerges is that different practices and requirements may need to be developed and applied in an ABS management tool for application by the same organizations, according to what stage of use they are intending, and what role they are playing. In particular, it will be necessary to determine whether the organization is acting as a provider or a user (for example botanic gardens, research institutions or companies can be both in different relationships); and, to differentiate practices by intended stage of use (e.g. for reference collections, training and public education; or research; or commercialization).

1 Introduction and Context

This report provides a selective review of a range of voluntary approaches used to guide the practice of access and benefit sharing related to genetic resources, and more broadly access to, use of and marketing of biological resources. Its purpose is to bring together in one place a sampling of relevant norms, standards and practices which will help the development of a management tool for facilitating access and benefit sharing activities consistent with the Convention on Biological Diversity and the implementation of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. Existing standards and practices are found in a range of international principles and guidelines, in the policies and codes of conduct of sector groupings of institutions and of professional associations, and in the policies of individual governmental, corporate and research organizations.

The review is not exhaustive. It is selective and targeted to cover a variety of different existing approaches and sets of principles, standards and guidelines of relevance to the providers and the users of genetic resources. The initiatives reviewed have been chosen to focus on where the authors' experience and that of others who have conducted other reviews indicates there are more promising and useful approaches and good practice guidance for access and benefit sharing related to genetic resources.

Specifically, the review focuses on substantive requirements which may be useful to inform the development of a consolidated set of standards of good practice for access and benefit sharing that are to be included in an ABS management tool. Thus, the report has been written largely for the purposes of the Swiss Funded Project on "Development of a Management Tool for Implementation of Access and Benefit Sharing". It considers a selection of different approaches that may provide useful lessons and specific best practices which can be applied by individual organizations in using the intended ABS management tool. However, it is hoped that the report will also prove useful to broader audiences.

There have been several excellent reviews of management approaches and guidance on accessing genetic resources and biological or renewable natural resources. These are summarized and referenced in Section 3. These also serve as sources of useful information that we acknowledge in section 4, along with original source documents for the different initiatives. This section provides the substantive results of the review. Section 5 presents a summary assessment of the results.

2 Methods Used

The research process for this report included three phases: (1) identification of key initiatives and development of a research framework for the collection of relevant information; (2) study of existing reviews of relevant international standards and practices related to access and benefit sharing and management of broader biological resources, including reviews of systems beyond those studies in

the detailed research phase of this work; and, (3) detailed review of source documents for each of the initiatives and systems covered in this report.

In the first research phase, the Project Team developed a research framework based on the operative elements of the Bonn Guidelines, as well as additional elements related to good practice for access and benefit sharing, including community involvement and transparency and information. The list of good practice elements used is as follows:

- Prior informed consent (PIC)
- Mutually Agreed Terms (MAT)
- Benefit-sharing
- Traditional knowledge associated with genetic resources
- Conservation and sustainable use
- Community participation
- Transparency and information.

The review also identified other important elements of good practice that are considered relevant requirements for ABS. These include the relationships between primary providers and users of genetic resources, and third party users and intermediaries.

In reviewing the initiatives, we also made note of key drivers, the supporting organizational and administrative structure, the management system elements including verification/certification and reporting, and the key challenges addressed by the specific guidelines or standards.

We selected initiatives for review based on a range of factors, including coverage of a range of approaches and systems, as well as initiatives with varying scope and geographical coverage (international, national, organization-specific). We drew on the project team's knowledge of important standards initiatives, past reviews by experts in ABS, and input from the Project Advisory Committee and other experts. The review focuses on learning from existing voluntary codes of practice, as well as systems and requirements in the fields of genetic resources, biological resources / biodiversity and renewable resources management.

Information for our detailed review was collected through an internet-based web search, a review of relevant literature, and telephone conversations with key individuals to both substantiate our research and acquire additional information. Where possible and appropriate, we have captured the most relevant provisions of each initiative, and have highlighted best practices that serve as examples to guide the development of an ABS management tool.

As mentioned above, we also reviewed several major studies and / or reports related to access and benefit-sharing issues, as well as biodiversity in general. We acknowledge theses sources, which include work by: Sarah Laird and Alan Pierce; Lyle Glowka; Kerry ten Kate and Sarah Laird; the Rainforest Alliance; the United Nations University; and the European Council. These pieces provided

a useful basis for understanding the key issues of concern with respect to access and benefit-sharing, and provide an overview of the strengths and weaknesses of different approaches.

3 Summary of Major Studies / Sources of Information

This section provides brief summaries of a number of publications that have reviewed existing experience and initiatives, and provide guidance on norms and practices for access and benefit sharing as well as broader initiatives for the ecologically sustainable and socially responsible management of biological or renewable natural resources. While the summaries included here do not go into great depth, the development of the management tool will draw from the principles, criteria and guidelines and other tools that are referenced in these publications.

3.1 "Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice"[3]

This book explains the practical methods involved in establishing equitable relationships between users and providers of biodiversity resources, and the communities and peoples that may be directly or indirectly affected. The book recognizes that concepts such as 'prior informed consent' and 'benefit-sharing' are increasingly being used, but that they still too often remain unrealized in practice. The focus here is on the development, implementation, and refinement of a range of tools that help define the terms for 'fair and equitable' partnerships.

The book includes sections on biodiversity research relationships, including in protected areas; community relationships with researchers; the commercial use of biodiversity and traditional knowledge; national policy contexts; and a section of conclusions and recommendations. A detailed appendix also includes direct references to a number of institutional policies, professional codes of conduct and indigenous peoples' documents, including:

- Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing
- Kew's Commercial Annex
- The American Association of Anthropology (AAA)
- The International Society of Ethnobiology (ISE)
- UN Draft Declaration on the Rights of Indigenous Peoples
- The Mattatua Declaration

The introduction outlines conceptual issues related to the concept of '*equity'*, as well as distinguishing between the concepts of '*equitable'* and '*fair'*. It describes the evolution of the concept of equity in common and statute law systems, where it developed as separate principles of justice applied in cases that were either not covered by the law, or where the law could apply unfairly or be too narrowly

[3] Laird, Sarah (ed), 2002; "Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice", Earthscan, London, UK. Information on this publication can be found at: http://www.rbgkew.org.uk/peopleplants/manuals/biological/index.html

interpreted and applied. It is suggested that, where equity cannot be reduced to universally accepted actions or outcomes, all that can be hoped is that setting up a fair "process" will lead to an equitable "outcome". This is similar, in some respects, to the distinction drawn by UNU-IAS (see below) between "standards" and "best practices". The lesson for the development of an ABS management tool, then, is that such a tool must address not only outcomes ("standards") but also processes ("best-practices").

3.2 "Annotated Collection of Guidelines, Standards, and Regulations for Trade in Non-Timber Forest Products (NTFPs) and Botanicals"[4]

This study was undertaken in February 2002 as a component of Phase 1 of the Rainforest Alliance's Sustainable Botanicals Project. The first phase of the overall project seeks to better understand:

- how botanicals are sourced by industry today, including existing constraints and opportunities for sustainability;
- what companies, NGOs, research institutions, community groups, and others in this sector are doing to promote sustainable and ethical sourcing of raw material; and to
- explore which strategies might prove most effective in promoting sustainable and ethical sourcing.

The study itself focused on compiling a general collection of standards and guidelines for best practice in areas both directly and indirectly related to genetic resources and access and benefit sharing activities (ABS). The codes, guidelines and standards reviewed are not exclusively focused on genetic resources or ABS issues, but include a range of relevant criteria from ecological, organic and fair trade certification programs, quality control protocols, good manufacturing practice (GMP), corporate responsibility codes, and legislation.

The study provides general background information on each guideline or code as well as a reference where more detailed information can be obtained. It does not review or extract the specific provision included in a guideline or standard that might have a bearing on ABS activities. As stated by the authors, the study is intended to act as a basis upon which organizations can draw to develop – in collaboration with other groups – broad standards for botanicals.

The standards outlined in the report are organized into distinct groups, by primary subject matter:

1. Ecological Sustainability
    - forest management certification
    - wild plant harvester regulations/guidelines
2. Organic Criteria
3. Other Agricultural Criteria

[4] Pierce, Laird and Malleson for RainForest Alliance – "Annotated Collection of Guidelines, Standards, and Regulations for Trade in Non-Timber Forest Products (NTFPs) and Botanical V1.0 February 2002", Sustainable Botanicals Project, available at: http://marketstandards.chemonics.net/resources/Critical%20Reports/botanicals-standards.pdf

4. Fair Trade
    - ethical trading
5. Quality Control
    - authentication of botanical references
6. Good Manufacturing Practices
7. Corporate Responsibility
8. Laws, Treaties, And Regulations
    - environment
    - health and safety
    - trade
    - labeling and advertising
9. A Sample Of Resources And Guides To Sustainable Sourcing

3.3 "Promoting Sustainable and Ethical Botanicals" – Strategies to Improve Commercial Raw Material Sourcing"[5]

This was the final report of Phase 1 of the Rainforest Alliance's Sustainable Botanicals Project. It incorporates findings and products from the activities in Phase 1, and makes recommendations for future activities for phase 2 of the Sustainable Botanicals Project. The study begins with a general overview of the botanicals industry, based on a survey of companies in Europe, the United States of America, South America, Africa and Asia. It goes on to highlight the trend towards "green" marketing, and the approaches that companies take towards sustainability or environmental management and policies.

The paper then reviews trends in the industry, including sections on research & development; use of traditional knowledge in product development; interest in diverse sources for new product development; raw material sourcing – including chain of custody; impact of sustainability on new product development – including use of certified materials; and the prevalence of community partnerships in supplier countries. Prior to making recommendations on Phase 2, the report also reviews the information in the report "Annotated Collection of Guidelines, Standards, and Regulations for Trade in Non-Timber Forest Products (NTFPs) and Botanicals" (see above) and outlines two case studies.

The study concludes with an overview of the strengths and weaknesses of several potential strategies to promote sustainable and ethical use of botanicals. The particular strategies identified are:

[5] The information in this summary is largely taken directly from: Pierce and Laird for Rainforests Alliance – "Promoting Sustainable and Ethical Botanicals" Strategies to Improve Commercial Raw Material Sourcing", Final Report prepared for the Rainforest Alliance, May 2002. The report is available at: http://www.rainforest-alliance.org/news/archives/news/botanicals-strategies.pdf

1. **Generic Guidelines for Industry Associations** – work with industry associations to develop generic guidelines for sustainable and fair trade sourcing; help to set industry-wide policy.
2. **Direct Sourcing Partnerships** - collaborations and partnerships created or supported between companies, NGOs and source countries to develop sustainable and fair trade sources of raw materials.
3. **Corporate policy and strategy** - working with companies to develop internal strategies, and corporate policies, for "best practice" in sustainable and ethical sourcing.
4. **Certification** - of sustainable and fair trade raw material; could be combined with organic, GMP, quality-control and other certification efforts that depend on identifying and tracking sources of material.
5. **Consumer campaign** - education and media activity to raise awareness about environmental and social problems associated with sourcing some species, and positive steps consumers can take to buy wisely and influence sourcing practices.
6. **Law and policy** - effective development/implementation of national and international law and policy for the management and trade in botanicals to promote sustainability and fair and equitable benefits for local groups.
7. **Brokering in material** - setting up companies or non-profit intermediaries that broker in (certified) environmentally and socially sound material.
8. **Domestication and sustainable management** - supporting research and applied activities to develop management plans for sustainable wild harvest and domestication of threatened species, or those in extremely high demand.

The authors note that most of these strategies are complementary, and none comprehensive: "It is clear that all of the above strategies, or at least a large majority of them, are required to achieve widespread sustainability and fair trade in botanicals."

3.4 "User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity"[6]

This report is one of a series being published by the UNU-IAS on issues related to international ABS governance, in the context of its wider programme on biodiversity[7]. The report focuses on measures taken to control the use of genetic resources within the boundaries of national jurisdictions into which the resources have been imported – referred to as "user measures". This term is defined as:

[6] "User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity", 2nd Edition, United Nations University Institute for Advances Studes (UNU-IAS) Report, December 2003. Available at: http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf

[7] For more information see: http://www.ias.unu.edu/research/research.cfm

> "A package of legal, administrative and policy measures designed to promote compliance by users of genetic resources and traditional knowledge with obligations regarding Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Benefit Sharing (BS). These measures can be applied by either the public or private sector and may be mandatory or voluntary."[8]

The report reviews five types of user measures, grouped under the following headings:

1. Information, Codes and Certification;
2. Import and Transport Regulations;
3. Disclosure of Origin;
4. Measures to Address Infringements; and
5. An International System for Documenting the Flow of Genetic Resources

The report contains information which is germane to the development of an ABS management tool, and which can be inputted in two different ways. First, the principles that underpin each of the user measures, and some of the specific issues identified under them, are of relevance to the development of the substantive requirements – the "good practices" – to be included in a management tool for ABS. Second, the section on "Information, Codes and Certification" provides specific information on corporate and institutional policies, codes of conduct and professional codes of ethics, which are relevant to the overall development of a management tool on ABS.

The report also draws a useful distinction between "standards" and "best-practice". It describes standards as: "succinct, specific statements describing various elements of the desired end-state." That is, it refers to standards as "outcomes". It then describes "best practices" as a set of more detailed, complementary materials that provide information and examples on how to meet a particular standard or set of standards. That is, it refers to "best practices" as the means by which a standard is achieved. Whether these terms or others are used to describe the differences, this is a useful distinction to make in the context of an ABS management tool.

3.5 "Second Report of the European Community to the Convention on Biological Diversity: Thematic Report on Access and Benefit-Sharing"[9]

This report responds to Decisions V/19.8 and VI/24 F of the CBD Conference of Parties (COP), requesting Parties to submit information on measures and arrangements to implement the Convention's provisions on access to genetic resources and benefit sharing (ABS), and on the associated role of intellectual property rights (IPRs). The report describes how the European Community's approach to ABS has evolved through negotiations within a variety of multilateral fora,

[8] UNEP/CBD/ABS/EW-CD/1/INF/1, Appendix II, paragraph 2.

[9] "Second Report of the European Community to the Convention on Biological Diversity: Thematic Report on Access and Benefit-Sharing"; October 2002, available at: http://www.biodiv.org/doc/world/eur/eur-nr-abs-en.pdf

legal, administrative and policy measures taken by the Community, as well as actions by stakeholder groups.

The report includes an overview of legal and policy measures on ABS implemented by the EC, such as those related to the conservation and sustainable use of biodiversity, and research and technology transfer. It also includes information on EC legislation as it relates to IPRs and traditional knowledge, the conservation and sustainable use of agricultural genetic resources and associated traditional knowledge, and research and technology transfer. An overview is also given of the EC's involvement in relevant inter-governmental processes including the development of the Bonn Guidelines, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, WIPO deliberations on ABS and IPRs, and WTO TRIPs deliberations on ABS.

Of particular relevance to the development of a management tool for ABS, the report outlines best-practice in the EU on Access and Benefit-Sharing, and lists Principles on Access to Genetic Resources and Benefit-Sharing. It lists a number of institutional policies and codes of conduct, including The Code of Conduct and Access and Benefit-Sharing System for Botanic Gardens (which later became the 'International Plant Exchange Network,); the PlantNet conservation policy; the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC); the CABI) Policy on Access to Ex Situ Genetic Resources; and the European Cooperative Programme on Crop Genetic Resources Networks ECP/GR. The EC report also includes a section on corporate policies, noting that with the decline in interest in natural products research these appear to be less important to corporate strategy than they appeared 10 years ago. Two of the most prominent examples of corporate policies in Europe are also given: the Novo Nordisk/Novozymes and Glaxo Smith-Kline policies. Neither the review of codes of conduct nor corporate policies provide information on the substantive norms or requirements. Finally, general examples of both commercial and non-commercial ABS activities are provided.

3.6 "Towards a Certification System for Bioprospecting Activities"[10]

This report undertakes a feasibility assessment for the design and operation of a bioprospecting certification system. It focuses on issues related to the development of such a system (i.e. the context) rather than on the specific requirements against which bioprospectors would be assessed (i.e. the content). It outlines and discusses the major factors that need to be considered, including:

1. possible scale and architecture of the system;
2. costs, and the need for supporting funds;
3. the stakeholders that would participate in it; and
4. the relationship of the system with other existing certification systems.

[10] Glowka, Lyle, 2002; "Towards a Certification System for Bioprospecting Activities", Study Commissioned by the Swiss State Secretariat for Economic Affairs (seco); available at: http://www.biodiv.org/doc/meetings/cop/cop-06/other/cop-06-ch-rpt-en.pdf

The report identifies three possible scales for a third party bioprospecting certification system (global scale, national scale and small scale), and demonstrates that all three scales have similar attributes. The report also outlines some outstanding issues for each of the three scales, and discusses issues relating to the harmonization of global best practice. The report includes two annexes, the first of which provides the author's outline of issues to consider in the development of different types of certification systems, and the second, which provides an overview of the governance, scope and operational structure of some key existing certification and accreditation bodies, including:

1. European Ecomanagement and Audit Scheme (EMAS);
2. Fairtrade Labelling Organisations International (FLO);
3. Forest Stewardship Council (FSC);
4. International Accreditation Forum (IAF);
5. International Federation of Organic Agriculture Movements (IFOAM);
6. International Organisation for Standardisation (ISO);
7. International Social and Environmental Accreditation and Labelling Alliance (ISEAL);
8. Marine Aquarium Council (MAC);
9. Marine Stewardship Council (MSC); and
10. Social Accountability International (SAI).

It is useful for the purposes of distinguishing between the Glowka study and the current report to note certain key differences in their scopes. Most importantly, the Glowka study focuses directly on the process and operational issues involved in the development of a certification system for bioprospecting (i.e. the context) – whereas the present study focuses on the good-practice elements (norms, standards, guidelines) that could be integrated into a management tool to facilitate understanding and implementation of the ABS provisions (i.e. the content). The studies' treatment of the various existing initiatives is illustrative of this difference. While the Glowka study focuses on the bodies developing the standards, certification and accreditation systems, the current study focuses on the substantive requirements in the standards themselves, and tries to identify which are relevant for ABS best-practice.

4 Review of Existing Initiatives

The following section provides a review of 16 examples of codes of practice, guidelines and standards that contain requirements specific to or relevant to ABS. It comprises a sampling of a range of systems and purposes related to genetic resources, or access to and management of biological resources more broadly. For each system reviewed, there is a description of key "requirements or standards", management system elements, and a brief assessment of best practice requirements that can be applied for access and benefit sharing relationships and agreements.

The section also contains tables summarizing the key substantive requirements (norms, standards, guidelines and model practices) of each guideline or code, organized by the elements of good practice for access and benefit sharing. These have been abstracted or paraphrased to highlight those provisions that are most relevant and illustrative of good ABS practice, and do not present the full set

of norms or practice standards contained in the original documentation. Where the initiative reviewed has a management system in place for operationalizing the substantive requirements, a schematic chart is provided to illustrate the main requirements and the structure of the system elements.

Information sources used in developing these reviews can be found in the back of this report, and are listed by sub-section.

4.1 International Guidelines

Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization/ CBD Decision V/26

CBD Decision V/26 provided the basis for the negotiation of the Bonn Guidelines. The Decision itself includes a number of elements of interest to the development of voluntary standards or best practices in ABS which are abstracted below, including:

- Trust-building and transparency are important in order to facilitate the exchange of genetic resources
- Information is a critical aspect of providing parity of bargaining power for stakeholders in access and benefit-sharing arrangements
- The development of capacities is required for all stakeholders, including: assessment and inventory of biological resources; contract negotiation skills; legal drafting skills; and means for protecting traditional knowledge associated with genetic resources.

The Bonn Guidelines themselves, of course, provide a specific elaboration of CBD provisions on Access and Benefit Sharing. The review of norms, standards and practices in other international guidelines and codes of practice is structured around the main operational elements of the Bonn Guidelines, with additional elements added on the basis of emerging good practice.

FAO: International Code of Conduct for Plant Germplasm Collecting and Transfer

The first international effort to set out guidance on genetic resource access and benefit sharing was the FAO International **Code of Conduct** for Plant Germplasm Collecting and Transfer, which was adopted by the Food and Agriculture Organization (FAO) in November, 1993. The Code is voluntary in nature, and aims "to promote the rational collection and sustainable use of genetic resources, to prevent genetic erosion, and to protect the interests of both donors and collectors of germplasm." The main provisions of the Code relate to the issuing of permits for access to genetic resources, and the responsibilities of collectors, sponsors, curators and other users.

The Code is supported by a set of **Procedures** for the issuance of licences for collecting missions, as well as guidelines for collectors and responsibilities and obligations for sponsors of missions, curators of genebanks, and users of genetic materials.

The Code is described as being "fully compatible with the Convention on Biological Diversity," and makes specific reference to the sovereign rights of nations over their genetic resources. While the

Code primarily targets governments as providers of genetic resources, it also outlines the responsibilities of collectors, donors, sponsors, curators and other users of germplasm. From the perspective of providers, the Code describes the general requirements for issuing, requesting and granting collectors' permits. Responsibilities of collectors/users have been specifically established for pre-collection, collection, and post-collection stages of activity. Other responsibilities, such as keeping local communities and farmers informed, are also described, as are the general procedures for reporting, monitoring and evaluating compliance with the Code.

Included in the section on responsibilities of users are requirements for respecting local customs and property rights, and recognition of the use of local knowledge; and, for sharing benefits arising from the use of plant genetic resources to be shared with the local community

The Code, despite its development in the early stages of CBD implementation, contains continuing useful guidance in a number of ABS practice areas. Its includes guidance for sponsors (funders) to ensure that the collectors they support, and curators who keep and use the materials collected, also abide by the code – to establish accountability between funder and user. It provides some general guidance and restrictions on conserving both wild populations and genetic diversity of cultivars collected, and on ecological information needed for assessing sustainability of collections. Further, there is guidance on respect for local customs, traditions, and values and property rights which has important implications for indigenous and other communities. These latter elements are stated as desirable rather than requirements of good practice. Information provisions, while providing for recognition of traditional knowledge, do not specifically take account of the need for the protection of such knowledge.

While not designed specifically for the purpose, the Code also contains general elements of a management system – including substantive practice guidance and procedures for monitoring and reporting.

Figure 1: International Code of Conduct for Plant Germplasm Collecting and Transfer

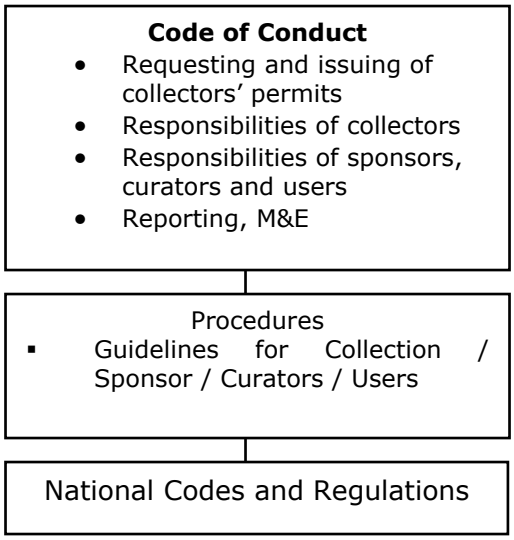


Table 1. FAO International Code of Conduct for Plant Germplasm Collecting and Transfer (abstracted provisions)

Scope	Plant germplasm (agricultural resources??) for XXX use??
General Provisions	
Prior Informed Consent (PIC)	Providers ▪ Indicate categories and quantities of germplasm which may/ may not be collected or exported, and those which require deposit within the country ▪ Define any financial obligation to be met by the applicant including possible national participation in the collecting team ▪ Indicate areas, species governed by regulation ▪ State any special arrangement or restriction placed on the distribution or use of the germplasm, or improved materials derived from it Collectors ▪ Provide indicative plans for the field mission - including provisional route, types of material to be collected, species and quantities; and plans for evaluation, storage and use of the material collected
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ Use of material transfer agreements including the sharing of benefits derived from collected germplasm by the users with the local communities, farmers and host countries
Benefit Sharing	▪ Without prejudice to the concept of Farmers' Rights, users of the germplasm, should provide benefit to the local communities, farmers and the host countries, and consider providing some form of compensation for the benefits derived from the use of germplasm such as: (a) facilitating access to new, improved varieties and other products, on mutually agreed terms; (b) support for research on conservation and utilization of plant genetic resources, including community- based, conventional and new technologies, as well as conservation strategies, for both *ex situ* and *in situ* conservation; (c) training, at both the institutional and farmer levels (d) facilitate the transfer of appropriate technology for the conservation and use of plant genetic resources; (e) support for programmes to evaluate and conserve local land races and other indigenous germplasm
Traditional Knowledge (TK)	• Collectors should respect local customs, traditions, and values, and property rights and there should be recognition of the use of local knowledge in the collection process
Conservation and Sustainable Use	▪ the acquisition of germplasm should not deplete the populations of the farmers' planting stocks or wild species, or remove significant genetic variation from the local gene pool. ▪ the collector should systematically record in detail the plant population, its diversity, habitat and ecology ▪ Deposit duplicate sets of all collections and associated materials, and records, with the host country and other agreed curators ▪ Alert the host country and the FAO Commission on Plant Genetic Resources about any impending threat to plant populations, or evidence of accelerated genetic erosion
Community Participation	

Transparency and Information	▪ It is desirable that the local communities and farmers concerned be informed about the purpose of the mission, and about how and where they could request and obtain samples of the collected germplasm ▪ Curators should take practical steps to ensure future enquiries from the local communities and farmers provides the original material, and the host country, are responded to. Samples of the plant germplasm collected should be supplied upon request.
Other relevant requirements	▪ Undertake to respect the relevant national laws; (Art. 7a) ▪ Sponsors should take steps to ensure, as far as is possible and appropriate, that collectors they sponsor abide by the Code ▪ Sponsors should, as far as is possible and appropriate, establish agreements with curators of the germplasm collected ▪ Relevant professional associations and other similar bodies accepting the principles embodied in this Code may wish to establish peer review ethics committees to consider their members' compliance with the Code

MOSAICC (Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct)

MOSAICC is a voluntary, international code of conduct designed to facilitate access to microbial genetic resources (MGRs), and to provide guidance to partners in the transfer of MGRs. Initiated in 1997, MOSAICC is described as a "tool to support the coherent implementation of the Convention on Biological Diversity, the WTO TRIPS agreement and the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure". Although designed to address microbial genetic resources, MOSAICC can also serve as a model when dealing with genetic resources and materials in general.

The MOSAICC system is based on two operating **Principles**: (1) that the *in situ* origin of microbial genetic resources be identified through Prior Informed Consent procedures, providing authorization for sampling, and ensuring the origin of the resource is identified in each consecutive transfer; and, (2) that the transfer of microbial genetic resources occurs under a Material Transfer Agreement (MTA), where the terms of the agreement are determined by both the recipient and the provider. Through these operating principles, MOSAICC aims to assist microbiologists as users in obtaining prior informed consent, and in establishing MTAs for access to and transfer of MGRs. It aims to assist providers of genetic resources in gaining access to and transfer of technology, technical and scientific cooperation, and other benefits. MOSAICC is also designed to assist countries that provide microbial genetic resources in issuing prior informed consent for access to genetic resources, and in monitoring the transfer of MGRs to ensure fair and equitable sharing of benefits.

MOSAICC has developed a **Material Transfer Agreement contents checklist,** which recommends that the following basic elements be included: (a) information about the *in-situ* origin; (b) information about the provider and recipient; and (c) mutually agreed terms related to access, transfer, benefit-sharing, and use of microbial genetic resources. The possible **uses** of MGRs are divided into three categories, including use for: (1) test, reference, bioassay, control and training purposes; (2) research purposes; and (3) commercial use. With respect to material transfer, MOSAICC recommends that

parties make the distinction between transfer where further distribution is excluded, and transfer where further distribution is permitted, and that all forms of distribution and utilization of MGRs be adequately monitored. This is an important provision in terms of tracing the use of genetic resources beyond the initial collector or user.

MOSAICC is a practical tool for guiding access to and use of genetic resources. It provides guidance on the contents of material transfer agreements (MTAs), with a specific provision for agreement on the intellectual property rights (IPRs) of the microbial genetic resources and/or derived technology before investing in research and development that could lead to the commercial use of the MGRs or derived technologies. The tool also outlines recommendations for monetary compensation in return for access to microbial genetic resources, including initial / up-front payments, milestones payments, and royalty payments. This specification of key benefit-sharing elements makes MOSAICC a useful model for access to other forms of genetic resources. The Code of Conduct is also noteworthy for its differentiation of different types of intended use; and for specifying whether further transfer is to take place beyond the initial collector, and requirements for monitoring transfers and information feedback to the original provider.

MOSAICC: CATEGORIES OF USE

Category 1: Use for Test, Reference, Bioassay, Control and Training Purposes

- No commercial use;
- No Intellectual Property Rights (IPR) on MGRs, derived technology and information;
- The recipient has to follow the protocols of standard test and reference procedures

Category 2: Use for Research Purposes

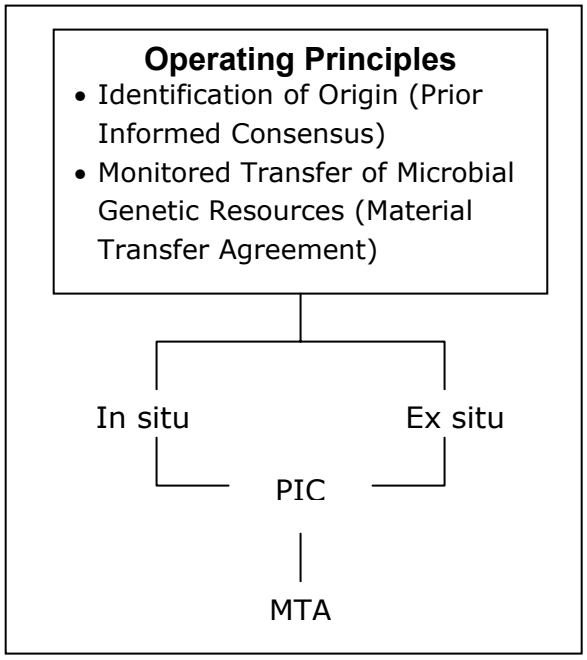
- No commercial use;
- No IPR on MGRs, derived technology and information;
- Scientific feedback: publications will mention provider, strain reference number and country of origin

Category 3: Commercial Use

- Terms on IPR, information feedback about patent application;
- Need for more precise terms for benefit-sharing (additional terms included)

Source: Desmeth, 1999.

Figure 2. Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC)



Decision-Making Process *(Desmeth, 1999)*

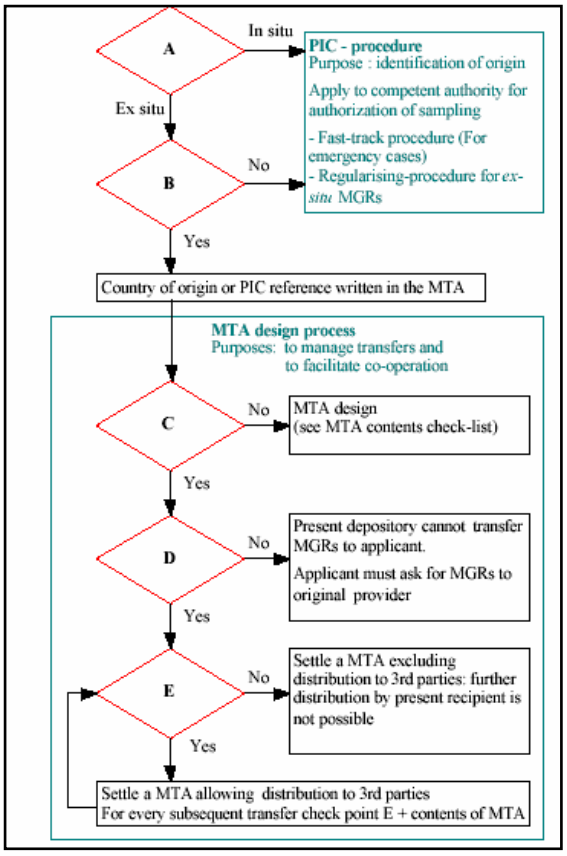


Table 2. Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct) MOSAICC (abstracted provisions)

Scope	▪ Microbial organisms, including from land and marine environments + applicability to broader sources of genetic resources ▪ Uses: 1) test, reference, bioassay, control and training purposes; (2) research purposes; and (3) commercial use
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ The PIC Application must be acquired prior to accessing the MGRs with effort to identify the competent PIC-provider ▪ PIC-documents information specifications including: - confirmation of the authority exercised by the « PIC-provider »; - a confirmation of the precise scope of the PIC being sought - reference to a Material Transfer Agreement, if any; - contains a clear indication about duration of its terms ▪ Always attempt to acquire written permission from landowner or other usufturary of land or sea area ▪ The recipient will not distribute the MGRs delivered, unless the following conditions are observed: - The recipient will keep records of all downstream recipients of the MGRs concerned. This information will be available on request (i.e. monitoring the transfers) - The Recipient will transmit back to the Provider information provided by the downstream recipient(s) of the MGRs concerned such as intentions for commercial use (i.e. information feedback)
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ PIC Material Transfer Agreements (MTA) to be negotiated, defined by two main criteria: - the kinds of use of the MGRs. - the possibility to distribute the MGRs to third parties, or not; ▪ MGRs be transferred with the necessary information about their in-situ origin, including reference to the original PIC, country, strain and species, information on who/how isolation of the strain .
Benefit Sharing (BS)	▪ Partners signatory of a MTA to include clauses in order to facilitate benefit sharing, especially scientific and technical co-operation, access to and transfer of information and technology, and capacity building ▪ Implication that return for each partner should correspond fairly with the time, money and intellectual and inventive effort invested by that partner and also reflect the respective specific values that will be added ▪ Recommend partners (Provider and Recipient) agree on the IPRs (from single to shared ownership) of the MGRs and/or derived technology before investing in research and development that could lead to the commercial use of the MGRs. ▪ MOSAICC recommends to calculate the importance of the initial payments in terms of the actual involvement of the provider in the delivery of the MGRs (e.g. local community participating or not to field survey; costs of maintenance of *ex-situ* MGRs, etc.)
Traditional Knowledge (TK)	

Conservation and Sustainable Use (C+SU)	▪ In addition, to avoid loss of interesting *ex-situ* MGRs in cases where individuals or institutions stop their activities, there should be an arrangement with culture collections that could take over the conservation of those *ex-situ* MGRs that have no known duplicates elsewhere. ▪ The Recipient will use the MGRs in a sustainable way
Community Participation (CP)	▪ Include indigenous or local communities as parties of an agreement in so far as the community is: - owner or usufructuary of area where *in-situ* MGRs accessed; - well represented by officially recognised representative(s) and willing to maintain knowledge, innovations and practices relevant for the conservation and sustainable use of MGRs
Transparency and Information (TI)	▪ All scientific papers should mention provider, country of origin, date and place of isolation and identification data ▪ Keep files proving efforts made and agreements to acquire PIC
Other relevant requirements	

4.2 Biological Resources Management Standards and Certification Systems

Forest Stewardship Council

The Forest Stewardship Council (FSC) is an international non-governmental organization that aims to promote environmentally responsible, socially beneficial and economically viable management of the world's forests. Driven by concerns over deforestation, reduction of forest quality, and marginalization of forest-dependent communities, the FSC includes principles and criteria designed to support national and international laws and regulation.

The core of the FSC is its 10 **Principles and** 56 **Criteria**, organized by environmental, social/cultural or economic conditions to be met or issues to be managed. While using elements based on ecological sustainability and community involvement, they address a range of issues relevant to ABS, with provisions pertaining to prior informed consent, mutually agreed terms, benefit-sharing, traditional knowledge, conservation, sustainable use, community consultation and information sharing. With respect to PIC, forest operations are not permitted to access community resources without free and informed consent to other agencies. Similarly, the principles and criteria state that Indigenous Peoples have the right to control forest management on their lands and territories unless they delegate control with free and prior informed consent to other agencies.

The FSC also requires that benefits from the forest be shared with local communities in the form of employment opportunities (e.g. through local processing of forest products), and the provision of education, training and community services. To ensure long-term economic viability of the community, forest management should also "strengthen and diversify the local economy, avoiding dependence on a single forest product." In addition, forest management planning should take into consideration the results of social and environmental impact assessments, and must ensure that harvesting levels can be permanently sustained. Forest management should also "conserve biological diversity and its associated values."

Beyond establishing international norms, the primary role of the FSC is to accredit and evaluate certification bodies, which in turn provide certification to forestry companies that voluntarily meet FSC principles and criteria. Certified companies, including harvesters, producers, wholesalers and retailers, are provided with an official FSC logo, and are subject to an ongoing monitoring and assessment process to ensure they continue to meet necessary requirements. The FSC oversees the development of **locally-defined forest management standards** and certification bodies, and ensures consistency and integrity of these standards through formal endorsement by the FSC Board of Directors. The locally-driven standards development process also involves an extensive consultation process that serves as a model for effective communication and engagement, and includes representatives from Aboriginal, environmental, economic and social organizations, as well as the public at large.

The FSC Principles are of interest to ABS because they cover the three elements of sustainable development - ecological sustainability, social well-being and economic benefits. They are noteworthy for emphasis on community involvement in decision-making, and specific provisions related to respect for indigenous peoples and their rights. FSC also stresses provision of benefits at the local or community level.

As a management system, FSC is of interest for its tiered process of standard setting, from universal global Principles and Criteria, to the specification of national or ecosystem-level criteria for each separate FSC entity. It also provides a strong chain of custody system, with products verified and labeled as having been collected in a manner which adheres to FSC standards.

Figure 3. Forest Stewardship Council

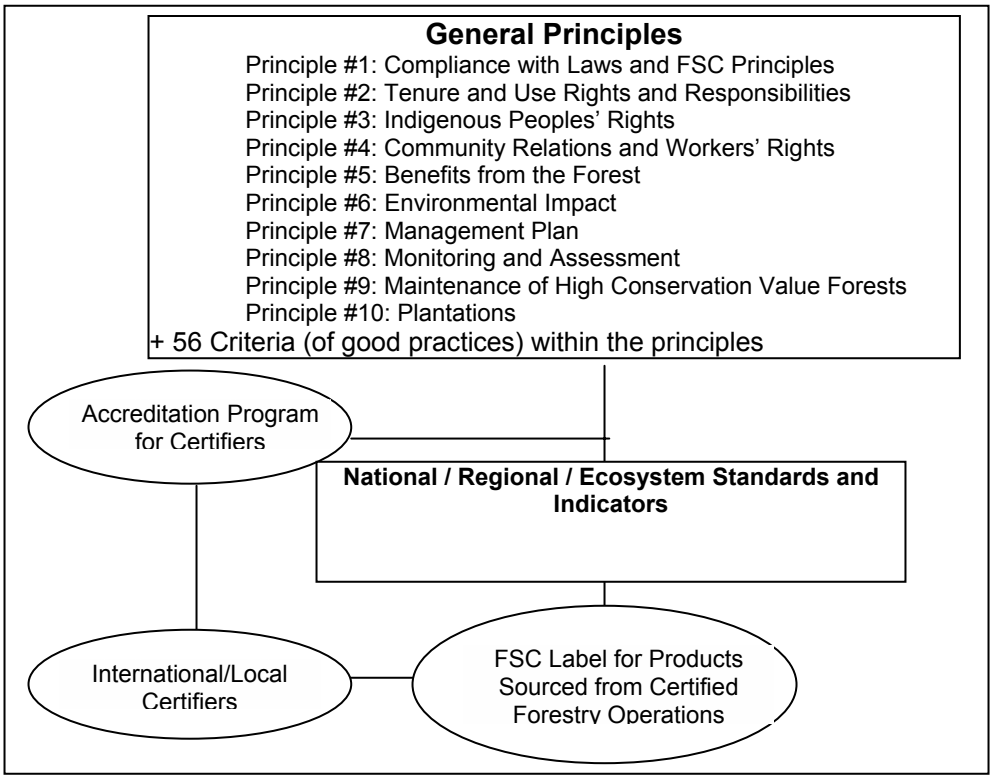


Table 3. Forest Stewardship Council (abstracted provisions)

Scope	
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ Indigenous peoples shall control forest management on their lands and territories unless they delegate control with free and informed consent to other agencies.
Mutually Agreed Terms (MAT) e.g. contract provisions	
Benefit Sharing (BS)	▪ Compensation shall be formally agreed upon with free and informed consent before forest operations commence ▪ Communities within, or adjacent to, the forest management area should be given opportunities for employment, training, and other services. ▪ Forest management and marketing operations should encourage the optimal use and local processing of the forest's diversity of products. ▪ Forest management should strive to strengthen and diversify the local economy, avoiding dependence on a single forest product
Traditional Knowledge (TK)	▪ Local communities with legal or customary tenure or use rights shall maintain control, to the extent necessary to protect their rights or resources, over forest operations unless they delegate control with free and informed consent to other agencies ▪ Forest management shall not threaten or diminish, either directly or indirectly, the resources or tenure rights of indigenous peoples ▪ Indigenous peoples shall be compensated for the application of their traditional knowledge regarding the use of forest species or management systems in forest operations
Conservation and Sustainable Use	▪ Sites of special cultural, ecological, economic or religious significance to indigenous peoples shall be clearly identified in cooperation with such peoples, and recognized and protected by forest managers. ▪ Forest management should minimize waste associated with harvesting and on-site processing operations and avoid damage to other forest resources ▪ The rate of harvest of forest products shall not exceed levels which can be permanently sustained ▪ Assessment of environmental impacts shall be completed and adequately integrated into management systems ▪ Safeguards shall exist which protect rare, threatened and endangered species and their habitats; Conservation zones and protection areas shall be established
Community Participation	▪ Consultations shall be maintained with people and groups directly affected by management operations ▪ Mechanisms shall be employed for resolving grievances and for providing fair compensation in case of loss or damage affecting legal or customary rights, property, resources or livelihoods of local people

Transparency and Information	▪ While respecting the confidentiality of information, forest managers shall make publicly available a summary of the primary elements of the management plan, and results of monitoring ▪ Documentation shall be provided by the forest manager to enable monitoring and certifying organizations to trace each forest product from its origin, a process known as the "chain of custody".
Other relevant requirements (ORR)	▪ Appropriate mechanisms shall be employed for resolving disputes over tenure claims and use rights, grievances and for providing fair compensation in the case of loss or damage affecting the legal or customary rights, property, resources, or livelihoods of local peoples

IFOAM (International Federation of Organic Agriculture Movements)

IFOAM – the International Federation of Organic Agriculture Movements – is a federation of organic agriculture organizations governed by a global General Assembly, and supported by a set of Norms and a formal Accreditation Program. The IFOAM Norms include both **Basic Standards and Accreditation Criteria**, and, together with the Accreditation Program, form the basis of the Federation's Organic Guarantee System (OGS).

Although not designed to be used independently, the Basic Standards provide a framework that can serve as a foundation when developing local, regional and / or national certification standards. The Basic Standards consist of (1) General Principles (the intended goals of processing); (2) Recommendations (practical suggestions for operators); (3) Basic Standards (minimum requirements for certification); and (4) Derogations (exceptions to specific standards). **Sector-specific requirements** are also established, and follow the general format of the Basic Standards. The IFOAM requirements include elements related to conservation and sustainable use of agricultural resources.

IFOAM seeks to provide a common system of standards, verification process and market identity for organic products. The Accreditation Program, which is administered by the independent organization International Organic Accreditation Service (IOAS), is offered to certification bodies that demonstrate compliance with the IFOAM Norms. Accredited Certification Bodies have the ability to certify organic products, which provides assurance to wholesalers, retailers and consumers that the product bearing the IFOAM Seal meets the requirements of the Organic Guarantee System. To receive an IFOAM Seal, a contract must be signed between the Accredited Certification Body (ACB) and the IOAS, and between an ACB and the certified party.

As an independent organization, the International Organic Accreditation Service provides valuable services to the Federation in the form of accepting and reviewing accreditation applications, conducting site evaluations, granting IFOAM accreditation to applicants, and administering the IFOAM Seal and Accreditation Program. To ensure equivalence at the level of the Accreditation Criteria (part of the IFOAM Norms), Accredited Certification Bodies have implemented a

Multilateral Agreement (MLA) that will streamline certificate acceptance, and further support the objectives of the Organic Guarantee System.

While designed for a specific and different purpose (ensuring covered agricultural products are organic), IFOAM contains some provisions of interest to ABS practices. It provides specific guidance on appropriate cultivation and wild harvesting practices, with an emphasis on both sustainability of these resources, and on their quality. It also contains a strong provision on protection of Aboriginal rights. From a management system perspective, it includes a full life-cycle tracking system from provider (harvester) to consumer.

Figure 4. International Federation of Organic Agriculture Movements (IFOAM)

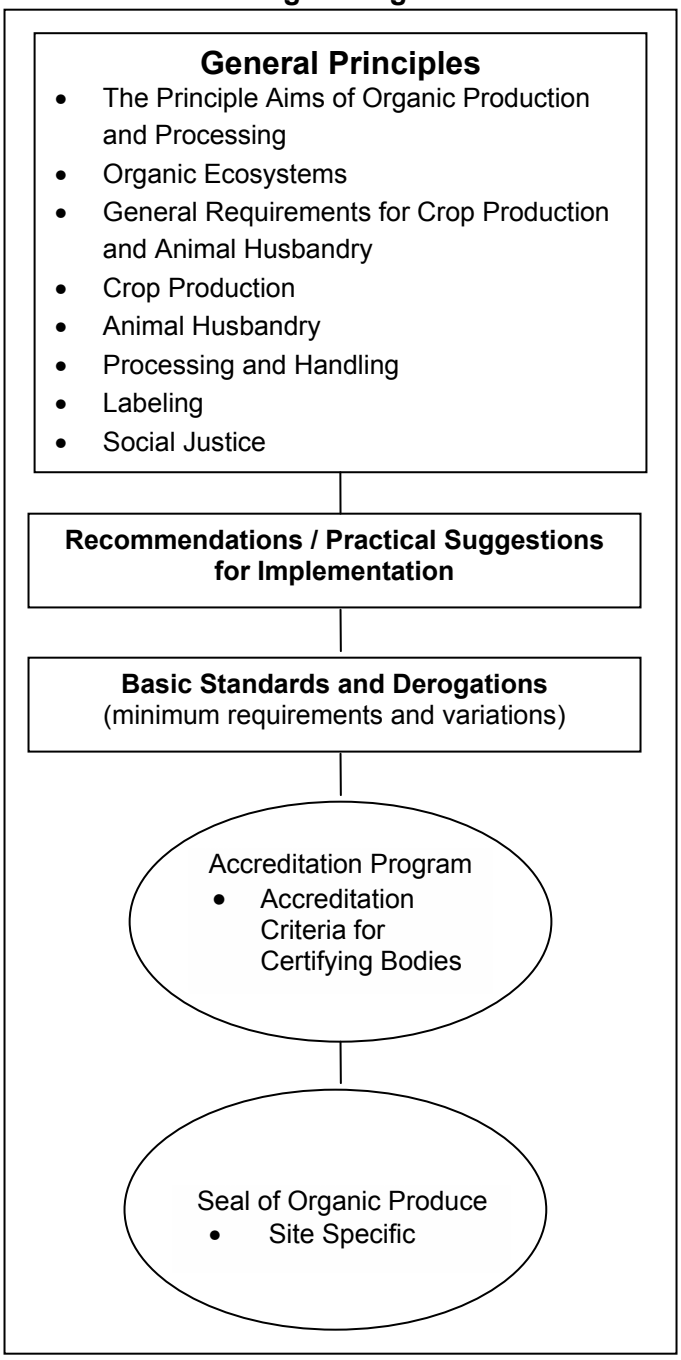


Table 4. International Federation of Organic Agriculture Movements (abstract of provisions)

Scope	Food products produced organically
General Provisions (GP)	
Prior Informed Consent (PIC)	
Mutually Agreed Terms (MAT) e.g. contract provisions	
Benefit Sharing (BS)	
Traditional Knowledge (TK)	▪ Operators should respect the rights of indigenous peoples, and should not exploit land whose inhabitants have been or are being impoverished.. or which is currently in dispute regarding legal or customary local rights to its use of ownership
Conservation and Sustainable Use (C+SU)	▪ Operators shall take measures to maintain and improve landscape and enhance biodiversity quality. ▪ Clearing of primary ecosystems is prohibited. ▪ Wild harvested products shall only be certified organic if they are derived from a stable and sustainable growing environment. The people who harvest, gather, or wildcraft shall not take any products at a rate that exceeds the sustainable yield of the ecosystem, or threaten the existence of plant, fungal or animal species, including those not directly exploited ▪ The operator who manages the harvesting or gathering of common resource products shall be familiar with the defined collecting area.
Community Participation (CP)	
Transparency and Information (TI)	
Other relevant requirements (ORR)	

Marine Aquarium Council

The Marine Aquarium Council (MAC) is an international consortium of aquarists, industry operators, conservationists and researchers. The goal of the Council is to "conserve coral reefs and other marine ecosystems by creating standards and certification for those engaged in the collection and care of ornamental marine life from reef to aquarium." The Council also hopes to increase consumer demand for certified aquarium products and species. Although presently receiving funding from a range of foundations, charitable trusts, and other independent and non-commercial sources, the Council intends to become a self-sustaining organization over the next five years, with funds being raised through its certification process. MAC is governed by a Board of Directors, comprising conservation and public interest group representatives, as well as individuals from a range of additional stakeholder groups.

The Council has established a set of Core Standards that outline the requirements for third-party certification of the marine aquarium industry, covering the "**reef to retail" supply chain**. **Three Core Standards**, each addressing a specific stage of use, form the foundation of the Council's

certification efforts: the Ecosystem and Fishery Management Core Standard; the Collection, Fishing and Holding Core Standard; and the Handling, Husbandry and Transport Core Standard. The Standards are supported by **Best Practice Guidelines,** which are designed to assist stakeholders in interpreting and achieving compliance with the Marine Aquarium Council's Core Standards. **Interpretive Manuals of the Standards** take local conditions into account, and were developed in consultation with stakeholders. The Core Standards and the Best Practice documents will be used until the Full Standards and Best Practice Guidance are finalized in the next two years.

When collecting marine organisms, organizations must develop a **Collection Area Management Plan.** Included in the Plan should be: documentation of stakeholder interests (including details of the consultation process); an assessment of the status of the marine ecosystem from which the species are being collected; a monitoring plan; an audit procedure; and, agreed upon measures for the regulation of collection activities within the designated collection area.

To achieve MAC certification, operators throughout the chain of custody must meet all appropriate MAC Standards. Certification is awarded by third-party organizations, which conduct detailed assessments of the company's compliance with the MAC Core Standards. The assessment process includes bilateral meetings between a certifying organization and the applicant, completion of a detailed self-assessment questionnaire, and follow-up to the questionnaire in the form of an assessment report, completed by the certifying organization. Organizations that meet certification requirements will bear the MAC label.

The Marine Aquarium Council has also developed a **consumer awareness program**, which received a considerable boost over the past year with the release of the film "Finding Nemo." The Council is also working in cooperation with other regional and international organizations to increase awareness of the marine aquarium trade and the role of the MAC in ensuring the industry operates under the principles of sustainable use and conservation.

The MAC is of interest to ABS for its specification of detailed ecological provisions in the collection of marine species. Its requirement for Collection Area Management Plans provides a tool for both collectors and providers of the resource to elaborate and review the intended collection practice in terms of conserving the resource and ensuring its sustainable use. Further, the MAC requirements address the role of collectors in the local community and their responsibility for ensuring sustainability of the resource. The MAC requirements also include clear elements on consultations and decision making process with local communities and stakeholders. In management system terms, the MAC is interesting for its set of tiered standards and guidance documents, from core standards to local area management plans. Finally, its "reef to retail" system is intended to allow tracking of collected specimens throughout the supply chain.

Figure 5. Marine Aquarium Council

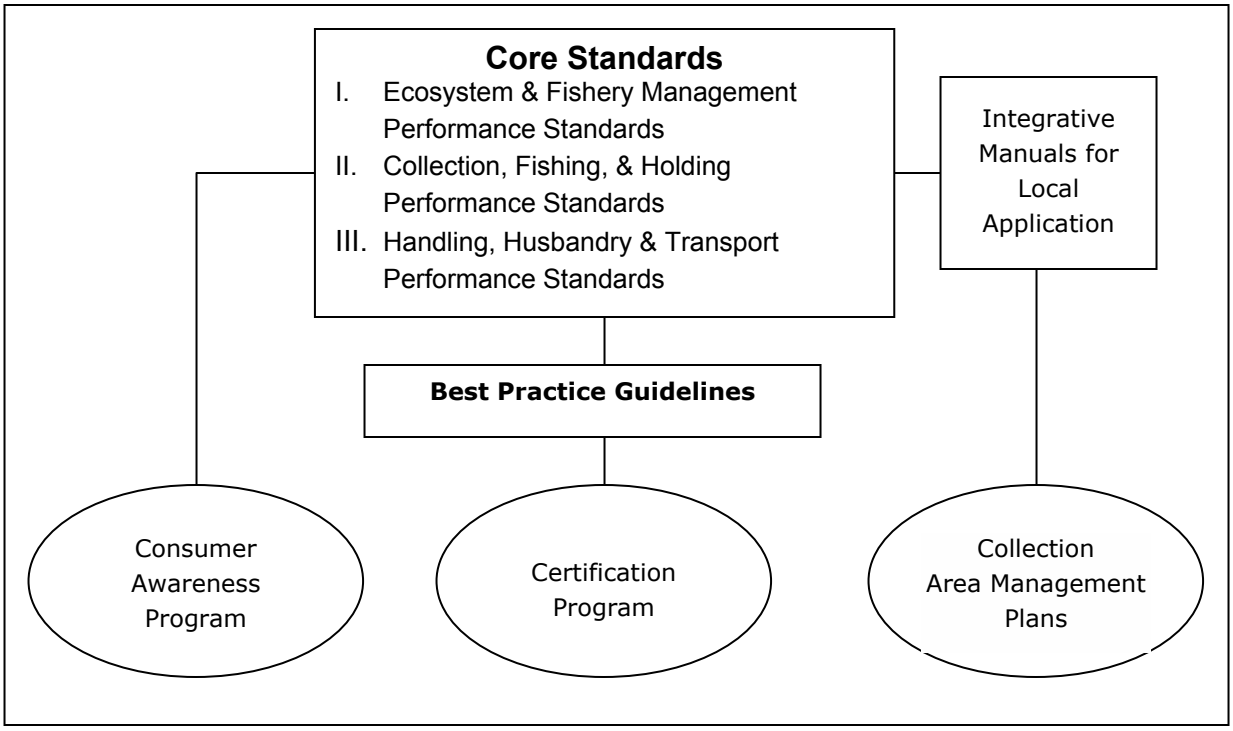


Table 5. Marine Aquarium Council (abstracted provisions)

Scope	Collection and transfer of ornamental marine life Users: aquarists, industry operators, conservationists and researchers.
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ Collectors and fishers shall comply with local laws and regulations with respect to access to and marine aquatic organisms taken from the certified collection area ▪ A carrier or agent in the country of origin should not accept a consignment of marine aquarium organisms for which no documentary evidence of an order is available
Mutually Agreed Terms (MAT) e.g. contract provisions	▪
Benefit Sharing (BS)	▪ Collection Area Management Plan to include: - Details of individuals or groups granted rights of access to the marine aquarium fishery; particulars of the nature of those rights - Details of planned education and training for stakeholders
Traditional Knowledge (TK)	
Conservation and Sustainable Use (C+SU)	▪ Collection Area Management Plan to include: - Basic description of the aquatic ecosystem, its status, and any particularly sensitive areas, features, or species - Description of other legitimate uses of the collection area that impact on the collection area ecosystem(s)

	- Details of any critical environments or sources of concern and required actions to address them. ▪ Collection should be managed so that: - A harvested reef section should be allowed to recover before reharvesting may occur; - Collection not be permitted on damaged, stressed, recovering reefs; - Communities or individuals involved in the collection of corals should begin to engage in activities that protect the reef - Collection and fishing activities within the collection area support the conservation of biological diversity in the collection area; - Basic principles of environmental management and ecosystem management ▪ Arrangements and responsibilities for regular monitoring, control and surveillance, and enforcement specified ▪ To verify that the collection area is managed according to principles of ecosystem management in order to ensure ecosystem integrity and the sustainable use of the marine aquarium fishery.
Community Participation (CP)	▪ The following items and content are required for the Collection Area Management Plan: - Particulars of the stakeholders with interests in the marine aquarium fishery - Details of consultations leading to the management of the marine aquarium fishery - Arrangements for on-going consultations with stakeholders - Details of decision-making process or processes, including the recognized participants ▪ Communication between stakeholders should be documented
Transparency and Information (TI)	▪ All organizations in the chain of custody should be able to document or demonstrate that they: - Fully understand the requirements of their buyer and inform him/her when it is not possible to fulfill a particular order; - Are aware of which species are available and aware of those that are in the MAC "Unsuitable Species" Annex of the Core Standards documents and should not be requested; and ▪ All organizations in the chain of custody should be able to document or demonstrate that they maintain traceability of certified status. ▪ All organizations and individuals in the chain of custody from the collector or fisher to retailer shall operate and maintain a documentation system for assuring that a marine aquarium organism comes from a MAC Certified collection area or supplier ▪ Where innumeracy and illiteracy are a problem, all organizations in the chain of custody should be able to demonstrate how all parties understand the requirements

Other relevant requirements (ORR)	▪ Those managing the fishery shall have periodic audits of the Collection Area Management Plan and update the plan at regular intervals ▪ All organizations in the chain of custody should have a log of complaints maintained by the supplier and buyer. This log if used properly can be an effective improvement tool and can contain problems raised by any person within or outside the collecting area

4.3 Sector Codes

Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit Sharing Arrangements for Participating Institutions (Botanic Gardens)

The Principles and Common Policy Guidelines were developed over 4 years (1997-2000) by the Pilot Project for Botanic Gardens for use by such organizations as botanic gardens, herbaria or other institutions involved in the collection and curation of plant genetic resources. This project involved 28 large and small botanical institutions from 21 developed and developing countries. Participating Institutions voluntarily agree to endorse the Principles, and to develop institutional policies that will ensure their effective implementation. The **Principles** cover (1) acquisition of genetic resources; (2) use and supply of genetic resources; (3) use of written agreements; (4) benefit-sharing; (5) curation; and (6) policy development. In addition, Participating Institutions agree to "honour the letter and spirit" of the CBD and CITES, as well as the laws related to associated traditional knowledge. **The Common Policy Guidelines** provide specific guidance to assist participating institutions in the preparation of institutional policies for implementation of the Principles.

The Principles and Common Policy Guidelines can be applied to the acquisition of genetic resources from *in situ* and *ex situ* conditions; and address specific good practice elements such as obtaining prior informed consent from stakeholders and the government of the country of origin (in the case of *in situ* collection), as well as from relevant bodies governing *ex situ* collections. Documentation of prior informed consent is required for all collections, and including for those involving *ex situ* collection.

With respect to the use and supply of genetic resources, the Guidelines suggest parties develop a policy on commercialization of genetic resources, and that this policy be made transparent. As part of the curation process, Participating Institutions should also document the use of the resource and / or derivative, whether it is by the Participating Institution or a recipient third party.

Acquisition and supply of genetic resources and their derivatives should be governed by written agreements that identify the terms and conditions under which the genetic resources may be acquired, used and supplied, as well as resulting benefits are to be shared. Benefits, including both monetary and non-monetary benefits, should be shared "fairly and equitably with the country of origin and other stakeholders". The Common Policy Guidelines also include a **Model Agreement for Supply of Biological Material,** as well as a **Model Material Acquisition Agreement (MTA)** between a participating institution and a participating botanic garden. Although not designed to be universal in

nature, the model MTA outlines the basic terms that should be included in specific agreements for material transfer, as well as the necessary legal language (based on English law). The model MTA also provides a framework for the Notification of Material Transferred under the terms of an MTA, and for confirmation of government approval for acquisition of genetic resources.

In addition to the Common Policy Guidelines, the Participating Institutions have developed supporting **explanatory text** related to each of the key Principles and Guideline elements. The explanatory text includes examples of draft statements to obtain PIC, as well as the model written agreements for both acquisition and supply of genetic resources. Guidance is also provided for developing policies on specific elements of ABS, including policies on commercialization, collection management, and staff management for supply of genetic resources.

As a purpose-specific set of ABS requirements targeted to a specific set of institutions, the 7 Principles and set of Common Policy Guidelines provide a number of examples of best practice. PIC requirements cover both governments and other stakeholders, and are designed to ensure that 3rd parties, which either acquire or provide genetic resources to botanic gardens obtain PIC from original providers of the genetic resource, where these are known. Of particular note is the specification of responsibilities for botanic gardens as primary users/acquirers of genetic resources that are differentiated from their role as providers/suppliers of genetic resources to 3rd parties. Specific requirements also differentiate the use of genetic resources for research from commercial purposes, with requirements to ensure that materials to be used for commercial purposes are subject to specific, and where necessary, separate prior informed consent and different forms of benefits. The Guidelines also provide for benefits, regardless of date of acquisition vis.a vis. entry into force of the CBD, and address the need for benefits related to derivatives of genetic resources.

Figure 6. Botanic Gardens Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit-Sharing

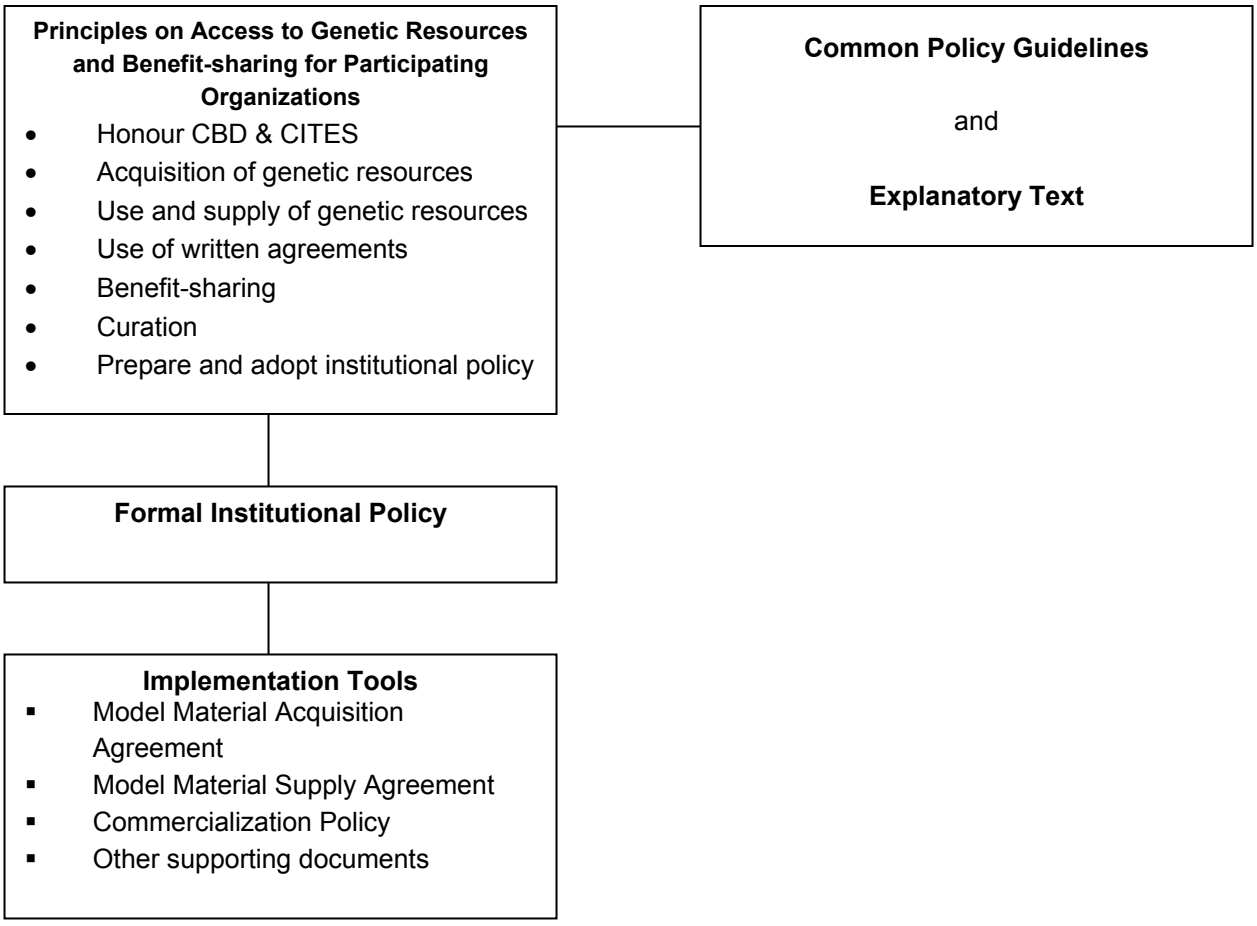


Table 6. Good Practice Elements of the Botanic Gardens Common Policy Guidelines

Scope	Plant genetic resources? Botanic gardens, herbaria and related users/curators of gr
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ Provide full explanation of how genetic resources will be acquired, used ▪ When acquiring *in situ* genetic resources (and associated knowledge) obtain and record prior informed consent from the government of the country of origin and any other relevant Stakeholders, according to law and best practice ▪ When acquiring resources from *ex situ* collections, obtain prior informed consent from the body governing collection and any additional consents that body; take steps to ensure they were acquired in accordance with law and best practice

	▪ When accessing genetic resources, obtain the informed consent of the Provider (or, if the Provider is not known, the country of origin), prior to commercialising the genetic resources, specifying in writing the terms and conditions of use, including fair and equitable benefit-sharing ▪ When supplying/providing genetic resources or their derivatives, use written agreements obliging each Recipient not to commercialise the genetic resources or their derivatives without the explicit consent
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ Use written agreements to acquire genetic resources ▪ Clarify in writing, based on a full explanation of how the genetic resources will be acquired and used, the terms and conditions under which the materials are acquired and can subsequently be used ▪ Clarify with the Recipient, whether the supply is for commercial or for non-commercial purposes.
Benefit Sharing (BS)	▪ Share fairly and equitably with the country of origin and other Stakeholders, the benefits arising from the use of genetic resources and, in the case of commercialisation, also monetary benefits. ▪ Share benefits arising from the use of materials acquired prior to and after the entry into force of the CBD in the same manner ▪ Provide resources for the conservation of biological diversity and the sustainable use of its components ▪ Benefits may include: taxonomic, biochemical, ecological, horticultural and other information and data: access to collections and databases; augmentation of national collections; support for community development activities; the transfer of technology; training; institutional development, strengthening and management; joint research and development, participation in product development, joint ventures; and monetary benefits such as royalties in case of commercialization
Traditional Knowledge (TK)	▪ Honour laws relating to access and benefit-sharing, including those relating to traditional knowledge.
Conservation and Sustainable Use (C+SU)	▪ Honour the letter and spirit of the CBD
Community Participation (CP)	▪
Transparency and Information (TI)	▪ Maintain records and mechanisms to: - record the terms/conditions under which genetic resources acquired; - track use in Participating Institution and benefits from use ▪ record supply to third parties, including the terms/conditions of supply ▪ record and maintain data on acquisition, including Provider; country of origin; collector; and, if available, dates, accession numbers, taxon names, etc; prior informed consent and terms, conditions of use
Other relevant requirements (ORR)	▪ Prepare a transparent policy on the commercialisation (including plant sales) of genetic resources and their derivatives ▪ Clarify in writing roles, rights and responsibilities of Participating Institution, Provider, country of origin, relevant Stakeholders

Society for Economic Botany: Guidelines of Professional Ethics

The Society for Economic Botany adopted Guidelines of Professional Ethics in the summer of 1995. The Guidelines were developed in recognition of the difficult ethical issues confronted by economic botanists concerning both collection activities, and dissemination and use of findings. More

specifically, the guidelines were developed in response to changing expectations on the part of "those researched" regarding access and benefit-sharing, as well as an increased sense of vulnerability of professional members to a loss of access to information and material for research. The Guidelines also represent a desire to clarify standards for ethical behaviour within the ethnobotanical research profession – particularly in this changing environment.

The guidelines for professional behaviour apply to all members of the Society for Economic Botany. The guidelines include five primary categories, which can be summarized as: (1) responsibilities to the public; (2) responsibilities to those studied; (3) responsibilities to host governments and other host institutions; (4) responsibilities to the profession; and (5) responsibilities to those who support their research. Although voluntary in nature, all members of the Society are expected to abide by the requirements outlined in the Guidelines, including those related to prior informed consent, equitable sharing of benefits, and disclosure of information.

The Society recognizes that the Guidelines can still be strengthened, and has encouraged its membership to provide input into future iterations of the Code.

The SEB Guidelines are of interest for the onus it places on professional researchers to behave ethically in making botanical collections and collecting information in the field. The focus of PIC is for researchers / collectors to obtain the consent of host communities, including indigenous communities, and to include information on any commercial intentions or commercial potential associated with the research. Onus is also placed on the researcher to do all that is possible within their control to ensure benefits are provided, including equitable financial compensation to local providers of plant materials and/or information.

Table 7. Society for Economic Botany, Guidelines for Research, Collections, Databases and Publications

Scope	▪ applies to all members in disciplines including botany, ethnobotany, agronomy, anthropology, archaeology, economics, ethnology, forestry, genetic resources, geography, horticulture, medicine, pharmacology
General Provisions (GP)	▪ Members have a responsibility to their profession to ensure their behaviour is consistent with the Guidelines.
Prior Informed Consent (PIC)	▪ Users are not obligated to seek PIC; PIC is a professional ethical responsibility ▪ Prior Informed Consent relates to "those studied" (i.e. subjects of ethnobotanical research, including indigenous and rural communities), as well as host governments and other host institutions.
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ members must comply with the rules of the host community and / or institution, as well as respect any request for confidence made by those providing data or materials
Benefit Sharing (BS)	▪ responsibility to assist collaborators in enhancing the physical and human resources of their institutions. With respect to technology transfer, members must supply reports and specimens, seminars and training, as required by the host institution.

	▪ responsibility of members to arrange with employers for equitable economic compensation for those who have provided the information and / or plants ▪ responsibility of members to ensure that equitable economic compensation is paid to "those studied", as recompense for information obtained with the potential for commercial payoff.
Traditional Knowledge (TK)	
Conservation and Sustainable Use (C+SU)	▪ Not specifically referenced.
Community Participation (CP)	
Transparency and Information (TI)	▪ Members are required to communicate clearly and honestly the objectives and likely outcomes of research, including commercial objectives and a "reasonable expectation" of commercial results.
Other relevant requirements (ORR)	

Code of Ethical Practice for Biotechnology in Queensland

In an effort to gather input into a new Biodiscovery Policy, and to pave the way for new legislation, the Queensland government issued a Biodiscovery Policy Discussion Paper, and subsequent benefit-sharing model agreement. The objective of the Discussion Paper was to establish a "streamlined and uniform approach regarding access to the State's biological resources for biodiscovery, in a way which will benefit Queensland's community, economy and environment."

Selected ABS Terms
Code of Ethical Practice for Biotechnology in Queensland:

- we will ensure that appropriate permits are obtained from the State Government for the collection of biological samples from State-owned lands and will negotiate reasonable benefit sharing arrangements with the State in return for access to the samples;
- where access to samples from State-owned land has been granted for scientific purposes only (i.e. not commercial purposes), we will undertake commercial research or development of the samples only with the prior informed consent of the State;
- we will transfer samples collected from State-owned lands to third parties only with the prior informed consent of the State;
- before collecting samples from privately owned land, we will ensure that the prior informed consent of the landowner is obtained and will negotiate reasonable benefit sharing arrangements with the landowner in return for access to the samples;
- we will ensure compliance with the Native Title Act 1993 (Cth) with respect to the collection of samples from areas where native title rights and interests exist; and
- where in the course of biodiscovery and research we obtain and use traditional knowledge from indigenous persons or communities, we will negotiate reasonable benefit sharing arrangements with these persons or communities.

Source:
http://www.iie.qld.gov.au/publications/biotechnology/coe_introduction.pdf

To complement the legislative initiatives, the Government also released a **Code of Ethical Practice for Biotechnology in Queensland**. The Code provides a fundamental ethical framework to guide development of biotechnology in Queensland, and was released for public comment in 2000. The Code applies to Queensland Government agencies, any organization funded by the State, and any co-operative research centre (CRC) funded by the State in which the State is a participant. In addition,

biotechnology companies must have a benefit-sharing agreement in place in order to be granted access to the State's biological resources. Biodiscovery Collection Permits are only awarded upon execution of a benefit-sharing agreement.

The Code includes provisions related to control of access to biological resources, the sharing of benefits arising from successful commercialization of biological resources, and ensuring that biodiscovery activities have no adverse impacts on local ecosystems and biodiversity. The Government intends to regulate such activities upon successful drafting of legislation; however, until such legislation is drafted, the Code arrangements serve as guidance to ethical behaviour

Queensland has also developed a **Model Biodiscovery Benefit-Sharing Agreement.** The model agreement aims to support three primary objectives for both the State and the organization involved in the agreement: (1) to facilitate the development of the Queensland biodiscovery industry for the benefit of Queensland's community and economy; (2) to conduct biodiscovery research on samples of biological material collected from Queensland and to undertake associated commercialisation; and (3) both the State and the Organization wish to capture an equitable share of the benefits (including non-monetary benefits) derived from biodiscovery research and associated commercialisation. Schedule 1 of the Agreement provides a sample process for calculating Royalty Rates, recommending a range of approaches for determining monetary allocations.

The Code of Ethical Practice is quite general in nature but does cover the appropriate principles of access and benefit sharing arrangements. What makes it noteworthy is that adherence to the principles, while voluntary, is seen by the government as a requirement for the granting of licences for biodiscovery/bioprospecting activities to be carried out. Biodiscovery Collection Permits are only awarded upon execution of a benefit-sharing agreement. It also emphasizes that landowners must grant PIC and be involved in the negotiation of benefit sharing arrangements.

4.4 Corporate Policies and Codes

Novozymes

Novozymes, formerly a subsidiary of Novo Nordisk, is a biotech-based company involved in research and sales of enzymes and micro-organisms. In 1995, then parent company Novo Nordisk developed a corporate policy to respond, in part, to the provisions of the Convention on Biological Diversity. **The policy, "Acquisition of Natural Resources for the Development of New Pharmaceuticals**" applied to all activities undertaken by Novo Nordisk and its subsidiaries, and included basic guidelines related to various stages of use of biological resources.

Since the release of the Policy, Novozymes has developed additional commitments and guiding principles related to the access and use of genetic resources. The commitments and guiding principles were largely developed in response to an internal review by Novo Nordisk, which determined that the company lacked an effective system for securing prior informed consent, and that increased awareness was required on the part of users to identify when PIC is needed. Novozymes

states that the "right to authorize access to genetic resources rests with the national governments and is subject to national legislation." Furthermore, Novozymes' **Guiding Principles** dictate that "Any microbial strain or composite sample collected after December 1993 without proper informed consent will not be screened for potential new enzymes."

Under the 1995 Novo Nordisk Policy, Novozymes itself committed to developing research agreements with provider organizations, in compliance with existing national and international law. While Novozymes has developed guiding principles and policy commitments to respect the provisions of the CBD and to establish contracts and/or material transfer agreements which meet these requirements, it does not appear to have elaborated specific model agreement elements to provide further guidance on their implementation. It is in the process of drafting a more detailed internal policy statement. The company has applied the requirements in specific contractual arrangement with suppliers of genetic resources (personal communication, Lene Lange, NovoZymes, January 2004). For example, Novozymes has developed an agreement with BIOTEC – a research institute in Thailand – where the company has obtained the right to investigate a particular type of fungus in return for transfer of technology and royalty payments, should the exploration result in a product. Details of the agreement are not publicly available

Novozymes' separate **Environment and Bioethics Policy, as well as its Social Responsibility Policy**, establish high-level commitments to ensure bioethical issues are addressed through all stages of use. The policies commit the company to establishing close relationships with the communities in which they operate, through consultation and / or other methods, and to communicate openly about their social and environmental/ethical performance for all aspects of their work. The policies also commit Novozymes to seeking partners that can demonstrate a similar level of social, environmental and ethical performance.

Novozymes takes an ethics-based approach to guide its ABS activities. It further elaborates it social responsibility policy into specific requirements for ABS including providing for all materials screened for pharmaceutical potential to be covered by contracts or material transfer agreements It emphasizes the importance of establishing close working relationships and cooperative working environments in the communities where it works.

Table 8. Novozymes Policies on: Acquisition of National Resources; Environment and Bioethics; Social Responsibility

Scope	Enzyme discovery for health care products
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ Acknowledge and respect that access to genetic resources requires PIC. ▪ No microbial strain or natural material obtained without proper PIC from the country of origin will be included in screening. ▪ All materials screened should be covered by contracts and/or MTAs. ▪ Contracts should be cleared by the proper authority in the country of origin.

Mutually Agreed Terms (MAT) e.g. contract provisions	▪ Conditions should be on mutually agreed terms and should include benefit-sharing, IPRs and technology transfer arrangement where appropriate
Benefit Sharing (BS)	▪ benefits arising from the utilization of genetic resources should be shared fairly and equitably with the country of origin, reflecting the contribution made.
Traditional Knowledge (TK)	
Conservation and Sustainable Use (C+SU)	The company's Environment and Bioethics Policy includes a requirement to reduce the environmental impact of operations, and to establish management systems to control performance. In addition, when developing new products, the company will also seek to behave in an environmentally and bioethically responsible manner.
Community Participation (CP)	In Novozyme's Environment and Bioethics Policy, the company states that it will listen to the bioethical and environmental concerns of their stakeholders, and that they will establish close relationships and cooperative working environments in the communities in which they operate. These sentiments are also included in the company's Social Responsibility Policy.
Transparency and Information (TI)	Novozymes is committed to reporting honestly and openly on environmental performance and bioethical issues, as well as social performance.
Other relevant requirements (ORR)	▪ The country of origin will be mentioned in relevant publications and patent applications.

GlaxoSmithKline

Although the company does not use natural product collection as a primary source for its pharmaceutical products, GlaxoSmithKline (GSK) – a research-based pharmaceutical company – does occasionally collect natural products that are screened by collaborative partners. Because of the potential impact on biodiversity associated with the collection of natural products and materials, GSK has developed a **public policy statement** on the collection of natural resource materials, outlining its position with respect to the sovereign right of nations over the resources within their countries, the sharing of benefits that arise from the use of natural materials, and recognition of the value of traditional knowledge.

The company states it will "ensure an agreed benefit is returned directly or indirectly to the country of origin in the event of GSK developing a commercial product based on a natural product," and will seek opportunities to provide local communities with education and training in natural materials collection and screening.

"Extracta" Case Study

A tangible demonstration of GSK's commitment to these obligations is the company's collaborative arrangement with Extracta Laboratories in Brazil. Established in 1999, the project has identified eight targets of interest indigenous to the Amazon Rainforest. These are currently being screened against therapy areas of relevance to the region in an Extracta Laboratory in Rio de Janeiro. Research and 'milestone' payments (potentially totalling several million pounds) are included in the three year contract. If any of the candidates identified are subsequently commercialised by GSK, Extracta will also receive a percentage of the net profits from sales. As part of the arrangement, technology transfer is taking place such that GSK has provided the cell-lines for the screening programmes and several Brazilian scientists have worked at GSK R&D facilities in the UK.

Source: GlaxoSmithKline web site.
http://www.gsk.com/ser/2001/ehs01/rep-37.html

In 1999, GSK (then Glaxo Wellcome) established a three-year agreement with Extracta – a small biotechnology company in Brazil – in which it agreed that 25% of any royalties arising from successfully exploited patents would be used to "support community-based conservation, health and education projects"; Glaxo Wellcome would also provide Extracta with 3% of the revenues from any drug marketed by the company. There is also recognition of the need to provide due compensation for the use of traditional knowledge in the product development process. This is also reflected in GlaxoSmithKline's public policy position with respect to the CBD, which states that "all nations have sovereignty over…indigenous knowledge within their territorial boundaries."

To ensure proper prior informed consent, particularly in developing countries, the company commits to "ensure that the governments in developing countries are informed of and consent to the nature and extent of any proposed natural materials collection." GlaxoSmithKline has also made a commitment related to the conservation and sustainable use of natural materials, stating that it will "develop sustainable harvesting procedures to preserve the ecosystem from which the source material is derived…"

GSK policy commitments and publicly reported practices provide good guidance on several important aspects of ABS. These include prior informed consent from the host country, specific practices to return benefit to the country of origin of the genetic resources used, including both development-oriented (community investment, and capacity building), and financial (e.g. royalties and share of revenues) in the event of commercial development of a product. While returning benefits to the community is explicit in its policy commitments, PIC is related only to governments, with no specific mention of community involvement in granting access. GSK requirements include a number of specific provisions related to biodiversity conservation and sustainable use of the resources being accessed, including through sustainable harvesting, and minimizing wild resource collection through promotion of cultivation and synthesis of active compounds and derivatives.

Table 9. GlaxoSmithKline (Glaxo Wellcome)

Scope	Pharmaceutical research and development
General Provisions (GP)	
Prior Informed Consent (PIC)	▪ ensure that the governments in developing countries are informed of and consent to the nature and extent of any proposed natural materials collection

Mutually Agreed Terms (MAT) e.g. contract provisions	▪ ensure an agreed benefit is returned directly or indirectly to the country of origin in the event of GSK developing a commercial product based on a natural material
Benefit Sharing (BS)	▪ Reimburse suppliers for the costs incurred in collecting natural product source samples. ▪ Reward suppliers for their expertise (e.g. in taxonomic classification). ▪ Use MTAs which may refer to intermediate forms of compensation and involve a financial benefit payable to the supplier if a commercial product results from screening the natural product supplied. ▪ Require a significant portion of this payment to the supplier to be returned to the source country to support science training and education at the community level. ▪ benefit sharing may amount to payment of fair and reasonable royalties or other means, determined by mutual agreement on a case-by-case basis ▪ Collaborate with organisations to educate and train local people in collecting and screening skills
Traditional Knowledge (TK)	▪ All nations have sovereignty over…indigenous knowledge within their territorial boundaries
Conservation and Sustainable Use (C+SU)	▪ Protect biodiversity by classifying samples of plants and other organisms taxonomically and only investigate species if their supply is reproducible and sustainable ▪ Neither seek nor knowingly support the collection of endangered species. ▪ Unauthorised or unrestrained removal of natural materials from their indigenous habitats can harm the ecology and economy of the country concerned ▪ work with small quantities of natural materials to discover bioactive principles. Where possible further supplies of lead compounds and derivatives are synthesised ▪ develop sustainable harvesting procedures to preserve the ecosystem from which the source material is derived where further supplies of the active compounds cannot be synthesised
Community Participation (CP)	
Transparency and Information (TI)	▪ Conclude agreements with prospective sample suppliers only when they can provide documentary evidence that they have permission from appropriate government authorities to collect such samples.
Other relevant requirements (ORR)	▪ Collaborate with bona fide suppliers. ▪ work only with organisations and suppliers with the expertise and legal authority to collect plant and other natural material samples. These include botanic gardens, universities and research institutes

4.5 Customary Frameworks

Kuna: Program of Research Monitoring and Scientific Cooperation

In 1983, the Kuna Yala of Panama developed a set of guidelines to govern scientific research by outside parties in a newly established nature reserve. The guidelines were included in its **Manual** - "**Program of Research Monitoring and Scientific Cooperation"** (*Programa de Investigacion*

Monitoreo y Cooperacion Cientifica), which outlines the Kuna's objectives with respect to forest management, conservation of biological and cultural diversity, scientific collaboration and research priorities. The manual also provides guidelines for researchers, including methods for determining benefits to be accrued to the Kuna Yala people in exchange for permission to conduct research within the reserve.

One of the strengths of the guidance manual was its recognition of the need for collaboration between Kuna and outside scientists, particularly with respect to improving documentation methods and managing cultural and natural resources. Management of the nature reserve was also enhanced with the establishment of PEMANSKY – the Study for the Management of the Forested Area of the Kuna Territory, which provides general oversight of the management of the reserve.

In addition to providing general guidance, the manual also identified specific requirements for researchers. Provisions related to obtaining prior informed consent include requirements for researchers to submit a proposal outlining the timing, extent and potential environmental and cultural impact of a research programme, which must then be approved by the Scientific Committee of PEMANSKY. In addition, researchers must receive approval from PEMANSKY for the collection of species; if approved, collection activities must be conducted in a non-destructive manner, and may not include any endangered species. Research programmes must also outline benefit sharing arrangements, and in particular should include in their programmes Kuna collaborators, assistance guides and informants.

Researchers hoping to conduct scientific studies and / or collections in the nature reserve must also complete "an orientation into the culture of the Kuna Yala, and respect the norms of the communities in which they work." To ensure conservation and sustainable use objectives are met, research is limited to specific areas of the reserve, and tightly controlled in other areas (i.e. forest areas governed by community management). Research in ceremonial or sacred areas is strictly prohibited.

The KUNA manual provides an excellent example of a "bottom up" set of requirements, established by the community itself, in a case where it is known to possess biological and cultural resources of value to others. It is well advanced in addressing in good practice requirements relevant to ABS, based on protecting biological and cultural resources, even prior to the CBD having been negotiated. It specifically requires community level prior informed consent, through a local KUNA organization created for the purpose. This cultural framework includes unique provisions such as requiring researchers to participate in an orientation program on the culture of the Kuna Yala.

Table 10. KUNA Yala Program of Research Monitoring and Scientific Cooperation (abstracted provisions)

Scope	▪ Research and collection activities in a forest reserve managed by the Kuna Yala people of Panama
General Provisions (GP)	▪ The manual provides an outline of Kuna objectives with regard to forest management, the conservation of biological and cultural diversity, scientific collaboration and research priorities
Prior Informed Consent (PIC)	▪ Collectors must receive approval from the Scientific Committee of PEMANSKY before removing any materials / species from the reserve. ▪ Researchers must develop a proposal outlining the timing, extent and potential environmental and cultural impact of the research programme
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ The guidance provided in the manual has served as the basis for specific written agreements between researchers and communities
Benefit Sharing (BS)	▪ The manual establishes guidance for researchers in identifying and benefits that should accrue to the Kuna
Traditional Knowledge (TK)	▪ Both Kuna and outside research knowledge were used when establishing the nature reserve, and in designing the guidance manual
Conservation and Sustainable Use (C+SU)	▪ All collections must be done in a non-destructive manner; furthermore, collection of endangered species for commercial purposes is prohibited. ▪ Research proposals must outline the potential environmental impacts of the study programme
Community Participation (CP)	▪ Outside organizations must include in their research programme Kuna collaborators, assistants, guides and informants.
Transparency and Information (TI)	▪ Researchers must provide the programme authority with written reports of the research, as well as copies of photographs or slides taken during the research process; ▪ descriptions must also be provided of newly discovered species.
Other relevant requirements (ORR)	▪ Outside researchers wishing to conduct studies within the nature reserve are required to undergo an "orientation into the culture of the Kuna Yala"

4.6 Contractual Arrangements

The terms and clauses included in contractual agreements are relevant for the development of a management tool for at least two reasons. First, the provisions stated in the Bonn Guidelines on mutually agreed terms (particularly those in pars 43, 44 and 46) suppose the negotiation of a series of clauses, which are part of an ABS contract or agreement between a provider and a user of genetic resources. From this point of view, understanding which provisions and clauses have been incorporated into the current bioprospecting contracts may shed some light on how mutually agreed terms have been implemented in practice. Secondly, an analysis of the most common clauses and provisions in these contracts can be of value in understanding the main issues that confront the negotiation, implementation and monitoring of these agreements, in order to facilitate the process of negotiation and implementation of agreements.

In general, not much has been written about ABS contracts, because a great majority are confidential in nature[11]. There are a range of studies related to ABS issues – some of which refer to, with different extent and depth, the negotiations that preceded the agreements. Some literature sources also provide details on the contractual clauses themselves, however the supporting legal analysis and specific contract provisions are not always provided in detail.[12]

The issues to be addressed in an access agreement can be outlined as follows:[13]

Indicative Elements / Clauses in Biodiversity Prospecting Agreements	
Definitions	**Other Protection**
Access	▪ Trade Secrets
▪ Source and Amounts	▪ Contractual Protection
Benefits	▪ Dispute Resolution
▪ Uses	▪ No Liability
▪ Licenses	▪ No Warranty
▪ Price / Benefits	▪ Authorization
Protection of Intellectual Property Rights	**Confidential Information**
▪ Right to Patent	**Procedures**
▪ Exclusivity	▪ Publications
▪ Copyrights	▪ Indemnification
▪ Trademarks	▪ Standards of Conduct
	▪ Accounting and Records

Diversa: Cooperative Research and Development Agreement (CRADA)

Diversa Corporation and Yellowstone National Park (YNP) have put in place a **cooperative research and development agreement** known as "CRADA". Its intent is to ensure that benefits related to **the use or transfer of specimens** collected from the Park, including financial benefits related to commercialization, are shared with the Park.

[11] Tobin, B Biodiversity Prospecting contracts: the search for equitable agreements y Gollin, M Elements of commercial biodiversity prospecting agreements, ambos en Laird, Sara (ed) Biodiversity and Traditional Knowledge. Equitable partnership in practice, Earthscan, London, 2002, Downes, D, Laird, S, Klein, K y Carney, B, Biodiversity Prospecting contracts, in Reid, W et al (eds), Biodiversity prospecting using genetic resources for sustainable development, World Resources Institute, New York, 1993 and Rosenthal, J., Equitable sharing of biodiversity benefits: agreements on genetic resources, 1997, unpublished manuscript.

[12] The web page of the Convention on Biological Diversity for the case studies on ABS www.cbd.org . Also, the database on contractual arrangements to access to genetic resources and benefit sharing, specially from the perspective of the IPR provisions, and the case studies of the role of intellectual property rights in access and benefit sharing arrangements developed by WIPO and UNEP, in the web page of WIPO, www.wipo.int

[13] Adapted from Gollin, 2002.

The potential for significant and profitable biological discoveries in Yellowstone National Park are considered large, particularly from microbial species in its hotsprings. The CRADA was designed to provide for joint public-private research activities, and to encourage shared scientific reporting, training, technology transfer and profit-sharing agreements. With respect to research specimens, the Agreement states that there is to be no "sale" of park resources, that there is to be no exclusive right of access to park resources, and that third-party transfers or assignments would not be permitted without Park authorization.

With respect to benefit-sharing, the Agreement states that benefits should flow directly to Yellowstone, to be applied for both research and resource conservation purposes. In addition, benefit sharing, recordkeeping and reporting obligations must continue beyond termination of the agreement. In terms of specific benefits to be shared, the Agreement established minimum royalty payments to be paid to the Park, in addition to an upfront fee of a minimum US$100,000 (payment terms to be negotiated). For its part, Yellowstone National Park agreed to provide services in the form of resource protection, labour, expertise, equipment, facilities, information, computer software and other forms of laboratory support.

The first product resulting from research conducted under the auspices of the Agreement was announced in 2002. Pending the results of an environmental impact study, royalties will be accrued to Yellowstone National Park as agreed in the CRADA.

The Diversa - Yellowstone agreement provides an example of a cooperative research and development agreement on genetic resources between the public-sector owner and manager of these resources and a private enterprise interested in collecting and developing the resource into commercial products. Financial benefits arising under the agreement are applied directly to research and conservation activities within the Park.

National Cancer Institute: Letter of Collection

The National Cancer Institute **Letter of Collection (LOC)** is a contract in the form of an agreement between a source country institution (or other organization), and the National Cancer Institute (NCI). The LOC serves as a framework agreement for collaborations between U.S. National research institutions and source country research institutions; intermediary "contractors" (public and private research institutions or NGOs); and governments (source country government divisions or departments). Communities are also involved as research informants.

The signing of the LOC itself is constitutes prior informed consent negotiation with the source country and /or organization. The terms set out in the contract are established through mutual agreement, and provide the NCI with permission to collect material for testing in bioassays, and for identifying chemical constituents from plants, microbes, and marine macro-organisms. Test results must be kept confidential by all parties until the NCI has the opportunity to file patent applications.

The Letter of Collection also outlines the process for transferring knowledge, expertise and technology related to drug discovery and development, to the appropriate source country institution. In addition, NCI undertakes to provide training for source country researchers at its laboratories, and to establish mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. Indigenous knowledge is treated as both a component of access (i.e. a source of useful information to guide collection and set research priorities), and as a component of benefit sharing.

With respect to conservation and sustainable use, the LOC includes elements to ensure sustainability of supply for production, protection of resources from deforestation, and use of suitable cultivation methods to meet production requirements.

The NCI Letters of Collection (LOC) is interesting for the specific requirements it sets out between the sponsor (NCI as funder) and researcher who are the parties intending to access genetic resources in other countries. The standard LoC includes provisions covering most elements commonly of importance to ABS arrangements. For some elements of ABS practice these provisions are limited. For example, PIC is with host governments or institutions, while PIC with local communities and indigenous peoples is not for access but for permission to publish information. Intellectual property rights are considered associated with the researchers, including from the host country, but do not extend to local and indigenous communities. Conservation provisions are included, but in common with most international and organization-specific ABS requirements, specific sustainability standards are not provided. Conservation status and sustainable use assessment is not excluded in the terms of access. It should be noted that the limitations on a number of these ABS elements often are found in other contractual arrangements.

Table 11. US National Cancer Institute (NCI) Letter of Collection (LOC) (abstract of provisions)

Scope	▪ NCI contracts collection of materials with various other organizations (e.g., universities, botanic gardens
General Provisions (GP)	▪ Researchers are required to act within the framework of the agreement between NCI + source country/ source country organization. ▪ Resources assessed include naturally occurring chemical compounds (or extracts) derived from plants, microbes, and marine macro-organisms. These materials are "biological" resources but may not all be technically "genetic" resources (may not contain "functional units of heredity").
Prior Informed Consent (PIC)	▪ There is an obligation for users to seek PIC ▪ PIC with government determined by signing of LOC -- letter itself constitutes PIC negotiation with source country organization ▪ PIC with local communities and indigenous people only for permission to publish their information
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ Substance of negotiation: - Roles and responsibilities - Permission to collect material for testing in bioassays, identification

	of chemical constituents - Resources: plants, microbes, and marine macro-organisms - Provider - source country government or organization - User/accessing organizations - NCI contractors (institutions contracted by NCI to undertake the collecting of specified resources) - Limitations of use and transfer: test results kept confidential by all parties until DTP/NCI has opportunity to file patent applications; licensees to be apprised of terms of agreement
Benefit Sharing (BS)	▪ Transfer of knowledge, expertise, and technology related to drug discovery and development to appropriate source country institution ▪ Training for source country researchers at NCI ▪ Research collaboration between NCI + source country organization ▪ Mutually acceptable guarantees for the protection of intellectual property associated with any patented technology
Traditional Knowledge (TK)	▪ Indigenous knowledge (IK) treated as component of access (source of useful information to guide collection and set research priorities ▪ IK treated as component of benefit sharing (preferred source arrangements with licensee) – if organism is widely distributed but associated knowledge can be associated with particular group and location ▪ IPR, innovation associated with researchers, including from source country, not with local/indigenous peoples.
Conservation and Sustainable Use (C+SU)	▪ C+SU treated as components of access (production stage) and benefit sharing (source country as first source of supply) ▪ Issues addressed: Sustainability of supply for production, endangerment from deforestation, cultivation to meet production ▪ Conservation status/resource sustainability addressed at the production for commercial market stage of access and use ▪ Licensee responsible for part of costs (to be negotiated) associated with measures required for conservation and alternate production

Source: *Cragg, Gordon M. and David J. Newman. 2003. The U.S. National Cancer Institute (NCI) Natural Products Drug Discovery and Development Program. Presentation to an International Conference, Medicinal Plants: Access, Use and Benefit Sharing in light of the CBD. Organized by The Centre for Development and the Environment (SUM), University of Oslo, Norway. 3-5 April 2003.*

Know How Agreement between the Tropical Botanical Garden and Research Institute, Kerala, India (TBGRI) and the Ayra Vaidya Pharmacy Ltd., Combatore, India

The Know How Agreement between the TBGRI and Ayra Vaidya Pharmacy Ltd. is a licensing agreement that outlines the requirements on the part of a pharmaceutical company and a research institute with respect to technology transfer, commercialization, terms of use of the 'know how', and the sharing of benefits. Signed in 1995, the agreement sets specific terms related to the use by Ayra Vaidya of know how developed and owned by TBGRI to manufacture herbal formulations based on the "arogyappacha".

The Agreement does not elaborate on specific PIC provisions, but the signing of the Agreement itself constitutes prior informed consent negotiation with the research institute. PIC with the Government of India is not addressed in the contract provisions. The main elements of the Agreement focus on the

use of 'know how', and in particular the granting of licenses, documentation and acquisition of confidential information, commercialization of resulting products, and rights surrounding intellectual property applications.

Although the Agreement does not make explicit reference to the use and protection of traditional knowledge, the agreement is supported by a separate benefit-sharing contract signed between TBGRI and the local Kani Tribe. The contract does provide for direct payment to the TBGRI for the use of 'know how' in the form of license fees, royalties, and other separate payments for services provided by the research institute (e.g. training). The TBGRI is also granted authority to inspect the premises of the pharmaceutical company to ensure compliance with the terms of the contract.

The TBGRI developed this agreement to ensure the institute received fair and equitable benefits in exchange for use of the institute's knowledge of the arogyappacha. However, prior to the signing of this agreement, the TBGRI's benefit-sharing arrangement with the Kanis was heavily criticized – particularly for the lack of consultation by the TBGRI with the local tribes. Although the Kani were offered .5% of the royalties and 50% of the license fee resulting from the commercialization of the medicinal qualities of the arogyappacha, many saw the agreement as insufficient in its awarding of benefits to the Kanis.

Table 12. Know How Agreement between the Tropical Botanical Garden and Research Institute, Kerala, India (TBGRI) and the Ayra Vaidya Pharmacy Ltd., Combatore, India

Scope	licensing agreement relating to the know how developed and owned by TBGRI to manufacture herbal formulations
General Provisions	
Prior Informed Consent (PIC)	The signing of the contract itself constitutes PIC negotiation with the TBGRI organization (as the owner of the Know/how).
Mutually Agreed Terms (MAT) e.g. contract provisions	▪ License to utilise the know how to make and sell the product ▪ know how associated to genetic resources in the herbal sector ▪ TBGRI a Source Country Organization (of INDIA) ▪ The Party shall not directly or indirectly and either by itself or by its agents use the know how otherwise than in accordance with the contract; ▪ the Party shall not, at any time, assign, mortgage, charge, grant sub/license or otherwise deal with possession or control of the license hereby granted; ▪ the Party shall treat as strictly confidential all information / knowledge obtained from TBGRI, in connection with or relating to the license hereby granted. ▪ Roles and responsibilities: o Responsibilities of TBGRI: transfer the know how documents; o demonstrate the know how to the Party; training of 2 or 3 of the Party personnel (paid by the Party); o assistance in how know implementation. ▪ Responsibilities of the Party: employ its best endeavour to work the know How and sell the product on a commercial scale; ▪ to fulfill all the procedural, legal and operational requirements for

	commercial implementation of the know how; ▪ not file any application for IPR in its own name or un the name of other person on any matter relating to the information disclosed by TBGRI, save with the written prior approval;
Benefit Sharing	▪ License fee (a lump sum) ▪ Royalties ▪ Acknowledgement of the TBGRI know how in product labelling, advertising., etc ▪ Separate payments for services provided by TBGRI (training, etc) ▪ Mutually acceptable guarantees for the protection of intellectual property
Traditional Knowledge (TK)	▪ TK treated as component of benefit sharing ▪ IPR, protection for the Know how; The Party acknowledges the absolute ownership of the Know How by TBGRI.
Conservation and Sustainable Use	
Community Participation	
Transparency and Information	
Other relevant requirements	

Contract between the National Authority of the Environment of Panama (ANAM) and the Smithsonian Tropical Research Institute

The National Authority of the Environment of Panama (ANAM) and the Smithsonian Tropical Research Institute (STRI) established an agreement outlining the requirements related to the collection, transfer, export, and use of biological materials. The agreement is intended to comply with the principles established by the International Cooperative Biodiversity Groups (ICBG).

The signing of the agreement was achieved through a bilateral process, and constitutes PIC as granted by the Panamanian Authority. Additional requirements are articulated with respect to authorization of use, transfer, and export of materials. The agreement provides STRI with the authority to use biological materials for the purposes of research and related scientific activities, including those related to biological and chemical assays, discovery and development of novel pharmaceutical agents, development of novel products for agriculture, development of novel phytomedicines, and dietary supplement and purification and analysis of individual chemical components. In addition, any collection of material that is based on traditional knowledge must be carried out with the prior informed consent of the appropriate individuals and organizations involved, including governing authorities.

Conservation is addressed as a component of access, where it is stated that STRI must undertake all collection activities under the agreement in such a way as to minimize adverse environmental impacts. Included in the agreement is the provision that no material known to be rare or endangered be collected – particularly those listed in the Appendices of CITES.

With respect to benefit-sharing, net revenues (including royalties and milestone payments), as well as access fees, will be shared by participants to the agreement. A percentage of the revenues and fees

will be paid to the Fondo Nacional de Vida Silvestre (National Wildlife Fund), the Environmental Trust (created by STRI and a local NGO), and directly to STRI and the Panamanian collaborators. The funds paid to the Environmental Trust and the National Wildlife Fund can be used to support conservation efforts within Panama.

To monitor compliance with the terms of the agreement, STRI is required to submit written reports on the progress of the research conducted under an approved research plan. Progress reports are to be submitted every six months, and must identify all non-commercial or industrial collaborators currently acting under the research plan, as well as provide a description of the status of any intellectual property and / or efforts to commercialize a specific material and / or its derivatives.

Table 13. Contract between the National Authority of the Environment of Panama (ANAM) and the Smithsonian Tropical Research Institute

Scope	A contract between the National Authority of the Environment of Panama (ANAM) and the Smithsonian Tropical Research Institute (STRI); Applies to any biological substance, either in whole or in part, which is collected within the Republic of Panama. Examples include, but are not limited, to plants, insects, microbes, and uncharacterized organisms such as microbial life present in samples or parasites transferred adventitiously, and extracts, derivatives and preparations thereof.
General Provisions	
Prior Informed Consent (PIC)	A research plan of the ICBG shall be provided to ANAM prior to beginning any research activities. Each request for material collection shall be delivered following the format in Appendix A and each request for authorization of use, transfer and export of materials shall be provided Any collection of material that is based on TK will be carried out with the prior informed consent of the appropriate individuals involved, with the express prior written consent of the appropriate competent governing authorities TK - Upon mutual agreement by STRI and the appropriate governing authorities of those groups, institutions or organizations offering traditional knowledge, such groups, institutions and organizations may participate as Panamanian collaborators
Mutually Agreed Terms (MAT) e.g. contract provisions	Access is for collection, extraction, transfer, export and use of biological materials. Access is in conformity with a research plan. STRI may use the authorized material for research and related scientific purposes, including but not limited to, biological and chemical assays, discovery and development of novel pharmaceutical agents, development of novel products for agriculture, development of novel phytomedicines and dietary supplement Collections shall not be more than 100 grams dry weight of each species In the event that one or more species of interest not previously authorized in the request for material collection is encountered and collected, STRI

	shall register the species unrestricted sale of authorized material is prohibited
Benefit Sharing	Percentage of all net revenues (royalties and milestone payments); Access fees; Publication of research results. A formula for determining the calculation of net revenues exits: a percentage of the revenues and fees shall be paid to the Fondo Nacional de Vida Silvestre (National Wildlife Fund), and a percentage shall be paid to an Environmental Trust (created by STRI and a local NGO) and a percentage shall be paid directly to STRI and the Panamanian collaborators.
Traditional Knowledge (TK)	IPR may be developed in connection with or as a result of the agreement. STRI and its collaborators (including TK providers) may pursue patent protection as they see fit pursuant to agreements they enter into. STRI shall own or manage the IPR shared with non commercial collaborators (see also section on PIC)
Conservation / Sustainable Use	Undertake all its activities under the agreement in such a way as to minimize adverse environmental impacts STRI shall not collected material known to be rare or endangered. Known endangered species include those listed in the Appendices, I, II and III of CITES At the BS stage, the percentage to be paid to the Environmental Trust or the Wildlife Fund may be used to support conservation.
Other Relevant Requirements	Six months after the submission of the research plan and every six months thereafter STRI shall provide ANAM with written reports on the progress of the research conducted under the research plan. Each progress report shall identify all non commercial or industrial collaborators currently participating in the studies conducted under the research plan Progress reports also describe the status of any intellectual property and any effort to commercialize any material or derivatives of material

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